

**FDASIA Workgroup
Regulations Subgroup
Transcript
July 3, 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 there is public comment on the agenda. And the call is also being recorded, so please make sure you identify yourself for the transcript. I'll now take the roll call of the subgroup members. Julian Goldman?

Ulian M. Goldman, MD – Medical Director, Biomedical Engineering – Partners HealthCare System – Director, Program on Medical Device Interoperability, CIMIT, Massachusetts General Hospital

Present.

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

Here.

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

Thanks Brad. David Bates? Todd Cooper? Anura Fernando?

Anura S. Fernando, MS, MD – Principal Engineer – eHealth – Medical Systems Interoperability and 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 Rob. Mo Kaushal? Joe Smith? Jodi Daniel?

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

Here.

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

Thanks Jodi. Simon Choi?

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

Here.

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

Thanks Simon. Matt Quinn? And for the full FDASIA Workgroup members on the line, Mary Anne Leach?

Mary Anne Leach – Senior Vice President and Chief Information Officer – Children’s Hospital Colorado

Here.

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

Thanks Mary Anne. Elisabeth George?

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

Here.

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

Thanks Elisabeth. Keith Larsen?

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

Here.

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

Thanks Keith. Drew Hickerson?

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

Here.

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

Thanks Drew. Jackie McCarthy?

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

Here.

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

Thanks Jackie. Are there any other workgroup members on the line?

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

Yes, this is Meg Marshall.

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

Ah, thanks Meg.

Michael Flis – Regulatory Manager – Roche Diagnostics

This is Mike Flis.

Lauren Fifield – Senior Policy Advisor – Practice Fusion

Hey MacKenzie, it’s Lauren Fifield.

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

Thanks Lauren. And who else is there?

Michael Flis – Regulatory Manager – Roche Diagnostics

Mike Flis.

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

Oh, thanks Mike. Okay, with that I will turn the agenda over to Julian.

Julian M. Goldman, MD – Medical Director, Biomedical Engineering – Partners HealthCare System – Director, Program on Medical Device Interoperability, CIMIT, Massachusetts General Hospital

Okay, thank you very much. Well today – the first part of today's meeting was intended to be a discussion about some of the reporting approaches that might be available to us that might exist elsewhere or that – and some of the requirements that we have for reporting, so that we can better understand some of the issues and in the future, in particular, have more comprehensive data to allow us to make decisions about safety. And that introduction is really very limited because the topic of reporting data, basing future decisions on more comprehensive data is something that has come up in virtually every meeting. And so I attempted to gather information in discussions with a number of you offline, develop a few examples, a few use cases that we can use and really just put together information that can serve as discussion points, so that we can kick off a discussion and dig a little bit deeper into this to better understand what our options are, what's possible and what's needed.

So with that, I'll start off with a slide set which certainly will not capture everything that's been discussed thus far, but should have helped capture the major points. And, let's see, I believe I have control – I do. So, looking at this slide, it's a specific example that will allow us to drill into some detail. And what I plan to do is stop for questions a few times, but for the most part, just try to present the entirety of the information, which isn't all that much or won't take very long, and then make sure that we have plenty of time for discussion at the end as well.

So one of the points that has come up is the issue of will we have data for adverse event analysis and do we have data for adverse event analysis. It's important that we accept the idea that an adverse event doesn't really mean an event in which a patient has been harmed. The definition of an adverse event as used by the Federal Drug Administration (FDA), for example, is broader than that and it includes events in which a patient could have come to harm, if there wasn't an intervention that was performed. So again, it doesn't mean that someone was harmed; it's a very broad category of issue. So when medical device and health IT related system problems contribute to an adverse event, I think we've already discussed at some length in a number of meetings that it is often difficult or impossible to find the root cause of the failure. And that is driving much of our conversation about a regulatory framework to address the safety issues. We know that many current systems, whether health IT or non-health IT don't lend themselves to complete data logging for the analysis of events and for the first example I'll use something from an FDA pilot called ASTERD.

Here on this slide you can see ASTERD stands for the ADE, I love this nested acronyms I guess is the concept, ADE Spontaneous Triggered Event Reporting. So an ADE stands for Adverse Drug Event. So over the last few years, there was an initiative at the FDA to model the detection or identification of device related problems in a way that was inspired by drug-related detection of problems – or rather detection of drug-related problems. And this was a proof of concept. You can see the URL at the bottom of the slide for those that are interested in digging deeper, and one of the examples that was held up, and this was a pilot that was performed I believe it was at Children's Hospital of DC, if I'm not mistaken, in which the Electronic Health Record (HER) was used to identify a ventilator problem.

And the idea was that one would not normally swap out a ventilator on a patient during care in the Intensive Care Unit (ICU). You normally stick with one ventilator. Swapping out a ventilator probably indicates a device-related problem. So they, in that pilot, they detected the replacement of the ventilator and then they used that to prompt – they collected some information automatically and prompted the user for additional information. One of the things that came out of that work was, and isn't surprising, is that yes you can detect some relevant information, but the vast majority of information that we need about the devices and about the events and the clinical impact is not necessarily available. So we don't necessarily have the settings of the ventilator that perhaps contributed to the device failure or to the patient injury, the error codes from the device, the status of the patient or oxygenation status and so forth and so on. So these are the things that you would normally obtain from a system level data log or what we think of as a black box recording of an environment of any kind. And data logs exist in many different systems, in wireless routers, in medical devices, but not necessarily complete, nor is there a systematic approach to either require them, collecting them, or analyzing them. And so that's the ASTERD example that I thought would be helpful for our thinking. Are there any questions on this at this point?

Okay. Now the next few slides are going to use a use case that was constructed for the purpose of this discussion. And this we're just calling, for lack of a better term, a wireless infusion pump use case. So there's the text, I'll read that in case anyone is having trouble seeing it. An intravenous infusion pump is capable of securely being programmed via WiFi either with a new drug library, in other words that's the purpose of the programming or perhaps to have the infusion rate adjusted for something like closed-loop artificial pancreas function. And by the way, for those who think this is Sci-Fi, this is in fact being done in hospitals today where the infusion rate of something like insulin or glucose is adjusted based upon blood sugar information that is obtained through lab testing and is the EHR. So I'll continue reading. Due to newly installed wireless equipment in the proximity of the IV pump, WiFi commands to the pump are delayed, by many minutes, or dropped entirely, resulting in safety concerns.

Now in this case, the pump functioned as specified, meaning it's doing its job exactly as it's supposed to. And let's say the manufacturer of the pump is contacted by the hospital and they state that the cause of the WiFi interference needs to be addressed. In other words, it's not our fault, I don't know what you did in your hospital, but the fact that we're not receiving commands suddenly, even though we've worked well for the last six months, clearly isn't our problem and maybe they even tested their devices and they've proven that they're working as specified. Now the next slide is a little bit of a diversion to clarify a point here, because we want to ensure that we're focusing our discussion today on health IT related issues and system issues, and not on the medical device itself. So, in order to make that clearer, here's an example of, let's say that the infusion pump instead of doing what I described, actually just starts producing smoke, the thing is burning up its failing. What happens in that case? Is it clear to – is how a hospital or other entity handles that issue, is that clear? The answer is, absolutely.

And for that, one just has to look at the medical device reporting requirements, otherwise called MDR, and you can see the details from 21CFR 803 and there are mandatory requirements for manufacturers, importers and user facilities to report significant medical device adverse events to the FDA. There's also a voluntary MedWatch Program, and there's a URL at the bottom of the slide for more details. So, I don't want to go off on a tangent with this, I just want to make it very clear that when the medical device is clearly failing or is highly suspected to be a problem, there's a clear pathway to address that, and that is not what we're talking about today.

So now going back to this wireless pump use case, the one in which it wasn't receiving a WiFi command, which puts the patient at risk or cause an actual injury, let's dig into this in a bit more detail on this slide. So we have to ask, if this happens in one hospital, or in a patient's home, there are certainly many patients at home with infusion devices, and the infusion pump is merely an example, is this instance a single event? Is this a one-time event or is this endemic with the pump model? Is it a problem across many hospitals, are there thousands of pumps that are having problems with communication that are intermittent perhaps, that are affecting the programming of the pump on the safety of patients? And what is the clinical impact or severity? How do we capture that information today? Is this just an irritating problem or is this actually causing patient harm? Is it causing a delay in uploading a drug library or is it causing inability to control the patient's blood glucose? And also we might want to know, is this problem specific with WiFi implementation? Is it because of a configuration error or poor instructions on WiFi configuration or misinterpretation? Or is this actually a larger problem, again, with the technology and something that the Federal Communication Commission (FCC) might have to address more fundamentally.

What if the data transmission to the EHR is lost? In other words, in this case, it isn't just programming to the pump, but many pumps send their data to the EHR, they send the status of the pump, its infusion rate, type of drug and so forth. What if that data now is lost in the EHR? Who cares about that? How will they find out? What do we do? What if data transmission is to another medical device and this invokes a discussion we had the other day about the distinction between sending data to an EHR versus another medical device. What if the reason that the pump is not receiving its information is because of a newly installed technology in the environment, such as the new MBAN or medical body area network technology? And that's certainly a very important topic today with manufacturers soon to be releasing a number of MBAN products, and actually some I think have just hit the market.

And so essentially the bottom-line of all this is, how would this information be collected today? Who would collect it, who would report it, who would analyze it? How would it be disseminated? How with the mitigations be proposed and confirmed? And of course, I think, based on our discussions and what we all know, it isn't – we don't have a unified approach today to report a case just such as this. But it may be fragmented and reported to different agencies in different ways and we'll drill down into that in just a moment. Before going there, are there any questions?

