

**HIT Policy Committee
FDASIA Workgroup
Regulations Subgroup
Transcript
June 13, 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 time for public comment on the agenda. The call is also being recorded and transcribed, so please make sure you identify yourself when speaking. I'll now go through the roll call. Julian Goldman?

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

MacKenzie Robertson – 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 – 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. Mo Kaushal? Joe Smith?

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

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

Thanks Joe. Steve Posnack? Steve Posnack's here. Bakul Patel?

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

Here.

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

Thanks Bakul. Matt Quinn? And any other FDASIA Workgroup members on the line, if you could please identify yourself?

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

This is Rich Eaton.

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

Thanks Rich. And I believe we have Mike Lipinski on the line as well. So with that, I will turn it back over to you Brad for the agenda.

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

And will you be able to give me rights to advance the PowerPoint?

Caitlin Collins – Altarum Institute

Oh yes, let me set that up for you right now.

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

So let me start with a bit of context. So thank you all for gathering on very short notice. Let me, and I'm going to turn it over to Julian here in a second, but let me cover what I think is the context for this call and then see if Julian has anything to add. But, so in our last call we started this process of looking at the specific FDA requirements, and we got about a third or maybe only a quarter of the way through those requirements in that first call. At the end of the call, we stopped and said, okay, so how are we going to tackle this, and the way we've basically designed this is today we're going to try and finish FDA, so we're going to try and cover all of the FDA requirements and we're going to cover the most difficult ones or the most controversial ones at the very end of the call, because I understand they'll probably only be one or two people still on the line. I'm kidding about that, we won't do that.

But what we are going to do is then in two subsequent calls, in June, cover ONC and FCC in a similar manner. We're going to go through the regulatory requirements, different folks on the workgroup have raised their hands and volunteered to organize those portions of those meetings. So we're going to tackle, in effect, all three agencies one at a time, looking at the regulatory requirements, asking ourselves the same basic set of questions, is the requirement well-focused, is it excessive, is it too little, is it inefficient, is there a better way to do it, sort of the full range of evaluating whether the regulatory requirements are appropriately tailored to the unique features of HIT.

Then in the first week of July, we're going to step back and look at holistically and say, okay, now that we've examined each individual tree, we're going to look at the forest and have we got everything covered, is it overkill, under kill, is there a better way of doing this. We're going to circle back to those big questions and grapple with them and try and come up with collective recommendations. So that's the general plan and Julian, I know you're going to have to duck out here, I appreciate you joining the group for what time you can. Do you want to do anything else to frame the discussion?

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

Well one thing I'll do is support what you just said and I think that the plan is very sound and gives us a framework to get the work done. It'll give us a very tight timeline, difficult folks have of participating just due to schedules, but I think it'll help everyone to understand what to expect. The – Brad, I just sent you a quick email, I don't know if you're on email or not, are you able to see what I sent you?

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

Yes, I'll look at it right now.

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

So, I just expressed a point about the work to Brad that I just want to ensure gets addressed or captured and stays on the agenda, and I'm going to give Brad a chance to digest that for a second. Do you want me to speak to that, or is there any need to Brad?

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

Yeah, please, let's not be mysterious, why don't you share, if you would, with everyone.

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

Sure, sure, I just didn't want to distract the folks on the call. So, in looking through the slides and looking at those things that have the green light, looks like they're covered, certainly medical devices most of us feel are generally covered quite well in the FDA regulatory scope. But I think the area that we really need to think deeply about as a group, the area between the other things, the communication and the implications or incorrect communication between medical devices and health IT, at the interface, in a sense. And the fact that today, when there's a treatment problem or other problem, due to the incorrect data showing up in the EMR or EHR, we don't actually know where the problem may happen, we may not have the right tools to track it, don't understand who's responsible and not sure how that will be addressed. And it's pretty clear that this is a broad issue today that – and we're just seeing the tip of the iceberg, and as adoption increases and usage increases, we'll see that more. I think that we've identified within the group and in our face-to-face meetings that that is kind of a big challenge, one of the tougher problems to address, but vitally important. So, I want us to – that only for a moment, I don't know the solution yet, none of us really do, but maybe we're not charged necessarily with solving it as much as ensuring that some of these important issues remain on the agenda. Brad, any thoughts on that?

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

Well, I think that's, I think what you just said last is terribly important, that I don't think we're necessarily answering every question, I think we're first and foremost trying to figure out what the most important questions are and to Bakul's description, we're coming up with kind of the specifications for what the system that the agencies design will do. So, if we can identify all those issues, that will I think be a good service to the agencies as they look to actually create the regulatory scheme. So, I think that's important.

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

So what I'll do at this point is, I'm going to be on mute and at some point I'll disconnect when someone tells me I have no choice. You know how it is here, flying, but I'm here and I'll step in if I can in any way, take it away Brad. Thank you very much.

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

All right, well thanks Julian, and safe travels. So, as I said, what we did last time is we got through about, I think it was the first 13 slides, and we're going to pick it up here. But what I wanted to do to try and be a little bit more efficient is a couple of things. Number one, I would ask your indulgence, and here's what I mean by that. I have a reasonably good sense of what the rest of the thirty slides cover, and there are going to be some that require more discussion than others. And so if you would permit me, we have about 80 minutes left, if you permit me to be a bit of a taskmaster when it comes to the clock, and making sure that we're moving forward at a pace where we'll finish this off, because in all honesty, one of the worst outcomes could be that we don't finish today. We really – we do need to finish this today in order to move on to ONC and move on to FCC. If you'll permit me to be a bit pushy when it comes to the time, I would appreciate it.

The second thing is, I thought maybe I could address some of the issues at a more thematic level, in other words, we are going to go section by section, but there's certainly a few themes that came out of the first 13 slides, and we don't need to state those themes each time, just notice when the potentially apply. So here's seven themes that I wrote down on the basis of our discussion last time. The first is, the difficulties or challenges of applying this regulatory scheme to use cases that do not have a well-defined system and all of the components of a system. So the complexity is, FDA regulates products, regulates them by manufacturer. If a manufacturer comes to FDA and says, this is one piece of a system, and we don't know every other part that will fit in that system, that's something that causes a little bit of confusion anyway, or uncertainty as to what the regulatory requirements are.

Secondly, the relative inability in the area of systems to necessarily put a fine point on specific, individual responsibility for an error or some sort of problem. We've talked in the past about shared responsibility and so forth, and there may be times when it simply isn't clear whose responsibility a given problem was, even if we know with relative clarity what the problem was, that may not tell us entirely what we need to know about who's responsible and so forth, how the problem arose. So we have that complexity. Third, we have the rather significant involvement of the end-user/customer to customize or modify software. And that creates confusion around who the actual manufacturer is, what latitude that end-user has to make changes without becoming a manufacturer and so forth. So that's another theme that we say.

