

**HIT Policy Committee  
FDASIA Workgroup  
Regulations Subgroup  
Transcript  
June 20, 2013**

**Presentation**

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

Thank you. Good morning 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 there is time for public comment on the agenda and the call is also being recorded and transcribed so please make sure you identify yourself for the record. I'll now go through the roll call of the Subgroup members first. Julian Goldman?

**Julian M. Goldman, MD – Medical Director, Biomedical Engineering – Partners HealthCare System**  
I'm here.

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

Thanks, Julian. Brad Thompson?

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

Good morning.

**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.**

Good morning.

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

Great, 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? Robert Jarrin?

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

Here.

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

Thanks, Jarrin. Mo Kaushal?

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

Good morning I'm well caffeinated.

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

Ah, great, thanks, Mo. Joe Smith? Jodi Daniel? I know Jodi is on. Simon Choi?

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

I'm here.

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

Great, thanks, Jodi.

**Simon Choi, PhD – Senior Science Health Advisor, Center for Devices & Radiologic Health – Food and Drug Administration**

Here.

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

Thanks, Simon. Matt Quinn?

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

I'm here.

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

Great, thanks, Matt. And are there any – for the full FDASIA Workgroup members I have Elisabeth George?

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

Yes, I'm here.

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

And Rich Eaton?

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

Yes.

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

And are there any other FDASIA Workgroup members on the line? Okay and any – Steve Posnack from ONC I know is on the line?

**Steve Posnack, MHS, MS, CISSP – Policy Analyst – Office of the National Coordinator**

Yes.

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

Thanks, Steve. And Kate Black?

**Kate Black, JD – Office of the National Coordinator**

Yes.

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

Thanks, Kate. Any other ONC staff members? Okay, with that I will turn the agenda over to you Mo.

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

Great, good morning everyone, so Jarrin, myself, Julian and Matt have had sort of went through the content today. I'm going to kick it off by giving sort of just a brief overview of the FCC what they have regulated classically, what they haven't and also more specifically some of their roles within healthcare given the national program fund.

I think importantly for the record I'm not representing the FCC here, I'm not talking on behalf of them this is sort of strictly public objective information and all these sort of comments and opinions will be my own. So, kicking it off, slide two.

The FCC was established by the Communications Act of 1934, it really was about regulating the interstate international communications, so all the communication infrastructure whether that be radio, television, wire and it really covers all of the US. We're now moving onto the next slide so let's jump to slide four.

So, this is an important concept and something I really didn't understand until I did actually go to the FCC. So, the FCC manages non-federal spectrum as opposed to federal spectrum. So, first of all spectrum is a sort of finite entity that we all learned about in physics that really enables and empowers communications from multiple sources and then the next slide will go into that. So, add to this finite, it has to be managed in a very correct way to drive economic growth. The federal spectrum is predominantly all the military applications.

So, on the next slide, I think this will sort of highlight the ecosystem right now, spectrum is needed by broadcasting TV companies, satellite, private wireless companies, commercial and mobile companies and enables our sort of mobile wireless as well. So, again, the FCC thinks really carefully around how to sort of fairly distribute spectrum and again to allocate it in the most efficient way.

And then slide six I think is very important for our discussion. So, on the left side of the slide it highlights what the FCC has classically focused on and one of the big areas of priority is interference. So, as an example, you don't want an Air Force Pilot using a certain bandwidth of spectrum for communication suddenly getting interference from other sources. So, the FCC is extremely concerned around interference control and the sub-points are a little bit more technical based than that. Also, focused on RF exposure, hearing aid compatibilities being a key area of focus as well in –

And importantly all these rules do really strive to be technology controlled. Importantly the FCC has not classically regulated – and I'm going to go from the bottom up because this is really where the FDA said that safety and efficacy has not been a component of the FCC regulation and some of these are around protocol, so there is a big debate of whether LTE or WiMAX will be the standard around 4G again, that's something the FCC does not jump into classically.

So, moving onto the next slide and I'm actually on slide eight now, so the National Broadband Plan came out of the Recovery Act it was published in March 2010, it was really a plan laid out by the FCC to really highlight what the communications infrastructure needs to be for the US for the next decade to really drive, again, economic growth. Importantly, it wasn't just about infrastructure for the sake of it, it was really about what could infrastructure enable, healthcare was one of those key protocols I led a black team and produced a plan in the recommendations for the healthcare specific piece.

So, before we come into healthcare again this slide highlights a piece that I didn't work on but arguably one of the most important pieces which again is how does the FCC make more wireless broadband available. I think the way I look at the world is that computers are becoming smaller and more connected, in other words we're getting sort of better mobile phones, so as the world is moving to mobility and the ability to do many things wireless mobile, wireless spectrum does enable this and it does create a whole amount of new opportunities, so the plan was very focused on if you had to empower this new growing industry. So, the pieces below I think are less relevant to this group. I would just take it as there was a number of rules and suggestions focused on how exactly to do that.

So, slide nine, I definitely covered this concept. So, again this is the notion that spectrum is finite, it does empower many different things and it has to be managed extremely carefully, think about it as any other natural resource.

So, moving onto slide ten and moving along which is the healthcare specific piece. So, let me create – sort of summarizing a range of the recommendations that came out of the broadband plan. I'm not going to go through all of them. I think there are two key areas relevant to this group, the first is the FCC has, and Matt can correct me if I'm wrong on this, if the situation has changed, but the largest sustainable funding for healthcare technology in the government via the Rural Healthcare Program which helps build a subsidized connectivity. So, this is how I view the technology spectrum and actually this will help you understand where the FCC fits into this.

So, right at the top is better clinical care, better clinical processes and technology that enables that, but in order to really empower and enable that multiple pieces have to be figured out. The FCC sits at the bottom of that technology stack. Think about it as we do need the prerequisite networks both wired and wireless that can handle the amount of data that we see coming down the line. Again, as I think about care getting pushed out of the hospital that means to me that from a clinical perspective that data needs to be captured from patients outside the hospital to enable better care.