Okay. So here's just a bit more background detail. The Federal Drug Administration (FDA) has another reporting pathway called MedSun, which is the Medical Product Safety Network, which was launched relatively recently and involves hospitals and facilities as partners and has a fairly easy to use Internet-based system. So that's one – so it's possible that the case we just talked about could be reported through MedSun, that's entirely possible. The FCC, of course, has reporting requirements and it's possible that that would trigger a discussion. And so here's the text from – let's see here the details. So general condition of operation, persons operating intentional or unintentional radiators shall not be deemed to have any vested or recognizable right to continue use of any given frequency by virtue of prior registration. In other words, just because it was okay to do it once doesn't mean you can keep doing it if it's causing a problem. And I won't go into all the text here and read everything, but this is kind of foundational information to understand the next points. I'll give everyone another few seconds to read through this text.

Okay. So now, kind of a little bit of interpretation and discussion of these points that then become relevant to the reporting requirements is that number 1, as you can see, certain unlicensed radio frequency devices, personal computers e-readers and things like that, are subject to the condition that they do not cause harmful interference to authorized radio stations. So, okay, that's pretty straightforward and I think probably doesn't apply directly to the example. The second bullet point is that licensed radio services generally operate on the principle that the most recently authorized service must avoid causing harmful interference to pre-existing services. Now this can apply to the example we just gave, because we are seeing new technologies rolling out to facilitate personal health, mobile health and even in-hospital essentially micro-nets and specifically that would be with the Medical Body Area Networks. So as we start to see that roll out in the next year to two years, what are the implications that that causes interference with pre-existing systems that are installed?

Number 3, most radio devices and transmitters must meet technical standards designed to minimize the risk of harmful interference. I think that's straightforward. And then the next point, and especially the underlined portion, in general there are no requirements to report harmful interference to the FCC, but there may be exceptions. So, FCC reporting is a bit different and different than FDA reporting. And in FCC reporting, it addresses more about the subsystem or components than it does the entire functionality of a device or system that we see, in terms of the way that FDA defines it. So when we go to the next slide, and actually, let me stop before that, let's stop on the FCC slide and just see if there are any questions before I go on?

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

No questions, Julian, its Jarrin. Just a point of clarification that I'll bring up at the end that we – continue and finish your thought and then we can go back to FCC.

Ulian M. Goldman, MD – Medical Director, Biomedical Engineering – Partners HealthCare System – Director, Program on Medical Device Interoperability, CIMIT, Massachusetts General Hospital

Okay, sure. Sure. And I'd just like to reiterate that there's been quite a bit of input on these slides, Jarrin provided input, the FCC and the FDA and a lot of folks helped to kind of gather key information. I'm going to move forward here to the next slide on EHR configuration use case. We talked about this yesterday in the meeting; it was brought up in another prior meeting as well. It's just another good example of a use case about safe configuration. In this case, the point was made that EHR configuration can greatly affect safety and that appropriate post-installation configuration, monitoring it and assuring that it's being done is not clear, and reporting when it isn't being done isn't clear. This also invokes the idea that there's configuration of other elements of the system and the same issue undoubtedly comes up, and it comes up, for example in that WiFi case, or it could come up.

So now, some of the broader questions and invoking the idea from the IOM 2011 report on Health IT and patient safety, to support health IT safety framework, is a system with feedback necessary? Some people might call that a learning system, but you could even just call it a system with feedback. To do that we have to think about what are we trying to achieve, what is the objective of system as a whole? And one way to succinctly state it is to improve safety and efficiency of healthcare delivery. So the stakeholders need a means, they need data to assess the safety and performance of the medical device and health IT system. Part of the challenge in front of us, I believe, and has been brought up in various discussions thus far, are identifying the stakeholders. Who needs to be notified and who needs to be involved in reporting? Device manufacturers, health delivery organizations and patients, regulatory agencies, payers, and that should be part of our discussion, who else should we be including in the list, to provide feedback on the system? Are there any points or questions on that slide?

Ulian M. Goldman, MD – Medical Director, Biomedical Engineering – Partners HealthCare System – Director, Program on Medical Device Interoperability, CIMIT, Massachusetts General Hospital

Is someone speaking? I can't hear –

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

Okay, does that work?

Ulian M. Goldman, MD – Medical Director, Biomedical Engineering – Partners HealthCare System – Director, Program on Medical Device Interoperability, CIMIT, Massachusetts General Hospital

Ah, much better.

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

Okay, Keith Larsen. Just a comment, again, a lot of this is about – what would be an interesting discussion too is as you pointed out there are mechanisms to report some of these things now. And do we think that we're getting the reports and what are the reporting mechanisms outside of governmental reporting agencies are there?

Ulian M. Goldman, MD – Medical Director, Biomedical Engineering – Partners HealthCare System – Director, Program on Medical Device Interoperability, CIMIT, Massachusetts General Hospital

Um hmm.

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

I mean, the missing layer to me is what do we expect – I've been involved in these cases before. What you have is a lot of reporting and cycling at the local level on the problem. And then if there's a feeling that this is – meets the criteria of the regulation, then a small subset, and I have to say, a very small subset then gets reported up through regulation.

Ulian M. Goldman, MD – Medical Director, Biomedical Engineering – Partners HealthCare System – Director, Program on Medical Device Interoperability, CIMIT, Massachusetts General Hospital

And are you saying that it's good or bad? Are we missing important cases that don't escape the local cycle or is that really very effective because of the filtering that it creates?

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

I think that it can be effective in the filtering because from the standpoint that you're trying to solve the problem, okay, and what the view is if I'm reporting it to the regulatory mechanisms, I'm really not solving the problem, I'm just reporting it and it's not helping me solve the problem. What I'm trying to do here is, I mean given the wireless infusion pump example, I'm trying to figure out why I'm having this and I'm contacting the device manufacturer, which again as Julian points out, he'd have his finger pointing, well it's not me, it's not me. But, I'd try to get to it. The interesting thing is can you make the reporting mechanism – the advantage again of reporting it to a regulatory agent would be if that reporting actually helped to solve the problem.

Ulian M. Goldman, MD – Medical Director, Biomedical Engineering – Partners HealthCare System – Director, Program on Medical Device Interoperability, CIMIT, Massachusetts General Hospital

Um hmm, sort of maybe on the line of the web analytics that we're used to using today or things like that, where we see signals in the data, which help us, point ourselves towards where the real problems are.

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

Yeah. That and/or to – I mean, again having better instrumentation of all these things would be helpful in analysis. But let me give you another example is if we have a problem when we're trying to program something, okay, and my programmers can't figure it out, what they do is they get on blogs, okay, and they raise the issue, hey, I'm seeing this, okay, or I'm trying to solve that. And what they do is they get kind of immediate feedback about other people that have seen the same problem.

Ulian M. Goldman, MD – Medical Director, Biomedical Engineering – Partners HealthCare System – Director, Program on Medical Device Interoperability, CIMIT, Massachusetts General Hospital

Um hmm.

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

And I think part of the issue with the regulatory reporting is it's not a two-way thing and it's not helpful for me to solve my problem, it's – it again feels legalistic and I'm reporting a problem rather than helping me solve a problem. And so if we talk about reporting, how do we make reporting an enticement. I mean again, like the idea of, I don't know what's happening, I just know I have a delayed signal, okay, in the use case. If I can't take it any further in my analysis, I don't know it's the manufacturer, so I don't want to report it to the regulatory thing, because they work with this manufacturer and I don't want to screw up my vendor relationship by getting the FDA on their back. But...

Male

I think that happens all the time, that's a great point.

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

Yeah, it's a great point. So I have reporting dis – discretion type thing when really what I want to say is look, I'm having this problem, I can't figure it out, has anyone else seen this problem. Now, that would also give you pattern recognition that you could sit on top of these databases and say hey, we're seeing a bunch of reports all involving this particular pump with the slow commands, and then it directs you kind of to kind of crowd-source your analysis. Anyway, I just throw it out that I think that there's kind of the regulatory level of reporting and there's below the radar reporting that happens all the time. And it's richer and how do you encourage getting that below the radar reporting? How do you lower the impedance so that you can see these patterns more rapidly and help you analyze local problems? Anyway, that's my comment.

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

Yeah, this is Elisabeth. I guess I'd like to actually support exactly what was just described because even thinking the description that was given of where we do have regulatory reporting, a user of our product would communicate to the medical device manufacturer, we do our own trending and monitoring, but we don't report to the regulatory authorities until it meets certain thresholds. So, again as you described, it's not necessarily in the support of the analysis if one's decision had actually already been made as to does this meet the threshold of reporting, does this meet the criteria that we're supposed to be communicating. So, the data is very controlled into a very limited environment so that just as you described is that maybe other manufacturers are experiencing the same problem. But none of us have that visibility because we only know what we know, there's not kind of a shared repository and there is no incentive to find out that, gee, everybody's having a wireless communication problem with this kind of device, no matter who the manufacturer is. And not until it becomes, and I don't want to necessarily profess that these – but if I look at what the FDAs doing with say metal-on-metal hips with registries, they're capturing all the data and not making decisions without looking at all of the data. So, I do support kind of what you're describing. I'm not sure how to go there yet, but I do support the concept.

Ulian M. Goldman, MD – Medical Director, Biomedical Engineering – Partners HealthCare System – Director, Program on Medical Device Interoperability, CIMIT, Massachusetts General Hospital

If I could ask for clarification from both of you, what I'm hearing is that the current approach – the current thinking is that there's divide between the more complete aggregation of data and ability to share and respond rapidly and intervene and use the data to solve the problem in contrast with the kind of traditional regulatory pathway where data is just data out and then it's not being used to solve the problem.

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

Right.