Fourth, you have the virtual nature of the manufacturing process for software. I've kind of experienced this firsthand a few times where being an FDA person, I've been brought in to a company and they say, well we have this guy sitting in India, he does this. We have a guy sitting in Austin, Texas, he does this and they tell me about these 20 people all around the country or all around the world, some of them working out of their homes and so forth, and then I have to figure out, for example, where the facility is that needs to register as the manufacturer, and it can get pretty complicated. Finally you have – not finally, but fifth you have the nature of the product itself, it's virtual nature, the fact that it's not a widget, the fact that it is ultimately written code and that its production process and physical nature vary from a lot of what else FDA regulates. Although to be clear, software is not new to FDA by any means.

Then you have the different model of distribution and purchasing for software, the fact that it can be downloaded directly into a home from a server, and the complexities that creates in terms of figuring out responsibility if, for example, the product is produced overseas but downloaded in the US and who bears various obligations. And then seventh, the need or uniqueness of software to be constantly updated as the uses evolve, as hardware evolves, as bugs get identified, there are lots of reasons to keep software up to date and that cycle is much more rapid than the cycle to fix or repair or otherwise address hardware of any number of varieties that FDA regulates. So those were seven thematic differences that I picked up anyway, listening to the discussion regarding how the regulations apply. And we will see those same themes raise their specter, I guess, throughout this, and I'm not going to sort of go through them each time, other than to sort of cryptically reference the issues that I just said. Any other themes that maybe somebody wants to identify before we start going through the requirements? Okay.

So let's turn back to the requirements and what I'll do in each of these is kind of briefly summarize what the requirement is and what, so far, we've identified in the nature of unique issues that have to be ironed out. So, you have certain labeling requirements for medical devices that apply to prescription devices and you have, through drug stores and other mechanisms, you have a ready way to control dispensing physical products that are prescription. It's different with software, as I noted, because of the download, the fact that you can get it from your home and don't need to go into a pharmacy and so forth, the meaning, if there were prescription software, the meaning or the implications for how you would control the distribution of that are presently unclear. Any other issues that you can spot with regard to the prescription status and the method of dispensing? Okay.

So there's this broad principle that says that you don't need to provide detailed directions for use if the directions are commonly known. And that raises some interesting questions in the area of software because software has its own kind of conventions based on whether it's a Windows operating system or an IOS operating system, that people are – users are kind of expected to know, if they're familiar with Windows or if they're familiar with IOS. And so the question is, in the context of a specific app or a specific software program, which features can we assume that people commonly understand and which ones require explanation? Do medical apps or medical software require kind of more hand-holding, more labeling than other apps? Well arguably they do, because the consequences are more significant, they're health and wellness, but how far does that go? Do we need to start labeling very simple things that we would expect an ordinary user to understand, but which my father, who's 82 years old, who never uses a computer, has no clue about. It raises some interesting questions. Anything else that you can think of in that vein?

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

Brad, this is Anura Fernando. One quick comment here, I'm not sure this is the best spot to raise this, but, when installing the – software, when it's downloaded, we've been looking at abstracting the software from the platform, where possible, it's seen as sort of the general trend. With IOS and Windows to some extent, that's relatively easy to abstract it, in particular from the platform, but when talking about Android, because there are so many different flavors of that operating system, there may need to be additional directions for how to install and where to install, relative to different platform and so the abstraction from the platform may be significantly different on Android versus IOS.

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

Okay, I was unaware of that, but that's interesting and I'll make a note. That does seem like a pertinent issue to be addressed.

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

Brad, this is Matt, a question also. Some of these systems, many of the systems are not designed so much by the vendor, but designed actually in the implementation process. And so a lot of the decisions are the implementer and not the product.

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

Okay, I think that's an important point as well. Let me – I'm just, while you guys are talking, I'm just writing these down so I remember them.

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

And one of the things also, and this is an issue in the usability research, is that there aren't consistent uses of colors, symbols, icons, etcetera the way that, for example, you could step into a car and know that the accelerator and the brake pedal are going to be in the same place, except if you're – and so that's one of those things too that makes it hard to say, anybody would know what red means or what a star would mean.

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

Okay, um hmm. Okay, good. Good. Anything else?

Lauren Fifield – Senior Policy Advisor – Practice Fusion

I guess – this is – Brad, this is Lauren –

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

Okay, yup, go ahead.

Lauren Fifield – Senior Policy Advisor – Practice Fusion

Hi, this is Lauren Fifield. I think another thing too is the sort of concept, maybe this is in general, but particularly when it comes to directions, to sort of think about directions for a product when it's a medical device makes sense, but if you're looking at something complex, like an EHR, there are directions for individual workflows and so I don't necessarily think that directions for a – product fits in the software of health IT world. It might be the directions for a particular workflow, because I think as Matt is saying, it's true that there aren't necessarily standardized features of an EHR and in some cases, that doesn't matter, just like having standardized colors of cars wouldn't – that competitive advantage maybe of having red leather seats. But that in other areas the brake pedal and the accelerator, that would be good to standardize. So, especially in the EHR world, I think that comes down to workflow areas or pieces of functionality within the whole product.

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

Okay.

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

Another dimension of that, just to continue the thought a little bit, is with regard to privacy and data sharing policies, and I'm not sure if that would be in the scope of this. But, you've seen one and you've seen one, as it relates to a lot of this stuff, both on the consumer side – specifically on the consumer side. And so in terms of that would fall into this labeling piece maybe.

Lauren Fifield – Senior Policy Advisor – Practice Fusion

Yeah potentially. It could also – some of the other areas of risk, I think we talked about were security and so, it might not necessarily even be what the content is, but maybe standardization around how it's written, yeah, so.

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

Okay.

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

Great. Any other comments? Okay, and by the way, I said this last time, but let me just repeat it. I view this document as organic throughout the month of June, so today is not your last opportunity to offer insight into it, I know you only got it yesterday, or maybe it was this morning I don't remember. But each time I'm just going to turn around a draft, I'm going to try and capture all these things and put them in here and I'll distribute it to the group and as things continue to occur to you, just send me a note. And if you would, use red font or something so I can see what you've added and I'll keep a master list. Okay, so the next area is the issue of there are labeling limits, limits is the wrong word, but, exemptions for a product that is not final, that is used for processing to make other products or repackaging or for further manufacturing, in which case, you're exempted from this labeling requirement that FDA has. A couple of issues that jumped out to us, and by the way, I need to again give credit to Kim Tyrrell-Knott and Scott Feil, who developed most of this. They point out software modules, are they finished products, aren't they – do modules need to be labeled or are they simply component building blocks that don't need to be labeled. And then, what happens, again, you work so closely with the end-user in many cases, a hospital for example, what are the circumstances when what you're delivering to the hospital is actually incomplete and therefore it doesn't need to be labeled, and in effect, becomes a product of the hospital. So, that's a unique complexity associated with this category of software. Other similar issues?