So, think of the FCC's role right at the bottom of that framework that as we go up other agencies become more relevant. So, then think about, okay the data that lives on these networks is the data going to be interoperable where I know the ONC is playing a big role. If the data is interoperable and lives in a mechanism similar to the Internet we can then think about applications, analytics to be created on top of the free flowing data, and again, I think as soon as we push further up that's where we get the interesting tool that enables patient care. So, the need for close alignment between multiple agencies to figure this out is key and again, Matt is doing a great job in heading that up for the FCC now.

Slide 12, again these are some of the great applications that many of you know that have converging telecoms and devices. The small patch in the bottom right is one of the more interesting applications in my opinion so it allows the monitoring of congestive failure patients. So, how do we pick up patients as they decompensate before they feel unwell so we can intervene earlier. Again, a great example of what connectivity can enable.

So, slides 14, 15, and 16 are highly relevant to this group and arguably some of the significant work has really led and pushed for some of the thinking now and hence this committee so, and then the notion here was for the FCC and the FDA to work more closely on current regulations as the world moves from just products and standalone devices and drugs to a world where we have solutions with embedded connectivity, analytics, devices.

So, first of all the important point here is that the FCC and the FDA really worked together for many years on a variety of different issues from thinking through interference to telemetry systems from direct TV back in the day to the hearing aid compatibility that I talked about and radiofrequency exposure. So, there has been a significant period of understanding between the both entities.

And then now a lot of overlap and consultation especially amongst the engineering staff who have very complimentary skill sets around the guidance of wireless medical Apps, the guidance of EMC and RF safety.

Slide 15 highlights a brief summary and you can click onto the links just around sort of a pre sample of a meeting between the FCC and the FDA where everyone came and sat down and tried to define roles and slide 16 sort of highlights the quotes, but an early real focus to work together and then this resulted in an MOU of understanding which Matt may want to give us a little bit more overview of between the FCC and the FDA to really work closely together on this. So, I'm going to stop there and maybe open for any questions and maybe allow Matt to add any other comments because he is living in this right now.

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

I'm drinking from the firehouse in it right now.

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

Hi, this is Bakul if you guys have comments on that MOU or questions I'm here.

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

So, maybe Bakul you can just highlight, because the MOU has been signed and then how it's progressed and some of the work that you've been doing I think that would be useful to the group.

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

Sure. So, as Mo just pointed out after the MOU – I mean, we had an ongoing relationship, but 2010 actually solidified and sort of formalized that relationship and also made us – made the two agencies be a little bit more programmatic and have methods to contact each other when issues arise not only there but also think about – and we meet regularly, we meet, you know, every 3 months and sometimes it's 2 and sometimes it's 4, but we meet regularly.

We try to get together between the leadership at FCC and leadership here at CDRH to think about not just tactical things and problems or issues, or devices, or technology, or spectrum issues at hand but also talk about what's next and we also talk about how should we move forward. So that's been working really well.

From FCC's side it's Bruce Romano, a partner in crime with Matt, will coordinate with us and from FDA's side it's me and the folks in the center help me sort of put together this working relationship. So, it has gone from a more ad hoc relationship and as needed relationship to more of a working relationship that FCC and FDA has created.

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

Bakul, I'm hoping that when we don't have all of these FDASIA meetings that we might actually be able to work together more.

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

Yes.

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

Great and then Jarrin has been – I think this is just an example of good policy and an example of how collaborations, because Jarrin has been heading up on the health collation and again they have a lot of interactions and recommendations. So, Jarrin do you want to maybe just give a quick sentence on that before we move to Julian who is really going to get into the meat of much of the discussion around the wireless test beds.

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

Yeah, sure, so I wasn't sure how relevant the discussion was going to be about the mHealth Task Force but very basically, last year former Chairman Julius Genachowski put together a group of wireless healthcare technology stakeholders and this included people from the industry, from government, from academia to discuss very specifically mHealth and when I say mHealth we actually ended up defining it in a pretty broad way to include not just mobile health but also wireless health and eCare technologies, and we actually used as the basis of that definition the definitions that were put forward in the National Broadband Plan that the FCC had put together which actually Mohit had a very big hand in assembling chapter 10 which dealt specifically with healthcare.

The idea behind the mHealth Task Force was to come up with findings and recommendations particular to what has happened in the area of mHealth since the establishment of the MOU and the establishment of the two liaisons, which as Bakul mentioned is himself and Bruce Romano. The chairman asked three people to help lead this private sector effort because really it wasn't something that was, you know, formal or official from the FCC it was really just bringing people together to talk about these things and say "hey, you know, can we move forward in some kind of a collective unit and put together some of these ideas."

So the three people that co-lead it were myself, my good friend Dr. Julian Goldman who is on the line and another gentleman by the name of Doug Trauner who is not on the FDASIA Working Group, and anyway we got together, we came up with 5 overarching goals for the FCC and other agencies, you know, and the goals had a lot to do with things like the FCC itself and how it should continue playing a leadership role in advancing mobile health adoption, a goal that established a working increased collaboration to promote innovation to protect patient safety and avoid regulatory duplication between federal agencies.

A goal to build upon existing programs and link programs when possible that could help expand broadband access to healthcare. There was a goal on continuing efforts to increase capacity, reliability, interoperability, radiofrequency safety event technology, some of the things actually that Mo was talking about in particular to securing more spectrum and making sure that we don't have a spectrum shortage. And then finally a goal, really on the industry, to continue supporting investment and innovation, and job creation in this growing healthcare sector.

So, at the end of the summer last year the whole thing began in June, at the end of the summer I think it was in August we had finally met with the group a number of times, the chairman had actually joined a number of the calls, the FCC really opened itself up to this collective group of interested parties to really discuss and collaborate on ways that, you know, we could come up with some good findings and recommendations for them and we presented those in a pre-publication draft that we submitted to the Commission in September and it's my understanding that since that point in time until now the agency has actually either accomplished or moved on at least 90% of those recommendations and I think in total there are about 24 recommendations in the document and I think Matt can speak mostly to those, because a lot of the things that he's been talking about, you know, really came from some of those discussions.

What I will say about the mHealth Task Force is that it's a great example of a working public/private partnership as informal as it was, because there was nothing ever really formally signed or documented with the FCC, you know, the agency really did open itself up. I think that the stakeholders when we started out we were about 20 strong and by the end of it, you know, we had probably doubled if not tripled the number of people who were involved in the effort.