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

Exactly, I mean – and what was pointed out is there are richer databases at the hospitals, for instance, people that are – I mean, we buy products that essentially help us create information knowledge bases and are continuously saying, "oh look, we're seeing a pattern here," because we have frontline support and we're trying to do the problem analysis. And what was pointed out, the vendors are doing exactly the same thing, they get these calls, they're trying to see patterns because again, it goes back to, they're trying to understand their product in the environment, they're trying to make it better, and they don't want any headlines about how they screwed up. But then you have all of this kind of teeming, iteratively used databases and then you're right, it's a one-way valve, I report it out to the regulation and it disappears. I can see what happened to my own request, but I don't get any payback for reporting it and it may be negative again because I'm – it impacts maybe my relationship with some of my vendors...

Ulian M. Goldman, MD – Medical Director, Biomedical Engineering – Partners HealthCare System – Director, Program on Medical Device Interoperability, CIMIT, Massachusetts General Hospital

Um hmm.

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

When – and so how do you switch the model so that the way that we do reporting close to the ground or at a vendor level, becomes more the paradigm and useful, anyway...

Ulian M. Goldman, MD – Medical Director, Biomedical Engineering – Partners HealthCare System – Director, Program on Medical Device Interoperability, CIMIT, Massachusetts General Hospital

Well thanks. Are there any other comments at this point?

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

Julian, I'd love to break in. Can you guys hear me?

Ulian M. Goldman, MD – Medical Director, Biomedical Engineering – Partners HealthCare System – Director, Program on Medical Device Interoperability, CIMIT, Massachusetts General Hospital

Yes.

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

So coming from the wireless side of things, I will say the following, and I'm not sure if it fits in this other paradigm that you guys are describing, but in the wireless world there are about three different ways of really waging a complaint or, if you want to call it a mechanism for enforcing certain things. The more proactive one is the market surveillance program, which is actually used by vendors and companies competitively sometimes, because even though it's supposed to be something that the FCC does randomly, it is random testing, but it's usually generally driven by public or competitor insight. And what they do is they go about doing literally random testing of devices in certain spectrum, to try to ferret out those that are harmfully interfering in spectrum or in services that are really implicating a certain operator or a certain service, etcetera.

Another way is through the Spectrum Enforcement Division, which also tries to resolve complaints that involve public safety or technical issues or complaints regarding spectrum again. And therein again, this is where one would go and file complaint, particular to whatever scenario it is. In the scenario that Julian described, if the device was accepting – harmful interference and they could not figure it out among their vendors, they could go to the agency and say – we're having some trouble. And then of course they have a consumer complaint channel, which is both formal and informal. Formal, you actually literally save the FCC \$200.00 and then they proceed with almost like a court-like disposition going against whoever happens to be the offending party. And they also have an informal way of waging complaints and the agency – takes this very seriously, again that feeds into the other two mechanisms.

So, I hear what you guys are saying, but in the wireless world, when you have operators that are paying a lot of money for a spectrum that's licensed, because therein we have to now go back to the example and this is what I'll bring up – where I said I need some point clarification Julian. I actually would argue that in your scenario, your very specific scenario, unlicensed spectrum is exactly what WiFi operates off of, and by virtue, it has to accept interference caused by permissible operation of other radio frequency devices. That said, if a device is not operating within – if it's that rule, and it's causing harmful interference, even though it's in an unlicensed spectrum, you do have a cause to go after the harming party.

So, it gets very tedious when you start thinking about the different uses of spectrum. If we talk about license by rule, which is in the – model, again, it's a medical device manufacturer that has a license to access a certain part of spectrum and you can contact the FCC to complain, and they can help you track down other sources of interference that may not be able to use that spectrum. Because there are some users that are going to be able to do it, you're going to have to share it – I think you have to share it with aeronautical spectrum. But anything outside of that is not permissible in that – and then if you went to the licensed spectrum realm, which is 3G, 4G and – operators, and you've got a medical device that's using a 3G or a 4G or – usually the manufacturer will try to investigate stuff on their own, figure out where it's coming from and then they'll contact the FCC to complain to help them enforce that their spectrum remains unencumbered.

Ulian M. Goldman, MD – Medical Director, Biomedical Engineering – Partners HealthCare System – Director, Program on Medical Device Interoperability, CIMIT, Massachusetts General Hospital

Um hmm.

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

So I would argue, I mean, in the wireless world, which is increasingly becoming the healthcare world because so many medical device manufacturers are interested in going wireless, the enforcement part of this is actually working with the regulators so that they can help enforce your spectrum. It's not so easy for you to do that on your own.

Ulian M. Goldman, MD – Medical Director, Biomedical Engineering – Partners HealthCare System – Director, Program on Medical Device Interoperability, CIMIT, Massachusetts General Hospital

I think you – thanks for bringing up these points Jarrin and I just want to emphasize that I think that, and have a slide later on to show this, that that's the limitation of using this particular use case. It's just a use case intended to invoke certain concepts. But, it has – it's a bit too specific in a number of areas, and that it is inherently a flaw. And you're bringing up excellent points that we have to decide how to best capture and include. Let me just ask, am I the only one who lost their view of the slides? Its wireless connectivity on my end but –

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

No, I can see it.

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

And who will you report this to?

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

Yeah, yeah, you just lost your wireless?

Ulian M. Goldman, MD – Medical Director, Biomedical Engineering – Partners HealthCare System – Director, Program on Medical Device Interoperability, CIMIT, Massachusetts General Hospital

I was reporting it to all of you, weren't you listening?

Male

Is this another use case?

Ulian M. Goldman, MD – Medical Director, Biomedical Engineering – Partners HealthCare System – Director, Program on Medical Device Interoperability, CIMIT, Massachusetts General Hospital

It's not a bad one; it's pretty annoying right now. But, at least – so, what we'll have to do is, I won't be able to advance the slides myself anymore, but I have a set of slides I can just work from.

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

I can advance them for you; just tell me what slide you're on.

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

I mean just a comment on the last comment. Again, if I determine that the problem is interference, then I have those things, but in your use case, I don't know, my only manifestation is I'm getting slow response and so I'm trying to analyze it first.

Ulian M. Goldman, MD – Medical Director, Biomedical Engineering – Partners HealthCare System – Director, Program on Medical Device Interoperability, CIMIT, Massachusetts General Hospital

Well I – so, let's just – let's tee – let's maybe drill down just another minute. So based upon the comments we just had before the discussion that you brought up Keith and Elisabeth brought up. There's the idea that if we somehow could pool the data early on, and it didn't have to meet certain more complex thresholds for regulatory reporting. And as you pointed out, people hop on blogs because issues are reported, we might see very early signals that there are a lot of people experiencing problems with either a specific wireless infrastructure or an infusion pump or pick something off the menu, whatever it might be, which could help very early. And then perhaps people would share troubleshooting logs, which we do all the time with other products and issues, determine what the timeouts and the retries are in that system, whether it's a configuration problem and so forth. So I think we're – I think that you're making an excellent point and I agree strongly that part of the problem is that we don't have the right tools available to us to both, analyze and detect, then share that information. And that was part of the conversation we had in a previous meeting that came out of the FCC mHealth Task Force in support of the FCC's Initiative for Wireless Test Beds, and that's just a piece of the puzzle which would hopefully include the sharing of information. So I

agree. And Jarrin's bringing up the point that if this was another radio using different spectrum, there would be different requirements, different reporting, and different expectations. And I think we have to capture that as well, in understanding what we're trying to accomplish here in FDASIA Working Group in terms of what – how will we look at the safety of the system, which means we have to consider some of these alternative issues with their reporting pathways.

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

Right.

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

If I can only add, I guess that what I heard from Keith and Elisabeth are that the reporting so that they could report in without – we could get a solution of the report is really just a waste. And...

Ulian M. Goldman, MD – Medical Director, Biomedical Engineering – Partners HealthCare System – Director, Program on Medical Device Interoperability, CIMIT, Massachusetts General Hospital

Thank you for saying that. I think that...

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

My perspective, the reporting is actually the solution, because I'm able to kick people off of my spectrum and hopefully reduce, mitigate or get rid of completely the interfering offender, and that's why the reporting is so important.

Ulian M. Goldman, MD – Medical Director, Biomedical Engineering – Partners HealthCare System – Director, Program on Medical Device Interoperability, CIMIT, Massachusetts General Hospital

So thank you for clarifying and restating that Jarrin, because that has to be captured, so that we understand sometimes reporting is the solution, sometimes it appears to be more of a waste of time.

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

Well, and I agree with that, in – and I'm not discounting that at all because that goes to now I know the problem, I see the pattern and the solution now is to invoke that reporting so that it gets solved, and that goes to the solution. That's good feedback and it gives me some benefit from that reporting again, so I agree with that.

Ulian M. Goldman, MD – Medical Director, Biomedical Engineering – Partners HealthCare System – Director, Program on Medical Device Interoperability, CIMIT, Massachusetts General Hospital

So Brad, could you go to the next slide please, and I hope everyone is seeing one that says...

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

This is the one with CPSC reporting?

Ulian M. Goldman, MD – Medical Director, Biomedical Engineering – Partners HealthCare System – Director, Program on Medical Device Interoperability, CIMIT, Massachusetts General Hospital

Yes, CPSC reporting. So I added a few examples of things that we've touched on, or have yet to touch on as just examples and I think this was mentioned, well, there are other ways things are addressed. So here's the Consumer Product Safety Commission, and as you see, it says if you are a manufacturer, importer, distributor or retailer of consumer products, you have a legal obligation to immediately report the following types of information, and so on and so forth. And there are some highly specific reporting requirements, such as a product that a child, regardless of age, choked on, has to be reported; then others – product that is otherwise hazardous and so on and so forth. So there's the CPSC model, which exists. I can't – I don't know the strengths and weaknesses of this model. I don't know if others on the call are aware either, but that's not the intent of this, it's just to show that there are perhaps a whole range of models that exist and these could be used in consideration of what we should be doing when it comes to health IT.