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

Sorry, this is MacKenzie, I just want to make an announcement. I know some people are probably in airports and we are getting a little bit of a background noise, so if you're not currently speaking, I just wanted to remind people to put your phones on mute. If you're in an airport and you still want to speak, that's fine, but if you're not, if you'd please mute your phones, thanks.

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

Anything on this intermediate work product? Okay. So the next requirement, I don't expect a lot of discussion around this, maybe, I guess. But there's a general exemption for non-medical uses. So product can be used in teaching, for example in a teaching hospital, for law enforcement purposes, for research and for other analysis, there is no risk of clinical harm because those intended uses are not on patients and not for purposes of influencing therapy. So, there's an exemption for those. Didn't see anything particularly unique for health IT, but does anyone else?

Okay. So that's all labeling and now we're moving to the next major subpart, which is medical device reporting. And at a high level, medical device reporting is kind of a sentinel system that FDA has in place to try to hear about and learn about and then proactively address issues where products are creating harm when used in the marketplace. So, generally user facilities that are the frontlines of using the medical devices, if one of the medical devices malfunctions or otherwise causes injury, their supposed to report that, in some cases to the manufacturer, in some cases to FDA, it's a fairly complex system and we don't need to really get into all the complexities here. But we do need to figure out kind of what are the unique aspects that could impact HIT.

So on this first slide, we've just listed the general structure for this section, and then we're going to go through each of these subparts and see if there are unique issues. So the general provisions basically try to, as you might expect, definitions for what are product malfunction and what are adverse events and so forth. It seems to us that one of the special challenges is figuring out which device and therefore which manufacturer is responsible for an adverse event, and therefore has a responsibility to report or to address the issue. So, this area of shared responsibility, the regs weren't written with that in mind. Conducting a basic root cause can be very complicated when you're talking about a system and you need cooperation from various vendors, even to figure out who's at fault. Those other vendors could be competitors and they may not be completely cooperative, it may be because they're worried about FDA, but it may be because they're worried about product liability or some other form of liability.

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

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

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

Sorry, Julian here. Just want to interject something. The other main challenge is not having access to the data when there is an adverse event, a near miss or injury. It isn't only the manufacturers but we should capture the notion that we don't have the source data, the data logs and so forth. They're virtually, almost always incomplete and a challenge to access or obtain. So, in order to understand a system failure, we need data.

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

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

Brad, Anura Fernando here again. One more item that relates to an issue from two slides back also, is relative to components. If the root cause of the potential hazard is related to a component that is general purpose and doesn't fall into the domain of regulated devices, then the traceability to that component may be a challenge and could, theoretically, be captured under the quality management system, but that may need to be made explicit.

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

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

Hey Brad, it's Jarrin. Actually, for the record, I have to jump off the call, it started to monsoon here and I've got to go pick up my kid, so I just want to make sure people know that, not blowing off the meeting, but I've got to run. Bye guys.

Bradley M. Thompson, MBA, JD – Epstein Becker & Green, PC
All right, be safe.

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

This is Bakul – there –

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

There are, in fact, tornado warnings in Montgomery County, so if folks need to evacuate, take care of yourselves and we'll catch you up.

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

Yeah, so that's a great point, if anyone else needs to drop off. Any other issues to raise here? Okay.

Lauren Fifield – Senior Policy Advisor – Practice Fusion

Brad, sorry it's hard to – sometimes. I think one thing to consider is that because we haven't necessarily narrowed health IT yet for our purposes, considering sort of who would be the reporter is important and in sort of even outside of technology, there are tremendous differences across care settings. So inpatient setting might have more best practices or common practices around reporting whereas an ambulatory setting it's far less standardized, there's far less infrastructure and then certainly in the realm of the consumer, in order to get the sort of – that Matt was talking about, you have to have reporters. And so I think, just sort of considering cultural awareness and education factors is really important in this.

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

Okay. Great. Any other? So slide 20, boy I'm losing my voice here, is the portion of the reg that defines the individual adverse event, what is the event? What's the nature of the event and what's the product responsible for the event? So kind of the same theme, again, figuring out which manufacturer's component is the one responsible for the individual event. Any other issues that we need to identify? And so a lot of these comments that you're making apply to multiple sections of this particular portion, and I'm making note of that, that wherever they pop up, they probably apply to more than one of these.

Okay. So there's user facility reporting and this goes really to Lauren's comment earlier, user facilities actually are obligated to report when a medical device hiccups. And obviously there's a challenge in figuring out which of them, which of the users in a complex system, actually has that responsibility for reporting. So, same issue again, different section though. Any other or new issues? Okay.

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

Brad, Julian here. I don't know whether this is a viable thing to consider, but historically, in fact, as you said, it's one user or there's always one entity that has responsibility. Maybe the notion of shared responsibility is part of the question on the table.

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

Well I think that is the challenge, yeah. I think that's a huge part of the challenge.

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

And, this is Matt, and in connected environments, that allocation of responsibility and accountability is particularly important. So, collecting data from one entity involved in, for example, health information exchange probably isn't going to be adequate to understand.

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

Yeah. Okay. The next section addresses importers, because when the manufacturer is a foreign establishment, the regulations like to have a US entity responsible for making sure that the reports are made. And here you have the problem of direct downloading, sort of bypassing any importer, as it were. So figuring how that would be addressed seems a challenge. Any other issues that you can think of here?

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

Brad, Anura again. Just one more very closely related – again, it seems like the precedence is that some of the app distribution sources like iTunes and Google Play Store or whatever and so forth, aren't considered distributors as medical devices, but in cases of apps that are introduced from overseas, it seems to raise the question of whether they should at least provide some level of traceability back to the source, or something along those lines.

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

Um hmm. Okay. Good question. Any others? Okay. So these are the manufacturing specific requirements and they're kind of mirror images of some of the other issues, so figuring out which particular vendor is responsible for reporting to FDA. So remember, you have – in many cases you have the user reporting to the manufacturer, the manufacturer investigating it, figuring out what the root cause was and then if it meets certain requirements, reporting it to FDA. So figuring out who has to do that is a big deal. And then this other comment probably doesn't belong here so much as other places, there are times when to do a risk analysis or to do an analysis of what kind of a recall or field correction needs to take place, you have to determine things like how many installed products there are, and with software, that's just more difficult. With physical products, you can physically account for them much more easily than you can with software that is downloaded maybe and installed by the user. So, this arguably needs to appear someplace else in the presentation, but it seems to be an issue.

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

So Brad, this is Bakul.

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

Yup.

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

Can I just ask a question on that? Is that – did you say it was easier with software or difficult with software?

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

It's just different; I don't know whether it's easier or more difficult, it just seems – .

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

Oh, it's different.

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

– to raise different issues. Counting issues, figuring out what the denominator truly is a definitional thing. I'm not sure that it's easier or harder, it may even be easier, but there are some definitions that need to be agreed upon.