And at the end of the day it was a good way of demonstrating how, you know, these recommendations can help an agency understand, you know, the needs and the worries of the private sector and of, you know, the interested people who are dealing in a specific space and I would say, at least personally, I feel that the agency really has moved forward in trying to, you know, answer some of those things and that's a really important thing and actually shows how nimble and agency can be. So, I think that is one of the biggest takeaways from the mHealth Task Force.

With that I'll roll it over to Matt and see what his comments are on some of the things that they may have been working on since then and also to go to the next section which is equipment authorization, which we think is probably best for someone from the agency to actually lead that discussion. Matt?

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

Good stuff and, you know, one of the key things that I take away from the mHealth Task Force work is that if you – if an agency that is working in an area of increasing importance but not necessarily an area that is as well-known as say data standards that if you engage with innovators as well as industry proactively to try to understand what they're developing and what they're doing then you can head off some of the challenges at the pass so people don't have to come to market with something that isn't going to get through the regulatory process or is going to, you know, have problems down the road if you anticipate and figure out what those issues are.

And so, you know, some of the discussion that we've had with FDA and internally about wireless test beds, some of the relaxing of standards and figuring things out around wireless use and test uses in healthcare organizations, and academic centers that have been, as a result of recommendations of this and interface with industry, is just us trying to ensure that people are able to come to market efficiently and effectively.

One thing that I would add is that, you know, the mHealth Task Force, as Jarrin described, is not an official FCC activity, but we have recently reconstituted a consumer advisory committee which is a federal advisory committee under FCC and the three chairs of the mHealth Task Force are on that and one of the things that we're looking at doing is putting together a Health Workgroup and so I think that that's going to be a great way to take what was informal and make it more formal but at the same time, you know, maintaining that connection with those folks.

So, everyone should have recently, in the past few minutes, received a PDF presentation. I'll go on the line here, a PDF presentation about the FCC Equipment Authorization Program and I am not Dr. Doshi, but I am going to give you an overview of the FCC's Equipment Authorization Program.

A couple of things to highlight with this is that number one we have one, number two we have moved it from doing it internally to using accredited test labs for this and that we also have a lab in Columbia that Dr. Doshi runs that has a team of folks working with them and working through some of these issues. So, with that I will jump into this.

And so our core role is we are a regulator of non-federal spectrum. The Commission establishes technical regulations for transmitters and other equipment to minimize their potential for causing interference to radio services and so, again, you know, our major focus is interference. Second, Commission administers an authorization program to ensure that equipment reaching the market complies with the technical requirement of Part 2 J.

And so there are three general categories of equipment one is radio transmitters so this is Parts 27 or 90 and licensed radio service equipment, unlicensed devices and this is Part 15 and so this is a lot of the wireless mics, this is Blue Tooth, etcetera and then there is telephone terminal equipment. The Next slide.

So, the authorization program is a product approval requirement as specified in the rule part under which equipment operates not all equipment requires FCC approval or accreditation. Generally products are still required to meet certain standards and so if you look on your cell phone or you look on your baby monitor, or you look on your Blue Tooth you'll see the little FCC logo.

FCC currently has four equipment programs verification, supplier declaration of conformity, declaration of conformity and certification. All four programs involve the use of the private sector to varying degrees and so the next slide talks about the different types and we can skip over part six and go to seven.

Test lab requirements, Part 2 specify the minimum standards for test labs that can perform compliance testing for FCC equipment authorization. Verification can be done at a manufacturer's test lab, declaration of conformity is done by accreditation test labs according to recognized standards and certification is defined for the test lab for Parts 15 and 18 referred to as FCC listed labs. So, those are three different sets of requirements depending on the type of equipment.

The testing performed in support of conformity must be performed by an accredited laboratory that has been recognized by the FCC and this sounds a lot like, you know, ONC's certification program and some of these labs actually can be outside of the US if recognized by the FCC. There are some slides at the very end that shows just how much equipment from outside the US that we test for products from outside the US and for other countries because we try to harmonize obviously with other countries.

And FCC listed lab, a description of the test site in which a product is subject to certification under Part 15, that's the unlicensed, or Part 18 will be tested for compliance must be filed with the FCC. FCC maintains a list of over 800 listed labs. Foreign labs may be listed to perform Part etcetera and then there is an online database of these.

And so slide number 10 shows the certification options. So, test and evaluate products to determine compliance, prepare test report and application, you can either submit the application to the TCB or submit the application then FCC grants certification, and then you can bring it to market.

And so if you go to slide 12 this is looking at the scope of certification trends from 1999 to 2011 and you can imagine the continued growth of that. So, we're looking at almost 14,000 certifications in 2011 and the vast, vast majority of them are done by TCB, these accredited test labs, versus the FCC itself, in fact almost down to none and that's just a capacity issue. And if you go back to slide 11 using the private sector to do this speeds up the ability to do this shorter product lifecycles and reduces uncertainty and delay in obtaining certification.

And so a little more about these TCBs, a TCB is an independent third-party certification body, it's accredited according to ISO, roles and responsibilities and again foreign entities may become a TCB in accordance with the rules and we don't need to go into those.

Something that I actually need to learn more about is the FCC audit and market surveillance program and the goal of the program is to ensure the integrity of the grants and ensure the compliance of the rules. So, not grants as in research grants but once we grant certification that we want to make sure that things are being done that we're not certifying things that aren't what they should be.

And there are various stages of test evaluation and sample of authorized equipment, there is pre-testing, post-testing and test samples from the marketplace, random testing, test samples submitted from enforcement bureau and FCC as an independent regulatory agency so we have an enforcement bureau and identify and investigate new technology, complaints received by public and competitors.

So, I'm not sure if Mo knows more about this but one of the things that I've been trying to learn more about is, so how do we learn about – how do we get information from the field for example to fuel post grant testing based on these issues. And issues where it's licensed spectrum and there is interference are a big deal and potentially these could put lives in risk or it could put interference on emergency broadcasting or it could put, you know, issues with transmission to satellites these are big deals and so when we hear about these it's important.