The next slide is labeled PSOs, Patient Safety Organizations. Everyone on the call knows about PSOs, I included this for the sake of completeness and included a link to the AHRQ page on PSOs. Dr. Bates the other day mentioned that there may be things that are – there may be a way that we need to fold-in PSOs into the structure or things we can learn from them or leverage them. I think from what I've been seeing in terms of the PSO world, there's been a lot of activity in the last two years. It still is unclear whether – I should say, this is one piece of the puzzle, more of the institutional healthcare delivery organization facing side of the puzzle as opposed to some of the other pieces we've talked about but again, it's here for completeness.

The next slide refers to NHTSA, the National Highway Traffic Safety Administration, and again there's a URL and just a brief quote from the page, and I think it's worth discussing this for a moment. Here it says, safety is NHTSA's number one priority, our mission is to reduce the number of deaths and injuries and so on. And I think that that broad mission statement is certainly applicable to what we've been talking about and to the efforts, we've had nationally to improve the adoption of health IT, to improve the safety and efficiency of healthcare. NHTSA again we can't dig into the details of the operation, or effectiveness of the organization. And I know it's controversial, but there are good examples of the fact that NHTSA seems, from what I understand and if there are any experts please jump in, seems to be an environment in where one, it enables an examination of an entire system.

The system in this case being automobile, let's say, the roadway, signage, lighting, fuel, all the things that might be relevant to the safety, restraint devices, airbags, whatever they might be. So, for example, if there was increase in the number of accidents in a certain region of the country or certain type of automobile or with a new road surface or a new design, it would be an environment where all the parties would – all the stakeholders would sit down and where all the issues would have to be addressed. Or at least could be examined so that one could return to the, as stated here, number one priority, which is safety. And I think that the value in bringing this example in is very much in the fact that NHTSA prides itself on sharing information and disseminating it very broadly and a very strong educational component that involves many different stakeholders. And that's been discussed in previous meetings and Elisabeth I believe you emphasized, for example, that the work that we do should not be focused solely on non-health care delivery organizations or not on patients that we have to include the totality of the stakeholders. And I think NHTSA has done a pretty good example – a good job with that.

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

I do think that that is imperative that we engage all of the stakeholders in that because I think that all of them are potential reporters and also potential recipients of the output of whatever the good, the bad, the ugly may be.

Ulian M. Goldman, MD – Medical Director, Biomedical Engineering – Partners HealthCare System – Director, Program on Medical Device Interoperability, CIMIT, Massachusetts General Hospital

Yeah, thank you for having emphasized that. So that's the NHTSA example and then the next slide is...

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

Hey Julian...

Ulian M. Goldman, MD – Medical Director, Biomedical Engineering – Partners HealthCare System – Director, Program on Medical Device Interoperability, CIMIT, Massachusetts General Hospital

Yup, go ahead.

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

This is Joe for a second.

Ulian M. Goldman, MD – Medical Director, Biomedical Engineering – Partners HealthCare System – Director, Program on Medical Device Interoperability, CIMIT, Massachusetts General Hospital

Joe.

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

Can you give any color on how reporting happens in the NHTSA, I mean, how public a reporting vehicle is it so that if there's a meaningful corollary we could look for it?

Ulilan M. Goldman, MD – Medical Director, Biomedical Engineering – Partners HealthCare System – Director, Program on Medical Device Interoperability, CIMIT, Massachusetts General Hospital

I cannot, I've studied this a bit over the last few years, but I don't feel that I could represent it accurately. I've looked at a number of these different reporting mechanisms, including the next slide, which is the ASRS or Aviation Safety Recording System and what I was hoping to do with the slide deck here was perhaps to inspire us to take that deeper dive and to do the comparison and understand it. But I'm not prepared to really do it justice in a quick answer.

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

All right, thanks.

Ulilan M. Goldman, MD – Medical Director, Biomedical Engineering – Partners HealthCare System – Director, Program on Medical Device Interoperability, CIMIT, Massachusetts General Hospital

Okay. I do – let me just emphasize though that I believe that an important component of anything we do has to be that we emphasize that the reporting and the discussion and analysis of the system includes the regulated and non-regulated components, otherwise I think we remain a little bit stuck where we are today. Would you agree?

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

Yeah. So again, this is Joe. I love this notion of reporting, but I don't think it's just – and I think you've probably said this, "it's not unilateral just to the safety aspect of this." Because it is the public reporting of the, for lack of a better phrase, the unmet need or the issue that people are struggling with, that also becomes the user requirements for the next innovator. So, it's not – it actually does solve the safety and innovation issues simultaneously, because clarity of these issues is what's essential for both the safety as well as the innovative part of this balance.

Ulilan M. Goldman, MD – Medical Director, Biomedical Engineering – Partners HealthCare System – Director, Program on Medical Device Interoperability, CIMIT, Massachusetts General Hospital

Yeah, I think that's an excellent point. I didn't prepare this as part of the presentation, but it's probably worth mentioning. One of the projects that we're working on within our research program now, that's a federally funded project, is to look at facilitating capturing the ideas, the gaps or the needs. In other words, if I could have an app, what would it do? And having the clinical community have a means to request that type of functionality, which then as you said, becomes kind of the engine for innovation. So, we'll see where that goes, it's kind of too early to tell – it's early in the project.

Woman

And Julian, this is – I think this is right on the money when we're talking about transparency and learning system and having a diverse reporting mechanism and the analysis part of that is, we should be mining it the way we're mining social sites and sending apps to people. I mean, I think it's really about reporting and data mining.

Ulilan M. Goldman, MD – Medical Director, Biomedical Engineering – Partners HealthCare System – Director, Program on Medical Device Interoperability, CIMIT, Massachusetts General Hospital

Um hmm, um hmm.

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

And this is Keith and I would agree with your comments. Again, with these local databases and Elisabeth can comment with the vendors, I know we mine our feedback loops all the time for ways that we can again, solve problems and make things better. And so it is an engine for innovation. And parts of the things that come in on those reporting mechanisms are enhancements, too. I think it would work better at this, there's no problem but I just want to get this registered as this is a – I think that if this change were made that it would be better.

Ulilan M. Goldman, MD – Medical Director, Biomedical Engineering – Partners HealthCare System – Director, Program on Medical Device Interoperability, CIMIT, Massachusetts General Hospital

And I believe...

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

And I agree; this is Elisabeth.

Ulian M. Goldman, MD – Medical Director, Biomedical Engineering – Partners HealthCare System – Director, Program on Medical Device Interoperability, CIMIT, Massachusetts General Hospital

We're missing so much of that – I'm sorry, go ahead.

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

Yeah, this is Elisabeth. I do feel that most definitely it is all data input, so it is customer feedback and not just the negative or just the things that are risky; it is all enhancements, etcetera. But I think one of the things; at least what I'm hearing described here is it would be opportunistic to be able to have a better mining solution for data collection, much broader than just our own solutions. And again, even as a vendor, one of the things we always do is we do reach out to our competitor information, we do see what is going on with our competitors. Obviously most of the time all we see is the really negative, because that's what gets captured in the regulatory databases. But you do see some of it when you have user groups and reach out and I know all of the different, whether it's hardware, software or anything, I mean, that's – the concept of eliciting information and having it as a continuous learning process.

Ulian M. Goldman, MD – Medical Director, Biomedical Engineering – Partners HealthCare System – Director, Program on Medical Device Interoperability, CIMIT, Massachusetts General Hospital

So you're made a number of excellent points and one of them, I just want to emphasize, is the idea that higher acuity or greater severity incidents are more likely to be reported but the potentially more informative, larger number of reports of more minor things, annoyances, problems, gaps, aren't easy to share publically. Or don't get shared publically, and therefore there's less of an opportunity to learn from those, and I think I heard that now in several different comments, stated in different ways. Would that be fair?

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

Yeah I would agree.

Ulian M. Goldman, MD – Medical Director, Biomedical Engineering – Partners HealthCare System – Director, Program on Medical Device Interoperability, CIMIT, Massachusetts General Hospital

All right, so just two more slides. The next one is on ASRS, the Aviation Safety Reporting System. And again, I've delved into all of these over the last few years, but I cannot claim to speak authoritatively about any of them, but they do seem to be potentially relevant for discussion. The ASRS is a reporting system that many of you may know from the old days as the Blue Newsletter, any of you that are that old – never mind, don't tell me if you're that old. ASRS and these days it's all online, it's a means for reporting of aviation safety incidents from pilots, controllers and others.

And it's really interesting to read because it's very much full of reports of what ifs or – they're not even near misses, they are, this is a problem wherein if it becomes worse, could result in a safety issue. Or there may be, gee, I caught this right before it had a serious effect on aircraft performance, for example. And it provides a means not only to collect the information, but as you can see in the text, which I copied from the website, that in the second bullet, the ASRS acts on the information these reports contain, identifies system deficiencies, issues alerting messages to persons and so forth. And there's an aspect to it that's a public repository, which serves the FAA and NASA's needs and those of other organizations. I think there's a lot of value in the ASRS model, in the way that the reports are done and there's much more sophistication to it than I'm presenting here.

What I included as the third bullet item is that I did not touch at all here on the slides on the NTSB. And it's just too much to cover in this time. But I think that there is an important message in how the NTSB does its work that's been thus far, we haven't really discussed which is that it's a dedicated group of experts that really understands how to look at issues that relate to aviation safety. And it isn't just a haphazard mix of people that try to understand very complex events. And I think the idea of the complexity and the specialized knowledge in health IT has come up a number of times in different conversations as well, and I believe that idea should be captured somehow, and this was just an attempt to do it. There's one more slide, which I'll – let me just see if there are any questions on the ASRS page before I go to the last slide. And again, I can't see the slides, so Brad, if you can go to the la – I'm sorry, it's the second to the last, I apologize...

