

**HIT Policy Committee
FDASIA Workgroup
Regulations Subgroup
Transcript
June 26, 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. And for the transcript being made for the call, please make sure you identify yourself when speaking. I'll go through the roll call of the subgroup members first. 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. Julian Goldman? David Bates? Todd Cooper?

Todd Cooper – President – Breakthrough Solutions Foundry, Inc.

Hello.

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

Thanks, Todd. Anura Fernando?

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

Here.

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

Thanks, Anura. Lauren Fifield?

Lauren Fifield – Senior Policy Advisor – Practice Fusion

Here.

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

Thanks, Lauren. 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 or Steve Posnack? I believe we have Kate Black for ONC.

Kate Black, JD – Office of the National Coordinator

I'm here.

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

Great. Bakul Patel? Simon Choi for Bakul?

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

Here.

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

Thanks, Simon. And Matt Quinn?

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

Here.

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

Thanks, Matt. And for the FDASIA workgroup members, Rich Eaton?

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

Here.

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

Thanks, Rich. 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. Meg Marshall?

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

Here.

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

Thanks, Meg. And Mike Flis?

Mike Flis – Roche Diagnostics

Here.

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

Are there any other workgroup members on the call? Okay. With that, I will turn the agenda right over to Lauren Fifield.

Lauren Fifield – Senior Policy Advisor – Practice Fusion

Okay. Thanks, MacKenzie, and for those of you who can join us. My apologies to everyone for getting content out at the last minute; our timelines here have been a bit crunched, and this was a bit of an undertaking, but hopefully will be well worth it. So there is a tremendous amount of content. Some of it we'll sort of blow through, with the goal being that, you know, we can talk about it, leave room for discussion, and then certainly if folks want to go back and reference the content that's here, it will of course be available to do so.

So in terms of what I was hoping we could do today, since we did a review of the existing regulatory regimes of our agency counterparts on the FDASIA workgroup, the FDA, ONC, and FCC, I thought it would be really helpful to take a look at both regulatory as well as non-regulatory approaches to addressing risk of harm, and to addressing the need for assurances of quality, trust, integrity. I think those are sort of what we are trying to get at as we're thinking through kind of the world of health IT and addressing patient safety, promoting innovation, and making sure that end users and patients are using technology that will do what they say it should and is quality, again, to promote innovation as well as to maintain patient safety.

So this deck, again, is pretty meaty, but the goal is to go through first sort of government approaches, and then second, to some private sector approaches, and then again, leave time for discussion. I encourage folks to kind of pipe in, ask questions as we go, but then also take notes for the end. MacKenzie, can I have control of the deck?

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

Caitlin, can you go ahead and upgrade her?

Caitlin Collins – Project Coordinator – Altarum Institute

I will.

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

Thanks.

Lauren Fifield – Senior Policy Advisor – Practice Fusion

Thanks, guys, okay, lovely. So here we go. So my goals for today, in addition to what I've articulated, are really to broaden all of our horizons. So I don't really want us to get too entrenched in the kind of regulatory pathways that already exist. It's not to say that those aren't appropriate for health IT or couldn't be used, but it's more to say, you know, let's not feel like we have to back into anything, or sort of jam square pegs into round holes, what have you, but sort of just really think broadly.

I think that particularly after going through all of these approaches, I think there's a lot to learn from other industries and other approaches, both good and bad. And then again, sort of I think by way of removing ourselves from health IT, right, because we get – we know it well. Everyone's an expert in their own way. I think we start to get into entrenched thinking, and it's hard to think about how we might consider risk of harm or market – without, again, kind of going back to the ways of thinking that we're so well-trained in.

So those are the goals. And I think one of the things that came out in the research for this particular deck is that there's a pretty simple equation, and I think – and I'm not necessarily laying out because I don't think that you folks are capable of thinking beyond the simple, but I like how simple it is because I think there's an important lesson for us to draw. So where there are consumers, there is potential risk of harm and/or need for assurances. And this is, you know, the case in any industry.