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

Okay.

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

This is Matt. When you throw in version numbers and unique implementations and everything else, it's tough. But another way to think about it is from the vendors side, is that they generally track those things.

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

Yeah, well, ideally. But I've seen vendors really struggle –

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

Yeah.

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

– they have a thousand questions, just when they're filling out a report saying, well what's the FDA asking here, what number are they asking for, is it this, this or something else and we're unable to give them guidance.

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

As a former product manager of software, it was one group of customers had one version and another group had another and another had exactly the same, as the first one except this little piece was different. Hairy, and support became that much harder.

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

Yup. So, let's go on to §806, §806 is reports of corrections and removal. So what we just covered was where somebody gets hurt and the person using the medical device, if it's a user facility, reports it and the fact that somebody got hurt ultimately gets reported to FDA. This is focused on reporting where a company takes a step to fix a product or remove a product from the market and the theory is that FDA should know about that if it was intended to address a significant risk. Because the FDA needs the ability to sort of step in and say, well, let's make sure you were thorough enough or let's make sure that you got to the root cause or that maybe more is necessary for you to do, that kind of thing. So there's a separate reporting for the fixing of a product as opposed to finding that a product hurt somebody. So let's go through this section fairly quickly and see if there are unique HIT questions.

So the basic requirements in §§806.10 are that you file these reports and you have ten working days in which to file it. And there are some unique features because for one thing, there are some practical challenges in how software is extracted and which vendors are responsible for actually participating in it. You might have a joint effort by more than one vendor for a joint fix and so figuring out kind of who has responsibility for making this report seems to be a question. There's a lot of updating that is done routinely for software and determining and then reporting for each of those updates that fix a substantial issue with the software, is at least an administrative burden if not an ambiguity. So, we raised that issue as well. Do those seem right? Are there other issues that we should note in connection with corrections or removals?

Lauren Fifield – Senior Policy Advisor – Practice Fusion

Hey Brad, this is Lauren Fifield. I think particularly because health IT is quite broad, the delivery mechanism can have a tremendous impact on the concept of a removal or recall and in sort of a software implementation where software is a version and it's been downloaded and potentially customized by end-user, sort of what you said makes a lot of sense. But then if you have a web-based product where all users are using the same instance of that product, the concept of a recall could just be rolling back a piece of functionality rather than the whole version and that can happen in five minutes, if it's called to the attention of a vendor. And I think mobile platforms can operate somewhat similarly in terms of making a fix within even 24 hours or rolling back pieces of functionality that are malfunctioning. So, it's actually I think a value-add with sort of newer technologies but you wouldn't want necessarily a process to slow that down.

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

So this, just to be clear, this is not a requirement that you get those changes approved by FDA first, we'll get to that, that's an issue. This is an obligation that within ten days of having done that, you report it to FDA. So in that context, can you help me just refine what the issue is?

Lauren Fifield – Senior Policy Advisor – Practice Fusion

I think in – on this particular slide, I think part of it would be defining again what constitutes an actual issue that has an impact on patient safety.

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

Right.

Lauren Fifield – Senior Policy Advisor – Practice Fusion

So having a really fine-tuned definition. I mean, we have rolled back stuff that's sort of frustrating to users, but that has no bearing necessarily on patient safety, or we've rolled stuff back that maybe could, but only if you sort of look at it in a certain way and go to like a 0.0001% of probability. So I think being really clear about what would constitute the need would be important, because you could be writing reports all the time, so yeah.

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

Yup. Okay. Excellent.

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

Brad, this is Bakul. I just want to make sure folks understand and you should clarify that their obligation to report is not for every change, even for today, for all medical devices.

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

Yup, we're going to get to that on the next slide actually.

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

No, even for §§806, is it on the next slide?

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

Yup, I think it's the next slide, because as Bakul says, you don't need to report everything, you need to report those that meet this high threshold for – they were done with the intent to basically save people. And then if it doesn't meet that, you have an obligation to maintain records. And so that's this slide is the record requirement, where for more modest changes or changes for more modest objectives, you need to do that. So here we just listed frankly volume is an issue with HIT because the number of routine updates, bug fixes, software support and maintenance is very high volume, so figuring out kind of what those records are, we just want to make sure it doesn't get too burdensome.

What kinds of records you need to keep when download is the method of delivery? So this is more just a clarity question, what those records need to say. And then, if you're selling software through a website, what are your obligations to basically keep track of who the users are, and therefore who's using the patches and the updates and so forth, seems like there's a need for clarity there. None of these are big obstacles, it just would take a guidance document or something to say, here's how you do it for standalone IT, but making sure, I guess, that it doesn't become overly burdensome given the high volume of more mundane fixes that occur in software.

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

Brad, Julian here. Just a quick interruption, sorry, I just wanted to say goodbye and thank you. I'm going to go – for the record, I'll be off the call now.

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

All right. Travel safely.

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

Thank you.

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

Brad, Anura again. Going back to the previous slide. If we have a situation where device-dependent data potentially compromises compliance with meaningful use regulations, then it seems like we may want to consider having a reporting mechanism that ties the HIT as well as the device itself to FDA reporting, which I'm not sure if that's currently the case or not.

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

I'm sorry, I just didn't track exactly what you were saying, do you mind taking another run at it?

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

Sure, no problem. So if you have a device connected to HIT, so the device is clearly under the auspices of FDA, the HIT that it connects into may be under meaningful use under ONC jurisdiction at this moment. If the device originates a problem, so for example, not having the time-stamp data that allows for proper understanding of the situation that's been caused by the device, then the HIT data can potentially become hazardous or irrelevant in a better case, and so it would potentially no longer comply with the meaningful use requirements. So currently with HIT being out of scope of what's covered under the device itself, it seems like that there may need to be clarification here of FDA's role in HIT as it relates to data from the device. Again, not sure that's real clear, but did that help at all?

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

I think I'm getting the gist of it, I'm scribbling down what you're saying and I may have to come back to you to understand it some more, but I think I got it.

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

Okay, thanks.

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

Brad, this is Bakul again, sorry. I want to make sure Lauren's things – question was captured or comment was captured. Lauren, did you get the point on slide two and slide one?

Lauren Fifield – Senior Policy Advisor – Practice Fusion

Do you mean do I kind of understand what you were saying about that reports and corrections aren't required for every change, but that it's a limited set or is it more – like kind of the things I was saying are well captured?

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

Yeah, so by regulations, there are two definitions, one is routine maintenance, and as Brad suggested, we need to define...the regulations currently define routine maintenance and gives examples of all hardware changes, but does not give examples of software changes, so the confusion can be there.

Lauren Fifield – Senior Policy Advisor – Practice Fusion

Um hmm, um hmm.