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

I'm on HITSA.

Ulian M. Goldman, MD – Medical Director, Biomedical Engineering – Partners HealthCare System – Director, Program on Medical Device Interoperability, CIMIT, Massachusetts General Hospital

HITSA, so, a few years ago, a research group that we have here and with a number of collaborators proposed some of these ideas as something called HITSA. A Health IT Safety Administration, which wasn't really intended to promote the idea of a new regulatory agency as much as to gather some of these notions and to start to look at the gaps in reporting and what we might be able to learn from these other approaches. And that was presented in a briefing to the White House Health IT Senior Steering Group in July of 2011, and I don't know if the report is online, but I will have to look into that and make that available if it isn't. It was just added that for the sake of completeness.

And then the final slide is labeled Use Cases and its point of discussion for the group, which is and Dave Bates really has been promoting this for us, for our work. Is it worth our while; is it worth our time to gather a few more use cases that convey some of these ideas that have been discussed in this meeting or are these best captured just as more bullet points in the slide deck and updating it as a resource for the group? And I leave that as an open question for the members on the call.

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

This is Mary Anne. I think the idea of a HITSA is a great idea. There may be a way we can do it with low overhead and keeping it as virtual as possible, but I think it would be great for us to have a mechanism for collecting and learning and sharing and promoting innovation in kind of a more organized way. I think it's a great idea.

Ulian M. Goldman, MD – Medical Director, Biomedical Engineering – Partners HealthCare System – Director, Program on Medical Device Interoperability, CIMIT, Massachusetts General Hospital

Okay, thanks for that feedback. I wonder what the next steps will be for that, we've – at least with our – within our group we've been exploring possible mechanisms for that, at least – not really for implementation but for assembling an expert group to discuss some of the needs. I think that the ON – the work that's been done out of – well, out of – in several reports that have discussed the need for sort of broader information on looking at system issues, and I think that's been an important part of the discussion. But what's been left out of some of those have been the medical device performance aspect and some of these larger system issues, such as wireless communication and so forth. So, maybe that will fall into the HITSA conversation.

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

So what I can – this is Jodi Daniel, I have a question. So this has obviously come up in the IOM Safety–Health IT Safety Report...

Ulian M. Goldman, MD – Medical Director, Biomedical Engineering – Partners HealthCare System – Director, Program on Medical Device Interoperability, CIMIT, Massachusetts General Hospital

Yeah.

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

And I'll tell you, so we – their Safety Plan, and obviously this would require new legislation, which doesn't mean it's off the table for discussion here, but it was obviously nothing that we could do. But in discussing this, the question came up about is health – particularly since the evidence that we have so far suggests that health IT is a small percentage – the connection with health IT represents a small percentage of all the adverse events that we hear about regarding patient safety. And this would be a huge effort to undertake, including legislation and lots of funding, what would be the – why would we do something for health IT, to create a health IT safety administration when the problem on patient safety is a much broader problem and health IT seems to represent a small piece of that. So, it was unclear to us in looking at patient safety broadly and health IT patient safety as a subset of that, how – why – what would be justification for a separate entity that is just focusing on health IT safety? I was just wondering if will talk about that.

Ulian M. Goldman, MD – Medical Director, Biomedical Engineering – Partners HealthCare System – Director, Program on Medical Device Interoperability, CIMIT, Massachusetts General Hospital

Well first of all, let me say that I think the name that we happen to have chosen for this initial briefing and the work that was started two years ago. And the work, by the way, was unrelated to the IOM report, it just happened to have happened a little – just prior to the IOM report being released, the work that we did on this within our group. It may be that that's the wrong name, right, so HITSA was not necessarily the right name for this because it implies too narrow a scope. And calling it a Patient Safety Administration might be the right term. So, I think it – I would urge anyone not to read too much into the letters of HITSA.

It has more to do with looking at the gaps across and the issues across both regulated and non-regulated parts of the health system that are technology based, which include health IT and some aspect of medical devices. But the challenge is and the theme runs throughout this slide deck, is that if this is framed the wrong way or stated the wrong way, people will react and say, wait a second, reporting of medical device adverse events is already covered in FDA regulations, so we don't need to address that. And similarly with FCC related spectrum and so forth, but the fact is we do have these fundamental system gaps when a problem either span multiple things or we don't know the source of the problem, because we don't have the data, we don't have the tools. So yeah, I appreciate the sensitivity, but that's half of my response.

The other half is that I think that the – we are thinking too narrowly when we think about problems due to health IT. I think that the bigger issue is the opportunity cost of all the things that we haven't achieved with health IT. And so, thinking of something like this only as a means to report problems is probably the wrong way to think about it. It's the discussion we just had before which is, this will identify opportunities for innovation, things that can't be achieved, gaps that can't be achieved. Over the last few years our research group undertook a number of sessions, focus groups and things like that to meet with a number of different clinical specialties and engineers and others and asked them not what the – well, didn't limit our questions to what are the hazards or problems that you're having? It's what are the missed opportunities and what would you do differently in patient care? How would you innovate if you had data wherever you might need it or if you could automate systems or if you could integrate health IT and medical devices? So that opportunity cost I think is what we have to capture here and so I agree, don't focus on that part. Joe is that – do I hear you.

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

Yeah, I just want to support that comment. I think that when you look at health information technology you don't see it rising up and so much causing direct harm as you see an opportunity to avert harm that hasn't yet been fully exploited. And so when we think about – I would support Jodi in the notion that maybe the "S" word in HITSA is a bit overstated and that we're not trying to address harms caused by health information technology as much as we are interested in trying to exploit it to its full benefit in preventing adverse events. Not that we need to stop it from causing them, because that's a thin sliver of the issue and the opportunity to do better is much greater as opposed to abrogate harm, because I think we'd all sign up that the harm associated with this technology is really often times...

Ulian M. Goldman, MD – Medical Director, Biomedical Engineering – Partners HealthCare System – Director, Program on Medical Device Interoperability, CIMIT, Massachusetts General Hospital
Um hmm.

Mary Anne Leach – Senior Vice President and Chief Information Officer – Children’s Hospital Colorado

I think we’re also – this is Mary Anne. I think we’re also introducing new risk and new safety potential harm that we don’t know – we haven’t studied it, we don’t know how the new technologies are going to introduce new risk and we need the data to understand that.

Ulian M. Goldman, MD – Medical Director, Biomedical Engineering – Partners HealthCare System – Director, Program on Medical Device Interoperability, CIMIT, Massachusetts General Hospital

Yes. Again, so we come back to the theme that it’s about the data of the system, that means to share it, aggregate, study and then act on it. That seems to be one of the core themes that we’re addressing. So, and I’ll restate that again, I used the term HITSA because it’s a few years old and this is a good opportunity to update it from the work that was done kind of foundationally. So, Jodi I think, I’m glad you brought that point up. Thank you, Joe and Mary Anne.

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

Julian...

Ulian M. Goldman, MD – Medical Director, Biomedical Engineering – Partners HealthCare System – Director, Program on Medical Device Interoperability, CIMIT, Massachusetts General Hospital

We’ve reached the half the top of the hour...

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

Actually, I was going to ask you a question though before we switch topics and that is, we’re into July and kind of the theme of July is to start crafting the output of the working group. So if someone asked you to make sort of your best summary of the regulatory spec that you would like to see the working group, or at least the sub-working group recommend. So regulatory spec would be what you’d want our report to say should be done, it’s not to design a system, but it’s what you think should be done, how would you summarize it in this whole area of reporting? What do you want to see done?

Ulian M. Goldman, MD – Medical Director, Biomedical Engineering – Partners HealthCare System – Director, Program on Medical Device Interoperability, CIMIT, Massachusetts General Hospital

I would summarize it that we need a more agile reporting system that covers the regulated and non-regulated space and that we’ll need – undoubtedly we’ll need further study so that we don’t violate some of the key existing principles of confidentiality with reporting. But we need something that’s more agile, more flexible that allows for the aggregation of information and that covers the health IT space and medical device space. We need better data logging or the means to have the black box recorder concept that we see in other domains and that with better data; we’ll make better decisions, both about health IT and about the need to address safety issues in regulation.

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

Okay. So could I propose that we’ve got a meeting on the 8th that Joe’s going to lead, but the very next meeting after that, the plan is to start actually drafting what our recommendations would be? Would you be willing to sort of take what you’ve done and start converting it into what you just said, kind of the –

Ulian M. Goldman, MD – Medical Director, Biomedical Engineering – Partners HealthCare System – Director, Program on Medical Device Interoperability, CIMIT, Massachusetts General Hospital

Sure.

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

Ultimate recommendations that you would like to see this group make.

Ulian M. Goldman, MD – Medical Director, Biomedical Engineering – Partners HealthCare System – Director, Program on Medical Device Interoperability, CIMIT, Massachusetts General Hospital

Yeah, absolutely, and then – and of course, I've been taking notes to help fold in the refinements and ideas that have been presented, so I'll take a crack at it and then circulate for comment.

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

Okay, super. So Caitlin or whoever is managing the PowerPoint, are you able to – there you go, thank you. So I had a couple of things that I wanted to do in the next roughly 45 minutes, and we do need to leave time for public comment. The second of the two, I'll tell you the second thing I want to do, is to go through this revised version of the regulatory weaknesses PowerPoint. When I say revised, basically I took the feedback that we got yesterday among the whole group, made some revisions, tried to clarify some things, I mean, we wrote this very quickly and so having a few more hours of time, I tried to refine it. And so now this is really this group's first opportunity to go through this and comment on it. But, I want everyone to sort of recognize that we're now moving toward whatever the – everything we've done now is intermediate and now we're kind of moving toward the ultimate recommendations and that's what – the sense I want to get from the group.