And so to echo that graph that you saw on slide 16 there has been tremendous growth in equipment approvals both in the private sector but also in the FCC lab where they process 200 application requests just there and then monitor the activities of the TCBs who processed lots and lots of applications.

So, where FCC participates directly as opposed to the private sector is for new technology issues and I don't want – special processing may not be the right word, but figuring things out or stuff we haven't seen before.

We have resources for sharing and distribution. So, [fcc.gov/labhelp](http://fcc.gov/labhelp) and then the overall equipment authorization process is at [fcc.gov/oet/ea](http://fcc.gov/oet/ea) as shown on slide 17. And that's really about it. If you look on slide 21 it shows some of the involved folks so it's FCC, NIST, ANSI, A2LA and we have five mutual recognition programs around the world. And so with that I will open it up to questions or if not I will pass it over to Dr. Goldman to continue.

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

This is Brad Thompson, I ought to know more about this but I don't so excuse my ignorance please, but so you just described this third-party certification program and my initial question is a scope question that is what range of devices are meant to be passed through it as a way of premarket review and if I can put a finer point on that question does it overlap at all with FDA regulations? Are there any FDA regulated medical devices that may produce a signal of some sort that need to go through both the FDA process and this FCC process?

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

Yes those that use spectrum and Bakul do you want to jump in and talk about, you know, maybe MBANs or an example where you've worked with ROET and the nuts and bolts of that?

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

So, Brad, typically licensing – if somebody uses spectrum that needs to be licensed, that needs to go through FCC's licensing authority.

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

Brad, this is Elisabeth a good example is the wireless telemetry system so for patient monitoring which basically performs the same activity as the bedside monitor but instead what it does is it's carried on the patient's body so that they can walk around the hallways and still be monitored at a central station and those devices do have to have a 510(k) and FCC licensing for the frequency band that they are performing in.

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

So, Elisabeth just so that folks don't get confused they have to go simultaneously most of the time the determination of using a wireless telemetry is done while the product is being conceptualized.

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

Right, right I'm sorry, yes.

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

And when that conceptualization happens they need to – so a manufacturer decides to use spectrum X and that happens to be a wireless telemetry spectrum they would need to go to FCC if it is required and get a license that does not necessarily mean they have to come to FDA for premarket clearance at the same time. Premarket clearance for medical devices only happens when they're about to introduce that product into the market whereas the licensing typically happens way before.

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

Early.

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

Way before and very early into the development cycle.

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

Yeah and maybe one of the other folks has a picture of it that they've shared, but the spectrum map for the US doesn't have a lot of free space and so if it's a device that is using something other than unlicensed spectrum that Part 15 unlicensed spectrum then there is potential for interference with something else. So in the case of MBANs it's sharing it with potentially other space and we have lots of issues that need to be figured out potentially so that it doesn't cause interference with something else going on.

Our approach, and I think that you're going to see us really focus on this and provide resources on this, is to help educate the developer and innovator community and to provide resources for ensuring that folks know where there is spectrum that they can use and where there is not and potentially the spectrum map will be changing as it's repacked as a result of incentive options and other things.

I mean, this is an issue that is going to get bigger in the future as opposed to go away and so as we think about this we want to make sure that in addition to regulating wisely and working closely with FDA and ONC, and everybody else potentially that's involved that we're supporting, you know, early on in the development process but also early on in the conceptualization of these products that we're figuring out what makes sense and what doesn't so that there aren't delays in going to market.

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

So, Bakul, can I ask, this is Brad again, can I ask you to compare and contrast the FDA process with the FCC process and so when I refer to compare and contrast I'm asking I guess how are they similar and how are they different, and in particular could you start with regard to objectives, you know, FDA objective being safety and effectiveness ultimately whether it's through substantial equivalence or PMA ultimately being concerned about the safety and effectiveness of the device and the truthfulness of the labeling, how is that similar or different to what FCC looks at? I mean, can you help me understand how they're similar and how they're different?

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

So, I wish Bruce was here because he has a really –

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

Yeah.

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

One liner and I will just try my best, so –

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

Put on your Bruce hat.

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

And maybe Jarrin can sort of help here as well. So, as you pointed out there is a safety and effectiveness making sure products are not misleading people are – I mean the two fundamental trigger points for FDA is – which means the product needs to work as intended and also needs people – the products need to be sold as intended, as they're performed and that they need to maintain their performance whereas from FCC perspective, and I'll be speaking out of turn if I get it wrong, correct me, is more on whether the product can sustain interference.

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

Yeah.

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

Or cause interference with something else and that's regardless of health or anything else.

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

Yeah.

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

So, it's just can it exist, can it sustain interference or radiofrequency, or any other interference from other devices or other products and don't always use the word devices and this product if it uses a spectrum will it cause interference to others so they test for that, they want manufacturers to test for that those triggers.

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

Yeah, I mean, this is Matt, the way that I would describe it is that our primary focus is minimizing interference and we do not view the safety and efficacy of the product as our regulatory focus that's FDAs and it's also the marketplace's to worry about those things. Where we do care is whether it's on the user end or on the manufacturer's end where there are instances of interference. So, our focus is not wide but it is an important one and I think it's complimentary.

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

So, I assume that if interference kept a medical device from operating safely and effectively that becomes an area of mutual interest between the agencies because it is both interference and safety and effectiveness, so how do you tackle that together as it were?

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

So, some of the unlicensed spectrum that is a common understanding, a common scope of interest so to speak where in an unlicensed spectrum basically there are set rules for acceptance and effecting other products.

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

Yes.

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

So, that's the way I look at it, but there are some, there may be potential for safety incidents or safety issues that may arise as a result of not appropriately accepting interference or causing interference.

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

Yes.

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

So, that's something that we work together and that's something that we are working together to clarify from a safety perspective for medical devices what people should consider, what manufacturers should consider that's a guidance from the wireless perspective that we would provide for folks to think through in either selecting and associating risks that could happen to patients and consider these issues as part of the risk management how they would address it. So, that's how we look at it.