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

So this slide – the previous slide which Brad is showing, then it needs to be corrected by saying manufacturer shall keep a record of corrections in ten working days only if those corrections were initiated – if the correction or removal was initiated to reduce is needed.

Lauren Fifield – Senior Policy Advisor – Practice Fusion

Yeah, again, I think you might even, as Brad has pointed out, there are kind of many updates that happen and so I think it would be important to pinpoint updates to particular areas of functionality or workflows where patient safety or other risk factors are implicated. Otherwise, most developers keep a record of all the different things they're doing, at really discrete levels, right, so this engineer is coding this and that, but in terms of reporting it or anything like that, just being really specific about the functionality and not making it general to a whole product, I think would be important.

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

Yes, and I agree.

Lauren Fifield – Senior Policy Advisor – Practice Fusion

So, yeah.

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

So I think we're on the same page.

Lauren Fifield – Senior Policy Advisor – Practice Fusion

I think so too.

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

I mean basically the reports are required and I've got the slide up that defines it, the last line or two of the definition at the top it says to reduce risk or health – that's not right – imposed by the device or to remedy a violation. So to reduce a risk to health, I think, imposed by the device or to remedy a violation is when you have to file a report. And then for the more routine maintenance, you just need to keep records.

Lauren Fifield – Senior Policy Advisor – Practice Fusion

Yeah and I guess I should – for the record, I suppose I should also say that I’ve been providing comments in response to each of these, part of me is sort of trying to put on the lens of could this fit health IT, so instead of saying I don’t necessarily think that this pathway or all of it is appropriate for different health IT types and components right now, like just sort of for the purposes of figuring out if what currently exists in the FDA, FCC and ONC regimes could be a fit. I just want to make sure that it’s clear that that kind of – providing feedback, so it’s not to say oh yeah, if you do X, Y and Z I think that we should, this is a – and we should go ahead and do this.

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

No, we’re all on the same page.

Lauren Fifield – Senior Policy Advisor – Practice Fusion

Okay. Great.

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

We’re all building up to the discussion about okay, now that we understand what the FDA requirements are, are they the right ones?

Lauren Fifield – Senior Policy Advisor – Practice Fusion

Great.

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

Is this the way we should do this?

Lauren Fifield – Senior Policy Advisor – Practice Fusion

Okay.

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

So yeah, we’re all headed in the same direction.

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

Brad, this is Matt. A question, just for –

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

Um hmm.

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

– the wording of the reporting seemed to be more that the device itself caused harm.

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

Um hmm.

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

So, a pump giving a wrong dosage of medication and it kills somebody or hurt somebody, that’s different than, I guess it’s possible for somebody to get shocked by the computer that they’re using and be hurt, but it’s more that there’s some sort of decision or something in the middle, often times with health IT. And is the wording of this – the section 806 reporting requirement just for direct harm or is it harm – from –

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

So I think, personally, I think the language is pretty clear around indirect harm and here’s why.

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

Okay.

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

A huge segment of what FDA regulates is in vitro diagnostic testing, laboratory testing, right? And laboratory testing, nobody gets hurt directly, the person who's drawing the blood misses the vein or something, I mean, that can happen but when a laboratory test hiccups, it gives wrong information, it says the person is positive for an infectious disease when they're negative or whatever. And so there's a long history of interpretation of this provision in the context of medical devices that solely provide information that might be inaccurate. So that same sort of built-up knowledge would apply to the health IT, I think, pretty seamlessly.

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

Okay, I just wanted...I didn't understand.

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

Yeah, okay. Good. All right, so let's go on to 807. The first portion of 807, there are a couple of parts to it, but the first portion is on device establishment. So people get this confused, this is not product regulation right here, this is focused on the establishment, which produces the product. And FDA likes to have, well not FDA likes to, Congress mandated that FDA develop a database of device establishments so that the agency would know where to go and inspect to make sure that the law is being obeyed. So they have this general requirement that you register establishments. One of the themes that I mentioned at the outset is this difficulty of the virtual establishments where in health IT more so than anywhere else, you have people located maybe all around the globe, each doing their own thing and then trying to figure out where the establishment is to be registered. Not an insurmountable barrier, but just one that requires sort of clarity so that people are applying it consistently.

The other main theme, and again this is one of the seven I mentioned at the outset, is the lack of clarity regarding when manufacturing stops and the difference between manufacturing and use. So that when you deliver it to a hospital, and they start to tinker with it and configure it and make changes to it, are they manufacturing at that point, or are they just using it, just as you would use a medical device. So those two issues need to be clarified, it seems to us, to properly understand the scope of these requirements. Any other issues that you can think of that need to be explained or clarified or addressed?

Lauren Fifield – Senior Policy Advisor – Practice Fusion

One thing that I think you're – it sort of goes along the line of what you're saying, that's interesting is that there are health systems and also medical offices that have their own homegrown solutions or that have taken something from a vendor and then have decided to kind of make it their own and develop on it. And so I think, not that the rules should be changed, but it is interesting that in the device manufacturer world there probably aren't whole health systems that are using a device that I created in my basement. Whereas there are sort of individual organizations might have a piece of health IT or health IT that is being used by a whole health system or office or something.

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

So actually that issue does come up periodically at FDA, because there are hospitals and other folks who produce things, but they are very thorny issues. One example of it is on the drug side where you have pharmacies potentially engaged in manufacturing drugs, pharmacy compounding, and there's a big controversy around that this year. You have clinical labs that develop their own clinical laboratory tests and you have hospitals that basically repurpose products that they've acquired and used them for medical purposes. So it actually does come up from time to time, but it's always a difficult issue to figure out and resolve, so it's a great topic.

Lauren Fifield – Senior Policy Advisor – Practice Fusion

Okay. Yeah and I think – had reflected in the bigger group that in some cases, some of the great innovations come from that, that I use this thing that's not only used to serve as a stent for this other thing during some complex procedure and _that risk actually_5254 is – the efficacy of the procedure went up. So, yes –

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

Yeah, there's actually the off label-use, which is a supplemental issue, so there's manufacturing done by user and then there's just pure off-label use, which is a different issue.

Lauren Fifield – Senior Policy Advisor – Practice Fusion

Got it. Got it.

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

So let's go on. It's actually tucked into the same part, but it's a major and different requirement and this is what people refer to the 510(k) process, more generally referred to as premarket notification and it's in this same 807 of the regulations. So you've got this idea that for certain devices, Class II principally, you need to go to FDA and prove that your product is "substantially equivalent" to other products already on the market. So here it seems like there are several issues that need to be thought through with regard to standalone health IT. You have the fact that there may not be predicate devices, some of this stuff is really novel stuff and so there's no predicate device, so it's difficult to go through this process, but it's admittedly low risk. And so there's a procedure at FDA called the de novo process that folks can go through for low risk, novel technologies, but just defining what that pathway looks like for health IT, seems like it would be a useful exercise.