And as a part of that, I want to continually ask the group to try and evaluate or make observations about prioritization, because we've got a ton of stuff, and I really want the group to start to say what's most important. Before we do that, and I don't know how long this exercise will take, so maybe I'm doing this in the wrong order, but the issue arose yesterday, for those of you who were on the full working group call, to start figuring out how to connect the work product of the three different subgroups. And on the one hand, the connection to safety and innovation is kind of more direct, because what we're doing is basically taking the output of the Safety and Innovation Committee. We're using that as kind of our starting point to say, "What are the safety issues we need to protect against and what the innovation risks we need to avoid are?" And identifying areas where the regulatory system needs to be improved to accomplish those objectives. So that to me is relatively clear. As you could tell from, at least my comments about the taxonomy, I was a little bit confused on that front because when we started the taxonomy exercise way back in late April and May, we originally framed it as what should the group look at, what should the working group examine? What's in scope for review and evaluation? Not, and I thought we were relatively clear at the time, but not defining for example, what should be regulated and what does not need to be regulated. What the output of the Taxonomy Committee did not basically check the scope of federal regulation, it scoped the – what was to be evaluated and considered as a part of this group.

So when we get to the point of the ultimate PowerPoint, which is I guess what we're all aiming for, to me I have great confusion regarding connecting what we're doing to what the Taxonomy Group is doing. So in my mind we kind of need to fill in the following sentence. The taxonomy definition, that whole framework that the Taxonomy Group came up with, specifies the scope of blank – fill in the blank, regulation. How do we connect in a concrete way the taxonomy definition to the scope of any regulatory observation that we're in the process of making? I'm stuck on that and I wanted to see – I want help from the group. Can anyone help me connect the dots? What is the import of the taxonomy definition on the regulatory work that we're doing?

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

This is Mary Anne. I sat on at least some of the Taxonomy Group sessions. Hopefully there's some set of outputs from the slides or the flow charts that could identify the scope of technologies or devices or systems that should be considered in scope for the Health IT Safety and Innovation Framework. So are medical devices in or out, or are medical device interfaces in or out. Are EHRs in or out? I think we could ask Meghan to maybe go back and simplify that thinking and that content into a couple of slides, Brad, if that would help.

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

Well simplification is always great, but let's be really precise about what we're looking for. So, we've spent three weeks, we've examined FDA regulation, we've examined ONC regulation, we've examined FCC regulation. How would we connect the dots to any of those three regulatory processes and the output of the Taxonomy Group? Are we saying that FCC regulation, for example, should be determined with regard to scope based on what the Taxonomy Group identified? ONC or FDA? How do we connect the regulatory apparatus that we've been studying over the last few weeks with the Taxonomy Group definition?

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

Brad, this is Keith. I mean I know we struggled with this yesterday and what, I feel your pain. But I guess it, to me, when I was listening to the discussion, it kind of gets back to the – what we talked about even how the FDA works right now with regulatory discretion. It's that I think it's the regulatory framework that we're trying to describe and which is the core of their recommendation, is that the scope of – or the subject to which it is applied can somewhat be independent. In other words, the FDA law with the medical devices was always there and it's pretty inclusive. I mean again, I read that, I don't know what you exclude and yet what we're saying is, now we're applying it to these different things that are software. What do we modify if the subject is medical software in particular, but not getting into does this particular medical software get regulated or not; if it does get regulated, here's the regulatory framework. I mean, does that work?

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

I think vocabulary might be stumbling for me. It may be just that we're using words differently and maybe that's the source of my confusion. So, FDA's regulatory scope is defined by a statute that offers the definition of medical device, and as applied right now, for example, that definition embraces certain types of HIT. One flavor, for example is, a medical device data systems that is software, which takes data from the medical device, is kind of the connective tissue, and transfers it, stores it, converts it in limited circumstances. But there are specific pieces of software. Certain CDS, clinical decision support software which is a flavor of HIT, is already regulated by FDA, the classic example being CAD, software that is computer-aided diagnosis. So software that looks at a mammogram, at an image, and helps the radiologist identify hot spots in the image for further examination. So there are all of these specific categories of software that would fit the broader HIT definition that FDA regulates.

Okay. Did the work of the Taxonomy Committee was it intended somehow to form the basis for a recommendation that FDA change the scope of what it regulates? I didn't think so. In fact, I couldn't in my wildest dreams imagine that the intent of the Taxonomy Group was to suggest that all that stuff that they were describing as HIT would now be regulated by FDA. So, I assumed it was not the intent of the Taxonomy Group to suggest that its definition be used to modify the FDA definition. FCC has specific statutory definitions around radiation emitters and accidental or unintentional and intentional and all of that. I didn't see anything in the Taxonomy Group's definition that would cause us to say, FCC ought to broaden or narrow the scope of what it regulates. Same with ONC, ONC's got a clear mission to certify certain EHRs and so forth. So, I don't mean to be too legalistic, but we are the Regulations Subgroup.

Male

And after all, you are the regulation.

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

We're talking about regulation; we're talking about regulatory weaknesses. This is not an academic exercise, it's an applied exercise. We are to identify the weakness that is ambiguities, duplication, areas where the regulation is broken and alternatives to the extent we want to identify them. I don't – I just don't understand the relevance – I appreciated what the Taxonomy Committee did because it scoped what we ought to be examining, what we ought to be thinking about and use cases that we ought to examine as we run through these analyses and so forth. But I can't connect the dots as a lawyer to any of the regulatory systems that we're to comment on.

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

Yeah and I don't – I guess what I'm saying is, I don't think that they do connect. I mean again, going back to what you said just then, do we – did we expect the Taxonomy Group to change the regula – the statute. I don't think there was an intent there, it was really again, I go back to this regulatory discretion, it's really saying what things should you pay attention to, given that you have regulatory or statutory capability. And so that's why I'm treating it somewhat independent.

Woman

Yeah, it's almost more of a driver for thinking about use cases and a driver for thinking about regulatory development.

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

Agreed, well said - very well said.

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

Yeah, I think that's a simpler way of saying it.

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

Okay. Well, I wanted to bounce that off everybody because I know we're going to start talking about the ultimate work product of the whole group and I just – I needed to get in my head, anyway, how we're going to fit all these pieces together. But that helped. So why don't we go on to the presentation. You all saw this, so I'm not going to do a whole lot of repeating, mainly this is an opportunity for you all to offer comments. So, I took, in fact on Monday when we met, I had a version of this that I went through with everyone and when we went through it, I went through the "B's," the broken areas because that was kind of the scope of what we talked about on Monday. Today let me just cover the "A's," but I'm going to cover them very quickly because I do want to get to discussion.

So, there have been basically eight, and the way this breaks out is the first few all relate to the scope of FDA regulation. So number 1, you've got the ambiguity between what is a disease related claim that FDA regulates versus a wellness claim that they don't regulate? So when you start talking about obesity and using software to help manage diet and so forth, when do you cross the line from an app used for management of general wellness into the disease related realm and therefore trigger FDA jurisdiction. It's a big issue in mobile health. Secondly, and we talked about this on Monday, the accessory issue. Understanding which accessories are regulated but then also in what class at FDA they're regulated, Class I being the lowest and Class III being the highest. When you get to things like cables that do nothing more than connect a medical device to, for example, a cell phone or something else, figuring out the regulatory status is a big uncertainty.

The third category is an area where FDA announced in September of 2011 actually they announced it before that, but they discussed it at a hearing in September 2011. The goal is to clarify the dividing line between CDS software that FDA regulates, and the software that they do not regulate. I just gave you an example of CDS software they do regulate, CAD, software used in mammography and other forms like that is standalone software, it's not connected to a medical device, it's merely meant to help a physician assess data that they're trying to assess.

The fourth issue is software modularization. And so here, my understanding is that why reinvent the wheel every time you develop software. There's functionality that's been very well developed, of all sorts of different types and then they form discrete modules and so much of software development is combining existing modules with maybe a unique proprietary layer of new software, new coding that allows you to do something that no one was able to do before. And then that software also interacts, when it's on a platform whether it's a mobile platform or otherwise, interacts with other existing modules like GPS and calendar and all sorts of other things. And so understanding the dividing line, so the regulatory implications when one piece is clearly a medical device, one piece of software is a medical device, what is the impact or implication for the other modules that are either embedded in the same program or access in practice.

You have the intended use issue, we discussed this a little bit on Monday. But the fact that the intended use of software often isn't clearly understood when it's first developed, and evolves over time as it gets combined with other both hardware and software, to be applied to different use cases that may not have been originally envisioned. It's a complexity, not an insurmountable one, but an ambiguity inherent in the FDA system. A big part of what FDA does, is require manufacturers to produce products, medical devices, to meet quality standards. The devices are supposed to be of a type that can be repeatedly manufactured to meet that quality standard. So FDA has quite a few regulations on this, but they were written largely with hardware in mind or physical medical devices maybe is a better way to characterize it. So when you're talking about standalone software, there's a lot of ambiguity, a lot of translation that needs to occur and that's also been identified as a major source of confusion and frustration for those developing software.

Pre-market requirements for interoperable devices, so, when you have a device that is supposed to be able to be mixed and matched with other devices, very open-ended in its intended use. How does the FDA review proceed? Normally, over the last 30 years, when someone comes to FDA with a device, they can characterize from a risk management standpoint the full intended use and the full system in which it might be used. But here now that that system is – specified, it creates an ambiguity in how the pre-market requirements are to be applied. And then on Monday we also talked about post-market requirements and the fact that when you have a network and when something goes wrong, everyone points to each other. And there may not be clear responsibility by any one part – any one component or any vendor of the components, that all of a sudden there are real ambiguities around what the requirements are and how they should be applied.