Broadly speaking FCC's role in the unlicensed spectrum is not just medical devices, medical devices happen to be part of it, but it includes everything including, you know, printers and walkie-talkies and everything that uses unlicensed spectrum.

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

Yes.

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

So, when I go to the doctor he's got this big sign that tells me I have to turn my cell phone off because it might interfere with medical devices being used at the doctor's office and I always grumble but I turn it off, but that's an instance of where an un FDA regulated product, a cell phone, use of the cell phone could interfere with the operation of the medical device presumably in a way that could impact safety or effectiveness. So, how do you – can you give me sort of a tangible example of how you coordinate in that zone where FCC's role might be with regard to the cell phone and the potential interference it could create with regard to a medical device and then the medical device?

So, if I understood you Bakul for example the manufacturers of medical devices need to understand that they might be used around cell phones and factor that into the risk analysis that they do and try and figure out technical ways to mitigate that risk but there may also be things that, you know, I assume cell phone manufacturers could do to mitigate the risk of interference. Am I right about that?

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

Yes, go ahead Matt.

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

I was going to say that the quickest way to market is with unlicensed, with a Part 15 device so an unlicensed spectrum device, but inherent in selecting that spectrum is the understanding that users and transmitters on that – in that band, in that area could have interference and so one of the things that we're thinking about and that we're doing actually is putting together – relaxing some of the rules around testing inside healthcare organizations themselves.

So, all of the possible permutations of use of spectrum in a particular building whether it be licensed or unlicensed in conjunction with, you know, unlicensed spectrum used on Blue Tooth headsets, on cell phones, on, you know, everything that somebody might bring to work can have implications at the end user level or the healthcare organization level that are unanticipated, you know, as part of the individual manufacturing process.

And so thinking about that and ensuring that safety and efficacy that's a great joint issue for FDA and FCC to work on together in conjunction with healthcare providers and it's not something that can be done – some of it can be thought about upstream in terms of, you know, what devices or what tools does it make sense to allow in those environments and where do we know that there is going to be interference and where do we know that if there is interference there are going to be bad consequences, but some of it is just local implementation again and trying to figure out what works and what doesn't work in a particular environment.

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

So, Brad you are bringing up very similar points that, you know, not just the healthcare facility but as you take transmitters on an airplane you're asked to shut down and those are some of the things that either as technology has matured and, you know, the other devices or other objects in the environment have – either the technology advances or other standards have evolved needs to be looked at and I think that's something that's actively being looked at by – not just now but continuously being looked at by FCC.

**M**

If I could jump in here just for a couple of –

**M**

Yeah, there we go.

**M**

Oh, hi –

**Julian M. Goldman, MD – Medical Director, Biomedical Engineering – Partners HealthCare System**

I'm on Skype, yeah, my connection is a little flaky but I wanted also to hear what our folks from FCC and FDA had to say and then I thought it might be helpful to give a bit of an update from the mHealth Task Force that Jarrin talked about earlier, it's easy to find the mHealth draft report, mHealth Task Force draft report on line, but let me share some of section 4.4 because I think it speaks to some of these gaps and needs.

In section 4.4 it says and I'll just quote "FCC should encourage and lend its expertise for the creation and implementation of wireless test beds" and as Matt said this work has been ongoing with planning in the background but let me provide a bit more detail here "testing and evaluating" and again I'm quoting "testing and evaluating innovative wireless healthcare devices is complex and expensive in part due to the scarcity of complete wireless test environments and expertise."

So, in the example that you gave Brad we've certainly dealt with some of those issues within Partner's Healthcare in our wireless management policies and meetings and it can be very, very difficult to assess whether there is a real issue with interference with mobile phones and other medical devices.

So, going back to – now that I just added that, I'll go back to quoting this document "a more effective approach to using spectrum for test bed environments is needed" and I'm going to go a little bit further down in the report to these last few lines in section 4.4 "specifically we recommend that the FCC encourage and lend its expertise to the following initiatives, number one creation of national centers with equipment, expertise, licenses and support staff. Number two, identification of tools and consensus standards to monitor and assess performance of wireless technologies in healthcare environments." So, this is the part that speaks to the monitoring and assessment post installation whereas the discussion we just had really was more focused on the head in preparation.

The next point, number three "easier access to spectrum or rules for healthcare that feed the quest for interoperability." Number four "encouragement for innovation of technology and other tools such as standards or publications." And then finally "encouragement of newer technology such as cognitive radio and applications that are built on a risk management approach."

When we were working on this topic within the mHealth Task Force and had several meetings and discussions some interesting things emerged that are not yet fully flushed out but one of the important points was that it seems to be very difficult for industry, and especially the smaller manufacturers and the FDA, and I don't want to speak for the FDA, but again this is what came out of some of the homework from the mHealth Task Force, it became quite difficult to have clear acceptance criteria for wireless, for radios and for the likelihood of interference or stated another way to assess the likelihood – to assess co-existence and that problem exists not only prior to the deployment of technology but also to monitoring it's performance after use.

So, there does seem to be a gap here to help facilitate the adoption of wireless technologies with regard to the things we just discussed. So, I don't want to keep going, I just wanted to share that information from the mHealth Task Force, again that background work.

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

This is Matt, I think that it really begs the need for assistance to folks developing solutions and developing solutions where there needs to be wireless interoperability we'll call it, but also on the implementation side where, you know, the permutations and the combinations with architecture that may not have necessarily been optimized for ensuring no interference is there and so the Task Force recommendations are really right on the question is, in my mind, whether, you know, in the recommendations of that group it rises to the level of need for regulation or if we can support it in some other way.

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

I was going to just add a little something to some of the conversation that was going on before, one thing that I would definitely – because we were talking about, you know, how the FCC rules really specify categories and I think that Rashmi's slide deck, slide number 3 in particular, is really pertinent because it really does try to at least identify what those radio transmitters are, so we have radio transmitters, unlicensed devices which are Part 15 and then telephone terminal equipment, and, you know, under unlicensed devices, because that's one of the things that we were just talking about, you know, there is this explanation or non-explanation it just lists incidental radiators, unintentional radiators and intentional radiators and I think that's kind of an important thing that goes to, I think what you were asking before Brad, you know, as far as, you know, what some of this, you know, I guess how do I parse this, in other words you were asking about what happens when the two agencies are looking at, you know, an issue of harm or interference.