And as the – you know, in most of the – at least the industries we'll talk about today, and in most, risk factors and/or the needs for assurances emerge. And if a sector fails to address those emerging risks, risk of harm or the need for assurances, then the government can come in and provide those via regulation. Again, it's not surprise, but I think it's important as we consider health IT, and whether or not risks exist, whether or not we can identify them, whether or not we understand them. I think also trying to understand the difference between risk of harm and the need for certain assurances.

So again, it's really simple, but I think when I think about health IT, when I think about this sort of framework, it really helps me take a step back and say, you know, maybe there are specific areas where we could apply this pathway, but not necessarily all.

And again, just on kind of what we'll explore today, and I point this out, too, because Joe Smith will be conducting a presentation in early July about what might be, today will be coverage of approaches that already exist. They coexist now with FDA, ONC, and FCC regulations. You know, we're looking for areas of redundancy, potential ambiguity, and then also identifying best practices and successful regulatory and non-regulatory tools, as well as some failures.

And these are just questions for you to consider. Certainly, you can consider a vast array of questions, and I'll sort of have these at the end as we get into discussion to kind of help frame that. But, you know, I won't read these, but, you know, definitely think about these as you go, and please take notes, and as always, if you need to stop me for questions, or if you have thoughts, additional feedback, or comments, please do so.

So without further ado, because, again, this is a lot of content, we're going to dig into our survey of approaches, and we'll start with those approaches – and again, this is to address risk of harm or to address, you know, a need for assurances of quality, integrity, trust. And we'll start with approaches from the government.

So I think, you know, this is not an exhaustive deck of approaches, but I am starting first with a very general approach. It's actually less an approach. It's actually an agency. So the Federal Trade Commission is an agency obviously that coexists with our three partners on the FDASIA workgroup, and I think for the point of pointing out that the FTC exists, and that they work to prevent fraudulent, deceptive, and unfair business practices in the marketplace, is to say that in our discussions, I definitely identified areas where there may be, you know, different types of health IT, or different assurances, or different protections that could maybe not entirely, but maybe in part be addressed by some of the work done by the FTC.

And if not the FTC, it's also to say that there is other common law that exists outside of the three regimes that we've spoken about that may be able to provide appropriate assurances or address some of the risks of harm that we have spoken about.

So I definitely encourage you also to just check out the FTC's consumer website, simply just to see sort of, again, another regulatory regime that exists, and for ideas as to maybe what they could or could not address in kind of I think conjunction or harmony with our partners. And they do address some areas of health and fitness, and so they have guidance around consumer protections for healthy living products, treatments and cures, weight loss and fitness.

Again, they really do focus on more labeling, so sort of whether or not something is deceptive or fraudulent, but certainly, we've discussed labeling quite a bit, and we may be able to draw best practices from them as our partners are implementing regulation, and they may also play a role in some of the areas of health IT where our partners may not. So again, I encourage that.

And as I said, they're sort of in healthcare playing a role in some product areas. And then we've also mentioned as a risk of harm to patients the areas of privacy and security, and they do have oversight over privacy and identity issues to protect consumers. And so it might be worthwhile to take a look at what protections they have in place, what they ask different businesses to do when it comes to issuing privacy policies, and both ensuring that they're following those practices, as well as techniques they have for enforcement.

So again, this is sort of in this broad one, and again, is meant to sort of cite that there are broad regimes that exist that could work in harmony, or that we could borrow from in terms of best practices.

A really interesting – and I think this has been raised in some of our discussion – an interesting area of regulation is by the FDA in the realm of cosmetics. And the way that I've split up the rest of the slides outside of the kind of overview of the FTC is by looking at precipitating factors for a particular regulatory or non-regulatory approach, and then digging a little bit into what the approach is, and then taking a look at some of the benefits as well as some of the downsides of that particular approach.

So when it comes to cosmetics, precipitating factors, you know, in the early 1900s, there are risks of harm and a lack of a trust due to poorly made or misrepresented cosmetics, probably no surprise to anyone here. And there were tragedies involving unsafe cosmetic process – products. So in 1938, the FDA passed the Federal Food, Drug, and Cosmetic Act; and, again, to mitigate harm and foster trust in cosmetic products.