So those – I should have explained, I got those by going over all the stuff we've talked about over the last several weeks, that's my distillation of what I would say are the – what through prior discussion seemed to be the most important ones. You guys remember about three weeks ago we went through a 60 slide FDA PowerPoint and that was a very detailed analysis. And so I'm talking that up to one higher level of generality and grouping issues and prioritizing issues somewhat, and that's what my analysis produced and what I want to do is see did I do a good job? Are those indeed the ones to identify? Did I miss ones? Are any of those – would you take issue with those, are they not the right ones to include? What do you think about these two slides?

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

Hey Brad, this is Joe. I actually think you've done a terrific job in distilling a lot of the issues. Obviously this is, and clearly by virtue of your outline, this is an FDA centric view. I might take subtle issue with the notion that as you described ambiguity, there is if not an implication an inference that this is somehow negative. But ambiguity in regulation provides latitude for innovation, and I would draw attention to two particular points where that shows up, and they're related, intended use issues, as you described them and also pre-market requirements for interoperable devices.

If you think of HIT as a tool, and not so much as a product with a claim, but as a tool like a scalpel, then you appreciate that that tool works in an operating room. It interoperates with everything else, and we don't get too excited about how the practitioners use it, we understand that they will use it differently, it will work differently in every hand and we'll leave up to local control whether the hand is using it well enough to continue to use it that way. And also, obviously intended use issues, as you look at innovation, it is often in using existing technology for some previously incompletely contemplated use, which turns out to be a wonderful attribute of the system. And so I can appreciate the word ambiguous, but to the extent there's either an implication or an inference that that needs to be addressed, I am less supportive.

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

So that's a very excellent comment and I can tell – at least it appears that you're a liberal arts student like I was. I live in the world of ambiguity and a lot of it is a good thing, you don't want, for example, rules to be too prescriptive. Being prescriptive is a way to eliminate ambiguity, but you give up a lot in the ability to innovate by asking for prescriptiveness. With that said, I'm using ambiguity specifically because that word is called out in the statute, the statute section 618, asks us to identify ambiguities that are obstacles. So, what you're raising is a terrific point and one that we absolutely need to talk about, because I was using, even though I'm comfortable with ambiguity in many situations, I was trying to use the word ambiguity here as the statute uses it, as something that is an impediment.

Now, I don't know Joe if you were in attendance at the earlier phone calls because this one actually wasn't in my original slide deck and it was proposed by the group on Monday. And so let me tease out a little bit, there's ambiguity in the intended use, that's not what I'm referring to. I'm referring to ambiguity in the regulatory system for how it deals with an ambiguous intended use. So the ambiguity that I'm, and this is great, it's not clear from the slide, so I appreciate even more your comment, the ambiguity that I'm referring to is how the regulatory system deals with an intended use that evolves over time. And the group on Monday felt as though this would hold back entrepreneurs who would be uncertain about how the regulatory system would handle or address these open-ended intended uses. So, we need to confront the issue that you're identifying. It is something that we need to as a group figure out which side we're on.

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

This is Keith. I would agree with Joe on this. When I – I mean my visceral response to this when I looked at it was, gee, I don't want you to resolve that ambiguity.

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

Um hmm.

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

And what would be interesting, I think, to get what you're saying because what I'm hearing is, we're both saying the same thing is that you're saying that the ambiguity in the regulation actually is an impediment for innovation and we're saying that the ambiguity allows innovation. So what would be interesting is to take one of these as a use case and walk through it and say again that the meaning in this is that the ambiguity is holding back innovation and look specifically at that, that particular use case and see how it holds back innovation or promotes innovation. I think it just – I mean I'm looking at CDSS software, for instance, and walking through the regulation would be useful.

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

So again, this wasn't my issue, I was just the typist. But, I think the way this was framed was not that the ambiguity was so much an impediment to innovation, now that I think about it. I think the issue was the innovation was an impediment to safety, that by not dealing with sort of the true intended use as it ultimately evolves, that the FDA system was impotent when it comes to protecting the safety of the end user. And that's why the second half of this paragraph exists, perhaps using risk management and post-market surveillance to manage the risks associated with the evolution of the intended use.

So as I reflect on it, I think the intent of the people speaking to this on Monday was if someone really isn't coming with the ultimate true intended use to the FDA, if it's going to morph substantially over time, we've got a problem. I think I used the analogy on Monday that this is kind of like a cancer treatment that when certain drugs are developed, they might be developed and then oncologists are famous for mixing and matching and making their own cocktails out of the various oncology drugs that are available. And they ultimately settle on whatever their cocktail is and the science continues to evolve well after FDA has opined on it.

So, we have to decide, as a group, do we think this is a safety risk such that it needs to be addressed or are we comfortable, kind of to Joe's point, that the practice of medicine just like in oncology, when we say oncologists are highly trained, they're regulated by licensing boards and so forth. We're going to trust those professionals to take various oncology drugs and use them in ways well beyond whatever FDA expected when the drug was approved. So this is a great issue, which I'm hearing a few people who are kind of saying, we ought to come out on the side of innovation here and let professionals use these the right way and not worry about regulating them. Is that the view of the group?

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

I mean Joe and I have that. Again, I'd like to hear from – I mean, you don't even have to go to oncology drugs, you can say any drug, because the FDA has labeled uses and then there are off-label uses that's tolerated...

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

Yeah.

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

And actually is very useful in the development and the science of using those medications. And what's difficult with intended use is that if I say, for instance, particularly decision support software, as a vendor you're creating a tool, you're creating a hammer and someone else is going to find the nails to pound. And so the nail that they pound may be this diagnostic decision making.

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

Um hmm.

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

That what they're doing is they're using the tool to look at different factors in the system and present something like, it appears that your patient has nosocomial pneumonia, do you want to address this, and we do this all the time. And so you say that does that raise a safety issue, it kind – I really like Joe's analogy of the scalpel is that what you have is a scalpel and you have dimensions of it. It's a sharp object and it can cut things and it should be manufactured this way, but then you turn it over to local control of how you wield that scalpel, who can wield the scalpel and what are problems that you apply it to. They're not having such a tight control, then produces good things or with the drugs with off-label.

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

Yeah, I'm perfectly comfortable with that and I'm perfectly comfortable removing this whole row from this chart, but let me just before we do that state kind of what the opposite argument would be. And that is, that the reason drugs, in that particular case, are – I should say the reason doctors are given that latitude is because they're doctors. And when you're talking about software, you're really not talking exclusively about doctors who are regulated by state licensing boards; you're talking about a lot of other people who are not as closely overseen by a professional licensing organization. So does that create a gap for software that would not exist with a scalpel? We wouldn't give a scalpel to a lawyer and say, have at it, cut at will.

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

I think that that is a great thing because what you're saying is that there's a different accountability model that provides feedback and takes care of the problem external to the regulation. And – or that other regulation makes the physician accountable for their medical decision. So they're making a medical decision to use a medication in an off-label fashion based on other information they have or observation and they're held accountable for that, that if it causes not benefit but harm, there's a way – there's a feedback mechanism to take care of that. So, I think that likewise what you have to say about software is, and this is what I was trying to say in the innovation slides, it's not just we want, we want, we want these freedoms, but we also have to put into place an accountability model so that you're accountable for that use. If I use the tool to create new suggestions to the physician on how to do the diagnosis, then I should be held accountable for the way that I set up that decision. And we mean either me personally or the hospital that goes through an endorsement mechanism of letting that to be used in their hospital. So I think you can address it without addressing it, and this gets back to what Joe was talking about, about local control.

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

Um hmm. Okay. So I'm quite comfortable with that. Are there any other thoughts from anyone?

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

Brad, this is Anura Fernando. Just wanted to see if it's even feasible to explore somewhat of a middle ground where if we look at for instance, addressing ambiguity and safety objectives while retaining ambiguity in the execution of those objectives. To give you an example related to the scalpel, if a clinician wants to use a certain piece of technology, in this case a scalpel; then they have certain expectations when they pick up that tool. For example, that the scalpel will be sufficiently sharp to cut through the tissue that they intend to cut through. And so if we were to look at ambiguity relative to safety-related attributes, could that be a middle ground for approaching this topic?

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

It's Keith, I like that. Again, I want to know that, for instance, using the decision support analogy again, what I want to know when I get it from the manufacturer is that they create good manufacturing processes that they tested this thing and the tool is safe to use and apply it to problems. Again, like you said, it's that there are certain attributes about it that I can say that in the case of the scalpel, it's sufficiently sharp, it's sterile, or whatever the attributes are. But now as I apply it to the problem, I'm extending its labeled use into a – well, its labeled use in this case for the CDSS is really that it allows the hospital or clinic to set up their own decision support and it's a safe system to do that. In other words it won't report – it won't grab data from the wrong patient, it will report the decision on the right patient and that sort of thing. But the content of the decision itself then is under the control and the local accountability that I have to be accountable how I use that and which problems I applied it to.

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

So it feels to me like we're converging, and that's a great thing. So, I think I have what I need; I'll take another cut at trying to summarize this issue. And I may not include it in this – intended use slide, I may put it on a subsequent slide, just like we have this issue about federal or FDA program administration being unclear, I might also put here that the system, to work, needs greater user accountability, much akin to professional licensing or something. I'll work on some language and float it for everybody to look at. Any other – so this is just the FDA slides, we haven't gotten to ONC and FCC and then the three combined yet, but anything else on the FDA slides? Are these relatively consistent with what people are seeing in the area of FDA?