And, you know, from an FCC perspective I think it's important to, you know, understand that the agency does have rules in place that are very specific to these types of devices, you know, even something like an incidental radiator, you know, which is not necessarily a device that emits radiofrequency energy it's more, you know, it's not even intended to really do that but it does so by virtue of what it is so I'm talking about things like motors or, you know, photocopy machines or a vehicle –

**M**

–

**M**

Right.

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

Hey, guys, Brad and Jarrin, sorry to interrupt I have to drop off but if there are any questions I can definitely follow-up later.

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

Okay, thanks, Bakul.

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

Thank you.

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

Thank you, Bakul.

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

You know, and I think, you know, drawing from that if you also think about licensed versus unlicensed spectrum because that is something that is important to kind of understand and I want to make sure that, you know, in no way shape or form am I trying to state that one, you know, type of spectrum is, you know, by virtue better than another or anything like that, you know, this is a very technical field and a very technical area even if you have unlicensed spectrum there are things that you can do with technologies to, you know, create redundancy and ensure that it's safer for use, but, you know, licensed spectrum is something that is used on an exclusive basis by licensed holders which are granted by the FCC.

And, you know, if you want to think of that practically today most wide area networks, so as you think about, you know, a 3G network or a 4G network, you know, those connections are licensed. So licensees are definitely protected from harmful interference or rather interference caused by other parties. Unlicensed spectrum is very different but it's not a wide area network it best supports short range connections whether it be a body area network or a personal area network, or even a wireless local area network.

And most of the times those technologies can be controlled by the user. So, unlicensed users may not interfere with licensed users and by virtue of that type of spectrum they must accept interference from all other sources. So, there is definitely a difference between the two types of spectrum, you know, I just wanted to point that out because I think we were kind of, you know, meandering through some of that earlier you know.

And I think that Matt brought something up that is incredibly important and Matt, actually Mohit did show a slide, I don't remember what number slide Mo you had it on, but you showed a small graphic of the actual spectrum map for the US, you know, spectrum is a finite natural resource and I don't think people realize that, every block of that spectrum map is allocated to something and, you know, within each allocated block you have very different rules that apply whether it be a licensed spectrum or licensed by rule or unlicensed spectrum and that's what typifies how you can use whatever technology it is that resides within that spectrum.

So, it's a very complex area, it is definitely regulated by the FCC and there are some correlations between the equipment authorization that FCC has as part of its regulatory process, you know, comparing it to something like the FDA, you know, whether you want to call it the premarket approval process or the clearance process or even if you have a class 1 device and you have to list it, if it emits, you know, radiofrequencies or some type of energy form, you know, it really should go through the FCC process as well.

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

Either the authorization or the certification.

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

Exactly. So, that's my only point Brad.

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

So, that's very helpful Jarrin and I was really trying to understand how sharp or how clear the line distinguishing the two processes are as well. So, I'm interesting in both similarities and differences and I was really trying to figure out for example can FCC as it looks at wireless, excuse me, as it looks at potential interference can it consider the potential impact of the interference as it looks at it?

It sounds like it's maybe a more mechanical task looking at whether there exists a certain type of interference as opposed to getting into considerations of what the potential health impact of that interference could be on a medical device I should be more specific.

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

Yes, absolutely, that's a good way to look at it.

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

Okay.

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

That those are considerations and technical aspects that are not our primary focus nor our technical expertise.

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

So, can we talk just a little bit about post market, because everything we've been talking about I think, at least I've been trying to frame it as premarket of how decisions about whether products are allowed to get on the market, but let's say a product gets on the market and there is an incidence of suspected interference where a medical device was effected either by spectrum emitted from another medical device or from a cell phone or something else that is not a medical device, so if healthcare professionals suspect that that has occurred – I'm familiar with the FDA requirement of adverse event reporting, is there anything similar at FCC?

I mean, what happens if there is suspected interference does it get reported to the FCC and if it does either directly or indirectly through FDA are there consequences? Can certifications be revoked? Are the things that happen in the FCC world, post market, if there is suspected interference?

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

I – this is Matt, you know, that's not something that I fully have my head around so I don't want to comment on it. It is something that I can provide as follow-up inside from our OET folks. I know that in cases where there have been interference for example there was a hospital system where there were some issues with interference with a television channel spectrum that it gets here pretty quick and that it's a really important issue, but smaller occurrences and local occurrences where – so for example let's say that a healthcare organization has implemented some combination of tools and devices and has some issues, how do we learn about that, I can't speak to that and that's something that I'll bring back to the group when I do.

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

Julian, Jarrin or Mo do you guys have any familiarity with that issue?

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

– I know the case but I do not know the full ramifications, this is a case down in Texas where TV did actually interfere with hospital equipment and I do remember there were ramifications I just can't remember the specifics I'll have to get back to you on that as well.

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

This is Elisabeth I'm actually familiar with some of that as well and primarily what transpired was is because the medical devices were not specifically licensed that, you know, the challenge occurred that we did have to submit medical device reports, we did work with the television groups to address those issues and we had to work in concert together because that was a challenge, but that was, you know, a long time ago that was when, you know, HCTV stuff first came out and it stepped on the telemetry systems and there had been also in the past copy machines as well as pizza trucks that used to – that were on, you know, the radios that stepped on it and, you know, we had to address those actions and subsequently we've had to do more testing of the devices and things like that, but I don't recall of anything specifically recently those are really more historical issues.

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

Yes, this is Matt, the actual potential patient harm type issues would I'd assume come through FDA – and that process. The spectrum issues would come to us and, you know, exactly how that works I owe you guy's better answers.

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

Well, yeah, I was just going to say, if I could add anything it's just that there is an FCC enforcement when we have an issue of, you know, harmful interference being caused, you know, by an incidental radiator or if we have, you know, a situation where an incidental radiator has not used good engineering practices, which according to the Regs that's what they should do, so there are laws on the books, regulations for it and there definitely is and FCC enforcement process and I think Matt is probably the best to get that information to you guys.