Then we've got an issue that Julian and others, Joe and others are obviously very interested in, which is the interoperability open systems, where you go to FDA and say, I don't know what all this will be used for. It's a generic tool that will be part of a system, but the system might have many different components and this is designed to work with those systems. How does FDA make sure that it's substantially equivalent, which is the regulatory requirement, but that it'll be safe and effective in its operation? Then you have the notion of the open-ended or really the evolving intended use, where a product begins with one purpose, but really this dovetails with the off-label use discussion, its actual uses tend to evolve quite a bit as folks experiment with it and come up with new ways to use it.

Not a new issue, every medical device has that potential, but there may be unique elements that can be predicted with health IT. What kind of data do you need to get 510(k) clearance for some of these devices? A lot of people want to know what the pathway looks like, what the data are that are required. And then one of the big questions, and I forget who, maybe it was Lauren, alluded to this earlier on. Software changes a lot, when do you have to do updates? And Kristy Foreman testified a few months ago that the low risk stuff would not be subject to 501(k) requirement. Today, actually, FDA held a major public meeting on this issue more broadly, for all products, but making sure that in the standalone health IT arena, we have sort of good, clear guidance from FDA on which updates trigger the need for a new submission and which ones do not. Those are the ones we came up with, what else – what have we missed?

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

Brad, Anura here. We talked some time ago about indications for use, so just wanted to put that out again in this context, that when we look at potentially these open framework or open interface kind of components, that indications for use be considered along with the intended use.

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

Okay. I'm just making notes, so, very good. Any other things that we've missed? Okay. This one isn't terribly interesting, only to lawyers, but I want to be complete. So, part 808 basically says – lays out rules by which FDA regulation preempts state and local regulation. And so this is there to really minimize product liability over areas that FDA actively regulates. So, if FDA actively decides that a given product is safe and effective, not inherently unsafe or ineffective and that its labeling is appropriate for the product and so forth, that then a jury in a product liability suit at some later point, or a judge, shouldn't come along and say no, it's not adequate. So, this really is meant to have legal impact and to make sure that the federal decisions are respected and create a one uniform body of law so that if we decide – if we figure out – if we comply with FDA, we don't feel at risk then for being second-guessed by a jury in a product liability suit. Didn't seem to be terribly unique issues if health IT is the subject, but did I miss anything? Is there a health IT angle to this?

Lauren Fifield – Senior Policy Advisor – Practice Fusion

Just in case in we considering privacy and security as a point of risk, one of the definite things where there are sort of individual state concerns is around those two areas. And then each state also individually were considering risk beyond just sort of patient harm, but also is around the treatment of health information with regards to minors, sort of the different age limits. And many health IT vendors actually sometimes just don't even provision their products to individuals between the ages of 13 and 17 because the state laws are so different and sort of difficult to navigate.

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

Okay. Good. All right. The next section is the IVD section, we didn't go through it and part 809 is a fairly lengthy collection of sections. But these are the special provisions for laboratory tests. So this is blood tests and urine tests and all sorts of things that you would use testing specimens in a laboratory. And it's applicability to HIT is actually probably more than you think because – well maybe you're way ahead of me, but a lot of software connects to laboratory tests and there is a specific category at FDA, classification for laboratory information systems, LIS, and so it seems addressed currently. But there may be awkwardness when you've got, for example, a piece of software that's an accessory to a medical device. So I'm thinking, for example, in the area of mobile health, if you have an app that sits on a cellphone and it takes control or gets data from your blood glucose meter, the blood glucose meter is an IVD diagnostic device. And so the software is an accessory to it and would be regulated under the same rules. I'm just not really aware of issues where the regs are not – where 809 regs are creating ambiguities or difficulties in that area, but I wanted to see if anybody had any specific areas where its causing an ambiguity, for example, that needs to be resolved. Any? No. Okay.

Medical device recall authority, I propose we not spend much time on this simply because it's so rarely used. The medical device recall authority is a mandatory authority that was given – a power given to FDA decades ago, but the FDA rarely uses it because frankly, there's a lot of due process that the agency has to go through in order to require that a manufacturer conduct a recall. So there's actually a separate section in Part 7, which is a voluntary recall process that applies to all FDA regulated articles, so it applies to food, drugs, veterinary medicines and medical devices. One of the things that I've asked Kim and Scott, remember, the authors of this presentation, if they would go back and just look at Part 7. As well as I also asked them to look at the sections covering the use of IRBs and informed consent and some of those more generic FDA authorities and just see if there are any HIT issues lurking in there. But here, I mean in theory if you tried to apply these regs, there are some ambiguities, what has to be recalled under a mandatory recall authority, is it just the actual code itself or if there were reports generated, do those need to be recalled. Some of the same issues might carry over to the other regs, which is why I raised them here, but I didn't want to spend too much time on this, because this particular section is so rarely used. Any issues worth mentioning here? Okay.

Investigational devices, now this actually came up in our face-to-face meeting, I forget who asked me – oh, it was Farzad asked me if there was a mechanism at FDA to allow, he didn't use the word investigational, but allow the development of data to show that HIT can be safe and effective. And there is, it's part 812, investigational device and it's a very common issue, right, because for any medical device, physical device as well as HIT, if it requires for example premarket submission, a 510(k) or premarket approval, you have to have evidence, so you have to use it, test it, make sure it works. So, generally the way it works is, if it's non-significant risk, and most HIT to my knowledge probably would fall into that category, you're allowed to put it out there under IRB oversight. So you have to have informed consent and you have to have IRB oversight and FDA does not actively oversee the investigational phase, unless it is "significant risk," in which case then you have to go through the process of getting FDAs blessing before you do the investigation. So most HIT, with a few exceptions, would be a non-significant risk.

So the issues here that we identified is number one, the common practice in software of beta testing, which is just wanting to get software out there in the real world. After you've done a certain amount of laboratory – I call it lab, but bench evaluation of the software, in-house evaluation of the software, you want to deploy it into the hands of actual users. And so figuring out the circumstances under which that can be done, if it's to be done under IRB oversight is an issue that you have to figure out. And when it actually – when you're evaluating the software for safety and effectiveness purposes as opposed to for marketing purposes, to figure out whether people like it, whether people will use it, gathering market data as opposed to safety and effectiveness data. So it seems to me that there are some issues there where there's ambiguities and we could use guidance.

For that software where you're going to seek approval, how do you design a study to study the safety and effectiveness of standalone software? It's not a completely novel issue, FDAs already addressed it, but there isn't a lot of public guidance, anyway, on that topic. So those were the two we focused in on, what other issues do people have with the investigational phase? Okay.

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

This is Jodi Daniel. I guess the one question is whether or not, if somebody's trying to – if there might be a way of leveraging that if there is only a small group of folks that a device might be used for, where you have a medical app whose software that its only targeting a very small group of individuals so it may have low risk because the chance of anything happening when you're only using it on a small population may be lower. Is there may be a way of considering how to kind of use that same kind of concept of investigational use, but for small populations?