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

Brad, in the spirit of the email that you sent out for July 3 where you asked about ambiguities in the regulatory systems and what needs to be classified so that health IT vendors and others could proceed more easily to innovation. One of the areas that I grapple with constantly with the FDA is the notion of enforcement discretion and you don't have it listed there and for me, it could fall under this category, as well as on the July 8 conversation that we're going to have, is there a better way to assure innovation's permitted to bloom, etcetera. But, a very practical example for me is products and product codes that they currently list on the FDA website, one being product code NSX for example, which is software transmission and storage patient data. And it sounds very familiar to lots of things that are out in the marketplace currently, yet they decided to not classify it by using enforcement discretion, which is a wonderful thing because it takes it off the table. And I think that this is one area that the FDA is clearly very ambiguous in how things fall into enforcement discretion, providing even – guidance what they are considering to put into enforcement discretion and then even once things are in enforcement discretion, what – how the agency even came to that decision. So I think that this is clearly an area of ambiguity that affects HIT vendors which would, in my opinion, help them proceed much more easily in innovation.

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

I think that's very well said.

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

I think, just one of the things that I tried to note in our slides, too is that because of regulatory discretion and even if you look at the Taxonomy Group, there was this dimension of how many people it affects. The idea that I'm below radar and all of a sudden I pop up, and I'm subject to these things, there's not a good pathway. I mean that's one of the things I think that is – because in the case of a physical medical device, my intent is to make a medical device at the beginning and I'm going to sell billions of these things, type thing. When we're starting off with medical software, because – and I'm a pretty substantial manufacturer, when I start off with software I'm starting small and my audience may grow. And how do I then get into the pipeline without it just saying, well you've hit FDA and we've killed you at this point, because you didn't have all this documentation of the process. How do I reduce that impedance?

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

And I think that's absolutely clearly the FDA could today literally, be able to work with a company like yours and specifically come out and say, based on what you're intended use is and how your device is being marketed, we actually feel that it falls into one of several codes that we have taken off the table through things like enforcement discretion. And it's a very powerful tool at the disposal of the agency that could be used aggressively to literally feed innovation. To me, time to market is the killer of innovation...

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

Yeah.

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

And when we have to think about and contemplate rules and regulations over the course of years, that's really unhelpful. And when the agency actually has a number of things at its disposal that it can do today, yesterday, a week ago, and it's not using it that way, then that's a problem and that's I think fertile ground for this group to discuss. I don't necessarily know what your specific device does, but I tried to take an example of something that I think really would resonate with a lot of people on the call. An NSX device is a non-alignment software that captures patient data from patient monitoring devices and transmits that data to a patient's electronic medical record where the data can be stored. That is very, very, very similar to a medical device data system, which is an actual regulated, Class I device.

We at Qualcomm chose to create a subsidiary that marketed some MDDS product and we did so as a strategic move and also because of what it does in being able to market it that way. But this other device, which apparently is not, because of enforcement discretion, does very similar functionality and again, it falls to your intended use and the way that you want to market your device, but I'd argue that many a device manufacturer may actually fall under that parameter and would not have to worry about that regulatory reach. But not everybody has people like us that work there, especially if you're a garage entrepreneur with a staff of two, you and your dog –

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

Yeah.

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

(Indiscernible)

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

Well and the use case we have is that we developed a ventilator weaning protocol, studied it, published on it, could show the efficacy of the protocol was excellent and saved lives. Another center wanted to use the same decision support, it then popped up on the radar of the FDA and they said essentially, we don't care what your results are, what we're about is how did you manufacture this, how did you create it? And of course, because it was developed over multiple years in an iterative process, that it could not be reproduced by that researcher, and so then that software actually for the multicenter is being tested in China and not in the US. So you know, it's how do I get an on-ramp to this if I've been outside the scope and now I'm within the scope, that's all I was raising there.

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

So I think that issue, in some measure, connects to this program administration issue...

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

Yeah.

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

Not just the statute, but really how can the FDA be more helpful, more user-friendly, more clear. How can they create the on-ramps to make it easy, as Jarrin says, for the garage entrepreneur? So I think we've captured that. We've got about 12 minutes left or so. Let me see if we're done with the FDA portion of this. Any other ambiguities relative to FDA that would sort of rise to the top of the discussion? Okay. So, we had ONC next and there were actually a couple more on this list when I presented yester – or I guess Julian presented it yesterday. And as I looked at them, they really fit, I thought, into the category of potential duplication or coordination or inter-agency issue. So I created a separate slide for the interagency stuff and reduced this just to these two, and I won't go through them back again, Julian covered them I thought well yesterday. Obviously the mandatory elements one was a bit controversial, the notion that something needed to be mandatory as opposed to simply voluntary was one that we're going to have to work through as an entire working group, I gather. But any other comments about any other items that should be on this ONC list?

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

Again, this is Keith. I think the focus or the regulatory – and it really is this mandatory issue, and as Julian and I talked about yesterday, is that the ONC with being a certification process and being volunteer, sort of, because you have – you do have a negative impact if you don't volunteer. But – and not being a law is really a completely different animal because it really is describing a particular product. I mean it would be like the FDA saying that the medical device, here's the exact requirements for an IV pump and if it doesn't meet these requirements, these specific requirements on display, on the sequence of the workflow, then it's not an IV pump. And that's a – the certification process is very much more about what is the product rather than what is the process.

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

So just to clarify, this description of the challenge does not say that the ONC Certification Program is defective because it's not mandatory. What it says is more generally, the ONC Program, which includes for example the broader, bigger picture safety programs that the ONC announced yesterday and generally the ONC method of operating is not law enforcement. It's not there to catch bad guys. And so this isn't an observation that we need to change that directly, but rather it needs to be addressed somewhere. Somewhere there needs to be law enforcement and it doesn't reside at ONC. So it's a smaller point or a bigger point, I'm not sure which, but it's not the suggestion that the certification be somehow mandatory.

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

And again, it kind of goes with this ambiguity definition; when you hear it, like Joe and I, when we looked at the FDA we said, hold it, don't jump in and change it, when it said "B" for broken and kind of gets that idea that this is completely undesirable and jump in. Yeah.

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

Well it's something that needs to be done, but it's not presuming that the fix is to make the ONC program mandatory.

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

Okay.

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

It really maybe belongs better over in the interagency slide, maybe – maybe that's the solution.

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

Yeah, because then you're really – you're looking at across the two.

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

I like that, I like that. Let's – because that really is the issue, not that the ONC Certification Program needs to be mandatory.

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

Yeah.

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

Good suggestion. Is there anything else on ONC? Okay. Let's see, we've got a few minutes left. We really didn't have much that was FCC specific. Again, we had three or four more items; I moved them over to the interagency slide because they involved things like coordinating the FDA, FCC reviews. So, this is the only one that was truly FCC unique. And again, we went through this yesterday so I won't repeat it, but, any other issues, any comments on this one or any other issue that we need to address with regard to FCC? Okay. We'll have more time as we go along.

So then we get to the bigger picture and we look at how the three agencies fit together and as I said, this is where I moved a bunch of stuff. So we have the reporting piece, that's the piece that obviously Julian spent the first hour of this session talking about. We have what was on the ONC slide, but I moved it here because it really involves the gaps, potential gaps between the FDA and ONC when it comes to interoperability issues. All I did is move what you saw yesterday. And then we've got the two, FCC FDA interaction issues that I again, just moved from the FCC slide to this cross-agency slide so none of this is new, it's just new to this slide. What do you think of these four issues? Are there other issues that you think need to be addressed? Obviously I'm going to move the mandatory issue that is, making sure that there's a law enforcement component where necessary.

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

So Brad, this is Joe. Those last two words, where necessary, I think winds up being important because one could imagine the market-based forces would speak to whether or not something is effectively mandatory. And then similarly, one could even hypothesize that the tort system is adequate for policing some of this, although I wouldn't support that, but I think it is an issue of enforcement, where necessary. And it may not be routinely necessary.

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

Agree. Completely agree. All right, so that's what we have and the next – we're going to go to public comment here in a second, but just the choreography from here forward. So next Monday Joe's going to lead the discussion, and he's been talking to a variety of people on the full working group and within this Regulations Group to identify kind of big picture alternatives. This is – we've gone kind of big, bigger and biggest, so this is the biggest, Joe's going to lead us through, and sort of the grandest.

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

That is pre-market approval advertising, I might point out.

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

Yeah, I was going to say...

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

So we're going to look at alternatives. Is there some better way to do what these three systems are trying to do in the status quo? Is there some non-status quo option that we really need to consider? So I think it's going to be a fascinating discussion. Then after that, we've got two sessions on the calendar of this working group where we're going to try to arrive at a report, a PowerPoint report of recommendations out of this group. So let's talk about how we're going to pull this together.

I imagine the slides we just went through will form part of the basis for what we'll start with; it's all open to group discussion. I think Julian is going to try and put together a few slides summarizing the need on the reporting. Again, it's sort of a cross-cutting issue across all agencies, so he's going to, I think, try and fashion some slides for the group to consider and then obviously we want to see what comes out of the discussion on Monday about whether there are some big picture alternatives that we ought to consider. But we have two meetings carved out for this group to really roll up our sleeves, hash it out and come to some written work product that we can then transmit to the full working group for its review. Any questions about that before we go to public comment? Okay. So, I don't know, MacKenzie, who's in a position to open this up to public comment.

Public Comment

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

Sure. Operator, can you please open the line 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

I don't know about anybody else, but we're having so many meetings I guess I'm skeptical that many people are continuing to dial in with interest. But, if anyone is and anyone has any thoughts on anything that we've just discussed, I'd be delighted to get them by email and we would factor them into the Committee's deliberation. But with that, I really appreciate – I know we met, as one group or another, we met three times this week and in fact, a few of us have a call at 4 o'clock. But thank you all for spending so much time invested in this. It's been really great discussion. Today's I found very stimulating and I hope you all have a wonderful Fourth of July and I'm really looking forward to the discussion on Monday. Take care everyone.

Ulian M. Goldman, MD – Medical Director, Biomedical Engineering – Partners HealthCare System – Director, Program on Medical Device Interoperability, CIMIT, Massachusetts General Hospital

Thanks Brad. Thank you everyone. Have a nice holiday.