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

Yeah, I mean, you know, an example outside of this domain is that there are pirate radio stations that pop up all the time and transmit in ways that are not authorized by the FCC and, you know, that's one of the things that our enforcement bureau does and also it's something that we map and so I know that we're getting a dataset from somewhere on that but exactly the process is something that I want to learn myself before I talk to you guys.

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

So, there are at least two different flavors in my very simplistic mind, there is unlawful interference and then there is potentially lawful interference, right? Unlawful interference would be of the kind that Jarrin was just speaking of where someone has done something wrong, they haven't used good engineering practices or the pirate radio station or any of those, so finding those and prosecuting those would be one subset.

The other subset would be where someone hasn't done anything wrong or at least not obviously done anything wrong but nonetheless, you know, interference is a fact of life in this area I assume and just, you know, keeping track of it to find out how frequently it occurs in order if nothing else to inform policy making so that we can be alerted to issues that we haven't previously recognized and if an issue is bigger than we thought it was, you know, keeping track of instances so that we figure out whether policy needs to be adjusted. I'm interested in both flavors of that if when you take a look at it if you're able to give insight on both of those that would be helpful.

**Julian M. Goldman, MD – Medical Director, Biomedical Engineering – Partners HealthCare System**

Brad, Julian here, I was trying to speak before but I had a connection problem, I think that the point you're bringing up and that's been discussed is vitally important. I would add that we can't necessarily determine initially which of those two categories is at the root cause of the problem, we don't know.

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

Right, yeah.

**Julian M. Goldman, MD – Medical Director, Biomedical Engineering – Partners HealthCare System**

Right, so, you know, as we approach a problem like this capturing the information and understanding it would then perhaps lead to the mitigation of the problem. And in some of the problems that I've observed with interference, and Matt gave examples, which we've experienced in our hospitals of regional TV stations interfering say with telemetry equipment it isn't clear that those reports are, you know, shared broadly. I think that they often are silo'd so the discussion may happen with the FCC or it may happen with the interfering source such as the TV station or it may happen with someone at the FDA but that someone at the FDA maybe a highly skilled and knowledgeable engineer with expertise in wireless and it doesn't mean that it will ever be included the appropriate database for example the MAUDE database or one of the other databases that can be mined at a later date. And I believe that we are missing the vast majority of these issues because they are partitioned in that way. So, I appreciate that you brought it up.

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

Yeah, your comment about partitioning is something I'd like to explore and better understand and maybe we don't know the answer as we speak here this morning, but so Julian as someone who works out in the field if you did observe a medical device that you thought was being interfered with and you didn't know necessarily the source of the interference you might have a guess, there might be another device in proximity that you might suspect or it might be, you know, some TV station where you have no idea of what's going on, mechanically are there ways to report that that you are aware of?

You just referenced the silo, it sounds like you might report it to FDA as an issue with a medical device and you might separately report it to FCC to some office within FCC is that – am I understanding correctly?

**Julian M. Goldman, MD – Medical Director, Biomedical Engineering – Partners HealthCare System**

In a sense if the problem occurs directly, if the interference can be detected directly with a medical device itself it simplifies the problem. If an event – and there have been reports of things like that, ventilators or infusion pumps that have been effected by interference by transmitter, but it becomes more difficult when it's somewhere, especially given the topic we're discussing here, somewhere within the Health IT chain of data flow which now includes – may include wireless access points for example that are not considered medical devices.

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

Right.

**Julian M. Goldman, MD – Medical Director, Biomedical Engineering – Partners HealthCare System**

The problem maybe there and so as we broaden the scope of Health IT the likelihood that we'll collect the information and deliver it in a way that will allow us to look at those statistics becomes remarkably more difficult, but if the device is directly effected in fact it simplifies things. I believe that most of those episodes are not reported either if there is no patient injury or likelihood of patient injury.

So, if someone sees for example that a mobile phone is interfering with a medical device because the phone is very close they'll just move it away from the device and I doubt it will be reported, which is unfortunate because then we still don't have a good, you know, we still have a good – you know, we still have very weak statistics and they're also not necessarily not leveraging the Health IT to facilitate detection, monitoring and reporting of these kinds of events.

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

Yeah.

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

This is Matt, you know, in corresponding with my colleagues here we have [fcc.gov/complaints](http://fcc.gov/complaints) is I think a key way that we get complaints of a broad variety. So, if you go there, there is complaint type, category and filing method and it's an online form for reporting these you can do it online, you can do it via phone, you can do it via even mailing it and faxing it in, but the question in my mind is, you know, at the operation center when we get these how does that work and it's honestly just something I haven't – I don't have my head around yet.

**Julian M. Goldman, MD – Medical Director, Biomedical Engineering – Partners HealthCare System**

Well, also let me add Matt just another challenge that exists is that we can't easily collect the data, so we're expecting an expert to, you know, somehow describe and report an event but we don't necessarily have easy access to a data log, you know, these are potentially very complex and sophisticated things if it's a data log related for example to the access point. So troubleshooting and managing these things is partly hampered by the inability to easily collect, store and share the data.

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

Yeah, I mean, and understanding what the conditions that led to the interference occurring –

**Julian M. Goldman, MD – Medical Director, Biomedical Engineering – Partners HealthCare System**

Right.

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

Are not necessarily readily apparent whether it's, you know, maybe somebody turned on the microwave down the hall or they, you know, somebody with a particular kind of brand of cell phone came into proximity of the device or maybe there were sunspots that day, I mean, who knows that's –

**Julian M. Goldman, MD – Medical Director, Biomedical Engineering – Partners HealthCare System**

Or a paper shredder.

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

Yeah or a paper shredder, who knows, exactly and that may or may not be apparent in the report, now I'd hope that, you know, just multiple occurrences of a particular report would key some sort of an investigation but again that's something that I don't know.

**Julian M. Goldman, MD – Medical Director, Biomedical Engineering – Partners HealthCare System**

Well, I think that as we look at a problem of this scope and importance we have to recognize that it may be difficult for manufacturers to provide the kind of support that might be needed, it may either tax their resources or they may not have all the data that they need or they may have concerns about encroaching on the medical device regulatory space and conveying that somehow they too are responsible for the medical device functionality of the system and we know that that does make some non-medical device manufacturers quite skittish.