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

So there is, FDA calls them feasibility studies, and it's the same logic that applies to any device. Basically, if you want to evaluate a new pacemaker or new hip, you start small and start with a very small population and evaluate it. So, that model does exist, I'd have to look at it and see if there are any questions regarding whether HIT – any questions about how you'd implement it, but the concept is very definitely there.

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

Thanks.

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

Um hmm. So let's go on. This is – we don't need to spend much time here because very little HIT is subject to premarket approval. Premarket approval is the most rigorous FDA approval mechanism. The premarket notification is for middle risk products, this is for Class III high-risk products. An example that comes to mind is CAD software, which is a little different probably from what engineers understand that term, but this is for assistive diagnosis. So for example, software used to evaluate medical images, x-rays and MRIs and so forth, where the software actually goes in and looks for tumors in order to flag them for the radiologist who's reviewing the images. Some of those are Class III. Doesn't seem like this would be a big deal for most HIT, because the vast majority of HIT would not be subject to this requirement, it's only a few very high-risk products that are subject to it. But, any issues that you can identify here? I mean the CAD, which is standalone software, has been regulated under this section for more than a decade, so it's not new to FDA. But any issues that people are familiar with? Okay.

So this issue, this is a big topic and here's how I propose to handle it. Quality system regulations are a whole series of sub-parts, it's a fairly long section that identified each of the elements of the quality system. And this particular version of the regulation dates back to the mid-1990s, when FDA made sort of a conceptual change and went for this quality system, moved away from the GMP language and moved to this quality system concept, which by that time was fairly mature in a lot of different industries around the world. And the concept is, if you control the process of manufacturing, you can increase the reliability and therefore the safety and effectiveness of the products that you've produced. You'll get standardized widgets out the other end that all meet the quality standards that you've set for yourselves.

Now when they wrote this, clearly they had in mind widgets, for the most part, they had in mind physical product and quality systems that were built around the physical product. HIT is different in a lot of reasons or for a lot ways that we've already said. And to that end, there's been an expert group working under the oversight of AAMI, the standards organization, to figure out really how these quality system rules ought to apply to HIT. And that group, and there's a link provided on the slide, just finished its work, I don't remember when, but sometime in the last I think six or eight months. And FDA was on the group, a lot of industry people were on the group and so a lot of people a lot smarter than I am went through and parsed these requirements to figure out what applied.

So I'm going to propose to this group that we kind of look to that group, at least as a launching off point, for how we would approach this. And so if you're interested you would need to read the report, actually the report costs money, we need to figure out a way for you to see it, because it's an AAMI publication. But basically what they do is they say look, out of all these sub-parts, these five that I have listed on this slide, management controls, design controls, purchase controls, corrective and preventative action and records are the most important and have a big impact on whether software is manufactured reliably.

Now the other one, I have to go back and ask Kim and Scott, the origin of this second list, because I didn't think that the report spelled out the list of things that are correspondingly less important, but I'll have to ask them the origin of it. But basically, as I look at this list, and I'll tell you what these are because I recognize we only wrote the numbers and no one knows that those mean. This is limited, in most case limited usefulness, not no application. In a few cases, it may be no application, but in most cases, it could be met, but it could be met very easily and in this working group – not this working group, but the AAMI working group's view, had limited importance.

So just to tell you the ones that were identified there. So you have traceability of a product, well actually, when you're stamping CDs and so forth, traceability may not be a significant, not completely unimportant, but not as important. A lot of production and process controls are included in this list, so you have things like inspection and measurement and test equipment and process validation, process validation being a very complex art for making sure that the production process and other processes themselves are reliably designed and validated and executed. Then you have a lot of acceptance activities, right, so you have in the world of physical product, you have a lot of inspection and so forth that takes place. So you have receiving and in process and finished product acceptance and inspection and you have rules around acceptance status.

Then 820.90 is non-conforming products, so you see a product moving along the production line, it has a defect or has some other aspect in which it's not meeting the production controls, you take it off the line and you quarantine it as non-conforming product. You have packaging, which has to protect the integrity of the product and may be less important, especially if you're in a download model rather than stamping CDs. Then you have things like storage, well, storage can impact a lot of sensitive medical devices, it's not so much a big deal with software, although there probably is some electronic storage type issues. So it's not as if these things are completely unimportant or completely lacking, they're just not central to how software ought to be regulated.

So I guess my proposal is, for today that I simply report to you the work of this committee, and in the interest of time, I suggest if you are interested in this topic, go read this report. Maybe we can figure out a way to get it for you, it's a hundred bucks for a non-member. Maybe some of you already have it, but that we kind of base our thinking on very extensive thought that was given by this – I can say this objectively, I had nothing to do with the AAMI group, but a very sophisticated group of people working on this. What do you people think from a process standpoint or are you willing to approach it that way or do you want this committee to sort of roll up its sleeves and start from a clean piece of paper and come up with our own? I'm not hearing.

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

Brad, Anura. I guess in the interest of time, I would advocate for using work that's already been done.

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

Anyone uncomfortable with – at least using that as a starting point. And I'm encouraging you all to read the report, study the issue and if there are things with which you disagree tell us and we can treat it by exception as opposed to trying to create the model ourselves.

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

Yeah Brad, this is Joe. I would go with the minimal path here, building on what's been done.

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

Anyone to the contrary? Okay. So I would urge you, look at the report, see if there's anything there that you're uncomfortable, see if you agree with it and we'll – if we're all comfortable with it, we'll sort of incorporate it by reference. So, I'm going to – these are all the different parts of the quality system, I'm going to go past all those. I go through the five and this is all taking it from that report, so I'm not going to go through each of these. You can study this reporting of it and you can study their report and see if you agree.

So, I'm going to go to medical device tracking. We didn't spend much time on this, this is one of those pretty idiosyncratic FDA requirements for certain classes of very high-risk devices, things like spinal implants and so forth. FDA requires that you put an actual tracking number on the physical product, so that you know which patient it went into and then that way, if later there's a problem with that particular product, not just the lot, but the individual product for example, you can figure out exactly who has it and go and get it or fix it or do whatever needs to be done. With software, it's just highly unlikely that this would ever apply to software. It could work, if there were, I would think – at least, I don't know if – there would be complexities, but I just don't even see the reason to go there, because I don't see this being used with HIT, it doesn't meet the threshold requirement.

Postmarket surveillance is an idea that actually industry advanced years ago, when approvals at FDA were really slowing down. FDA said, how about this, how about if we prove that products are safe and effective based on reasonable amount of evidence and then, as an extra sort of belt and suspenders, we proactively survey and gather data from the marketplace to make sure that it's not causing harm after its been released. And the theory was, FDA could approve product more rapidly if they had that safety net afterward to conduct that surveillance. It is only for high-risk products that would justify this kind of expensive, postmarket surveillance.

So our first observation was, not sure we need to talk about this because it would be very rare, we couldn't think of hardly any circumstances where this would be used for HIT. Julian also said, quite apart from it being applied as a regulatory requirement, HIT is actually part of a solution for surveillance on other products, which is an interesting point. And I noted it here and we ought to capture it, but it's not a regulatory requirement for HIT. So it's a little bit out of scope, but it was important enough I wanted to make sure I captured it here. Any reason to talk about this?

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

This Jodi Daniel – go ahead –

M

Go ahead Jodi.

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

This is Jodi Daniel. My question, so you mentioned about postmarket surveillance being very expensive, my question is, how does the cost of postmarket surveillance compare with the cost of premarket approval and is it possible that some form of postmarket surveillance could be done in lieu of – so that you could say, well, this is low enough. An the opposite, where there's not as much risk, where you say, ah, this isn't that risky, we're going to just like not have any oversight up front, but we're going to keep track and if there seems to be risks that crop up later, we'll start paying attention. So is there a way to actually use the concept of postmarket surveillance and not necessarily as it's been implemented through these slides, but as an – for dealing with lower risk products and keeping track of them over time that we know risks may occur?

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

So, I mean you're thinking the same way that industry has thought about this issue, can it be used to moderate the FDA requirements. And so my initial response is yes, it could be used, that is in fact how it can be used. The reason it hasn't been used very much is the expense. In the drug world and so forth, they refer to these basically as Phase IV clinical trials, post-approval clinical trials and the way it's been implemented in the therapeutic side, whether it's a pacemaker or whatever the high-risk product is, it can be pretty expensive to do. But for HIT, given HITs core strength of collecting information, right –

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

Right, right.

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

– I could imagine it being a whole lot less expensive to develop a reasonable postmarket surveillance approach. So number one, I would say yes, we ought to keep thinking along those lines. The statute is written with the high-risk stuff in mind, so this would take a statutory change, we said we were going to flag if it regarded statutory change. What you're talking about would require statutory change because it was written to address the high-risk products, but it could be re-written by Congress and it could be made useful for these purposes, I do agree with you. I'd have to think more, as everyone else I'm sure would.

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

Okay, thank you.

Lauren Fifield – Senior Policy Advisor – Practice Fusion

Hey Brad, oh, I'm sorry, go ahead.

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

This is Bakul. I was going to say, yeah, so the agency has been thinking, similar to what the industry has been thinking and through – discussions and everything else that's going on, is looking at options of using postmarket surveillance or postmarket studies as a lever for premarket as well. So, where science is not there and not only just for health IT, but for other areas as well, where access is more important and benefits are more important than the risk it may pose or there's less understanding.

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

Yup. So guys, time check. We are five minutes before the end, we are obliged to have and look forward to public comment. Let me whiz through a couple of things and then if we can – you can give me your comments later, you can email them to me, whatever, I'll just note what they are and then we can get to the public session, if that's okay. Everyone all right with that? Okay. So medical device classification, so the way this system works on the medical device side is, you figure out what the regulatory requirements are for your product by first figuring out into which Class, I, II or III you're placed and FDA affirmatively facilitates that by classifying broad categories of technology. So that's what they would do in this instance is they would come up with classifications. Actually, these are in order but they don't make logical sense.

One of the other things that FDA can do is create performance standards for products. Now people might get excited about this, don't get excited about this, this is not standards developed by voluntary associations or voluntary groups, that's a separate process. This is a rarely used procedure by FDA to create standards that have binding regulatory impact, and they rarely use it because it requires a ton of agency resources to go through all the notice and comment and process and so forth required to do it. So what the agency does instead is it recognizes standards developed by appropriate non-profit bodies and uses those in the context of approval and elsewhere. So, this particular section, don't get excited about it, but the idea of standards and the use of standards is something that FDA is very familiar with.

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

So can I just make a comment here Brad.

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

Sure.

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

One other reason why the agency shies away from creating its own standards is we feel that the community and the industry actually can come up with better standards than the agency by itself.

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

I think that's a very good point and so for the 99.9% of times, it's better for the community to develop the standards. The only time FDA would do it is if they're being regulatory, if they're pushing industry someplace where industry doesn't want to go. So specific product classifications, this relates to two slides ago. The issue here as we see it is the need for FDA to actually develop classifications appropriate for HIT, so the agency did it for MDDS, took a few years, but a couple of years ago they published it. A number of people would like FDA to do more of that, in order to make sure that stuff doesn't get overregulated, because that's the risk, until there's a product classification maybe to put something in Class I, the risk is that FDA will treat it in Class III and it's burdensome and all that. So getting classifications for HIT products is something that industry in the past has advocated.

Ban devices, FDA almost never does it because it requires a huge amount of resources, so I wouldn't recommend we spend time on it. Here is a performance standard, electrode lead wires, obviously it doesn't apply, but it's in the regs, that's why we included it. So big picture this is, we're not going to tackle this today, we're going to tackle this big picture in about 2-1/2 weeks and we're going to talk about this in the aggregate, when we look at FDA, ONC and FCC all together. So, I know I breezed through a couple of things there at the end, if you have any comments you want to submit on any of those, please email them to me and I'll be glad to incorporate them into the next draft. But I thought as it's almost 5 o'clock, we ought to make sure that we give the public opportunity to participate. So can I turn it over to somebody else.

Public Comment

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

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

Rebecca Armendariz – Altarum Institute

If you would like to make a public comment and you are listening via your computer speakers, please dial 1-877-705-2976 and press *1. Or if you are listening via your telephone, you may press *1 at this time to be entered into the queue. We have no comment at this time.

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

Okay. So to anyone in the public and to anyone in the working group, as I said, this is an organic document, I've been taking notes here, I'm going to try and capture some of that as best I can in another draft. If other people, if you think of something after today or you're not sure you said what you wanted to say, just send it to me, I'm going to keep this in this document and then we'll figure out, come July, whether the document has some use to the group. But I'm trying to capture all of these comments to preserve them in the meantime. So what we're going to do is we're going to have a couple more calls in June, I don't think those are scheduled yet, but the first one's going to be ONC and, I think this is the order, first one ONC and then the second on FCC. And then we'll look at the big picture, as I said, the first week of July. That's all I have, anybody else have anything before we adjourn? If not, thanks everybody.

Lauren Fifield – Senior Policy Advisor – Practice Fusion

Thank you so much for putting this together.

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

Oh, my pleasure and thanks all for the great comments, I thought it was really helpful. I know we went fast, but I really appreciated all of the remarks folks offered. Take care everyone.

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

Thank you everybody.

Public Comment Received During the Meeting

1. AAMI SW 87 is the application of quality systems to Medical Device Data Systems not all of Health IT
2. AAMI is current working on a document for the application of Quality Management Principles to Health Software