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

Yes, well and I would assume, I mean, this is not backed by any science or data analysis, that these sort of issues would probably come to FCC first and, you know, the folks over there would raise them to our technical staff here and bring them up as issues that we need to work on jointly rather than folks in the field, in the healthcare organization knowing to go to [fcc.gov/complaints](http://fcc.gov/complaints) or some other place and raise that issue with us versus raising it with FDA. So, the more transparency and maybe integrating those reporting processes the better.

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

This is Elisabeth again, as a medical device manufacturer who has wireless I can tell you that whenever our wireless equipment has any kind of issues we're very quickly notified so it goes through our standard complaint process and analysis, and investigation, and as appropriate we would be, if we determined that it meets the definition of a malfunction, we would be submitting it into MAUDE so there would be that visibility there, but again I think what you've all said is, is that depending on who the recipients of the information is could determine where that information goes so it may not be the superset of all the information in one place.

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

Yes.

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

This is Mo, unfortunately I have to drop out to another meeting, so apologies and actually I would be happy to follow-up on any of these other topics at a later date.

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

Thanks, Mo.

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

Thanks, Mo,

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

Thanks, all, bye.

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

So, Jarrin and Julian, you know, I look to you guys to lead the discussion whatever direction you want to go. I know that really I kind of jumped in and starting asking questions before Julian had an opportunity to present some stuff that I think Julian was going to present, so we've got about a half hour left before we need to turn, you know, to public comment, so I don't know how you want to spend that half hour, but I'll leave it up to you guys.

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

So, I think that Julian may have definitely already touched on the subject of test beds because I think that's what he really was going to be speaking about, Julian are you still on the line?

**Julian M. Goldman, MD – Medical Director, Biomedical Engineering – Partners HealthCare System**

Yes, I am and I covered really the majority of it. I'm not sure that I made it clear that, you know, as we explored this for the mHealth Task Force we discovered that there is a significant amount of interest in it but the notion or the words test bed can be a bit confusing and people have different ideas of what it might look like, but we, you know, certainly heard that there are issues both in the premarket side, the need for national tools to assess performance and some of the other things that we touched on.

I did send, I did excerpt some of the content from the mHealth Task Force and created two slides which just because I couldn't get the e-mail to work I couldn't get in on time for this call, but they were submitted and so they may be able to be added to the documents that are available to the public.

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

So, Brad I actually thought that when we discussed this internally meaning Julian and myself, Mohit and Matt we we're not sure that there was, you know, much more than what we've covered this morning to discuss we think really it was at this point best to just, you know, continue the conversation and answer questions and/or, you know, give folks back some time. We didn't think that we would go the full two hours.

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

Okay.

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

You know, obviously in the context of Health IT the most probative part I feel is the equipment authorization, you know, which again compares nicely to something like the FDA classification system and, you know, that premarket notification, premarket approval listing and again the ONC's EHR certification requirements for certified EHR, certified EHR modules, but, you know, when we're talking about Health IT in the context of software, you know, I think more the issues that we're discussing here today, you know, lead to a discussion of actual hard tangible products as opposed to software.

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

So, if you guys have any more questions you want to pose to the group great we can do that, if the group has questions that they want to raise to you guys or for a more general discussion we can do that. So, first let me see if Jarrin and Julian have any other questions you guys want to pose to the group?

**Julian M. Goldman, MD – Medical Director, Biomedical Engineering – Partners HealthCare System**

Julian here, nothing that I can think of at the moment just happy to answer any that surface if we can.

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

Okay, Jarrin you?

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

The same, yes, the same.

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

Okay, so let me ask the group any questions from anyone in the group that they'd like either Julian and Jarrin to comment on or more generally to be discussed? Okay, so I think at this point we're probably done with our discussion and can go to public comment to see if there are any comments that anyone would like to offer. So, MacKenzie can I ask?

## **Public Comment**

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

Sure, 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, all right, so and always if people think of questions or comments that they'd like to make please by all means send them by e-mail to me or anyone else you'd like to share them with. Just for the Regulation Subgroup I know MacKenzie that we were trying to pick a date for next week where we would have a call that will be led by 3 people, it will be led by Lauren who led the call yesterday on ONC, Meg from Cerner and Mike Flis from Roche Diagnostics are all going to collectively lead a discussion of other regulatory and non-regulatory schemes that are relevant to what we're looking at namely the safety and innovation of HIT.

So, among other things they'll be talking about OSHA and far flung, you know, state requirements that impact on it, I assume probably the Federal Trade Commission and sort of a range of other regulatory systems that are out there that need to be factored in when we look for potential areas of duplication. It will also include private activities, so it will include groups like the Continua Health Alliance that is developing a certification program for certain Health IT, they'll cover private standards development by AMIA and other bodies that are working to develop standards to make Health IT safer.

So, it will be a very interesting discussion. MacKenzie do you happen to recall is there a specific time they've settled on for that phone call?

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

It will be the 26<sup>th</sup> at 2:30 Eastern.

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

The 26<sup>th</sup> is that Wednesday?

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

Yes.

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

Okay at 2:30 Eastern Time. So, invitations, electronic invitations will go out for that, we will have that call next week and I think it's Monday July 1<sup>st</sup> we're going to get together and start to synthesize some of this, we've been going kind of on a silo'd basis looking at each individual agency and as I said next week we're going to look at a lot of different regulatory systems.

Then we're going to start the process of synthesizing it, pulling it all together looking for what's working, what's not working, what's over regulation, what's under regulation that discussion will begin on July 1 and then you also should have seen an e-mail from me outlying basically another 5 or so calls that will occur through the month of July to try and bring this all together into one work product that the Subgroup can submit to the larger working group.

So, that's the big picture and that's all I have for today, anything else we ought to discuss before we adjourn? If not I want to thank Mo and Julian, and Matt, and Jarrin for their terrific job organizing the discussion today, it's been really helpful and look forward to talking next week. Take care everyone.

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

Thanks, everybody.

**M**

Thank you.

**M**

Thank you.

**M**

Bye.