And what's really interesting about the regulation of cosmetics is that there is general prohibition of marketing adulterated or misbranded cosmetics, so again, to protect the consumer, and the FDA can pursue enforcement through the Department of Justice to remove products that violate this. And cosmetic firms have to substantiate the safety of their products and ingredients before marketing.

However, there aren't any – in the cosmetic realm, there aren't pre-market approvals in place. The FDA relies heavily on surveillance and on the accountability and ownership of the individual cosmetic companies, manufacturers. And, you know, collecting data, collecting – relying on consumers, and, again, the manufacturers themselves. The only sort of unique products are dyes that are made for hair – for example, hair coloring, and those do require pre-market approval. But again, this model relies very heavily on post-market surveillance and relying on industry.

A lot of accountability and responsibility to industry with this particular intervention and certainly as a downside, some unsafe and wrongly advertised products have made it to the market. But this has also – this sort of accountability and reliance on industry prompted the cosmetic industry to create their own voluntary form of industry assurance, so the Cosmetic, Toiletry, and Fragrance Association. And as an example, Estee Lauder has on their website a commitment to product safety, testing, and consumer awareness.

What I think is really interesting, too, about the regulation of cosmetics and the industry response is that the industry has used safety as a competitive advantage. In fact, they've also started to, as you're well – probably well aware, use testing of products as a competitive advantage, and have gotten sophisticated enough and refined to sort of compete on whether they test with animals, and how rigorous their testing is. So I think, again, I'll remind everyone, this is not to say that we should adopt any one approach, but, you know, definitely some interesting lessons from each of these.

And a next approach that I found to be really interesting was with the Department of Transportation, the Pipeline and Hazardous Materials Safety Administration. So precipitating factors here – that there is a significant risk of harm when it came to construction of pipeline facilities and construction of pipelines. So the design, construction, testing, operation, all of those different operations were causing potential danger. And folks needed assurance that the pipelines were, you know, being regulated and held up to standards for both environmental safety as well as public safety.

And so this PHMSA or PHMSA, I'll leave it to the DOT experts, created some responsibilities for industry. So it relies – this sort of safety administration relies on incident reporting, data aggregation and analysis. They – the responsibilities also include that manufacturers or the pipeline manufacturers have to respond to NTSB recommendations. They have to establish safety goals. And the organizations have to invest in research and development to increase safety reliability. And there are reports made about achievement of goals or progress towards those goals, as well as to incidents, so a high level of transparency.

And the sort of strategy of reporting incidents and analyzing data and then enforcing safety issues is definitely working. A great example of that is around careless digging. So careless digging was causing a number of accidents and sort of poor creation of pipelines, and so the Common Ground Alliance was formed by the industry as a result of that data being reflected to industry around incidents.

And the sort of downside, of course, is that there's a high investment associated with kind of creating any reporting body and operating that reporting body so that it can provide recommendations and that it can hold industry accountable. So it certainly seems to have had a positive impact on that – on pipeline manufacturing, but again, you know, comes at a cost. But the use of data we definitely found to be really interesting, and also a great way to identify high priority areas where industry could actually take more action and accountability.

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

Lauren, this is Elisabeth. In that area, it's also my understanding that there's quite a bit of international standards that are now being aligned so that – things like that, you know, that's one of the discussions I know we've had a number of times about international standards in other areas, is that this is one of those areas that they're relying heavily on that, so that there is consensus and agreement, so that it's clear and transparent as to what the expectation is, so that there's a balance of understanding what's expected, and everybody holds each other accountable.

Lauren Fifield – Senior Policy Advisor – Practice Fusion

Yes, absolutely, and I'm glad you mentioned international standards as well. I believe, and I don't want to promise for him, but Mike Flis will be presenting on international standards in a subsequent meeting, or at least that content will be reflected in a subsequent meeting. But definitely also – to your other point, the Common Ground Alliance was a great example of sort of industry really taking pride, and, oh, we're seeing incidents around unsafe digging practices, and we are going to promote awareness about that, and make it a point of pride that those incidents are reduced, and that – and that education through our workforce and to the public is made around that.

So another Department of Transportation example, and this is slightly comical for those of us who have recently heard about another PRISM, but the Performance and Registration Information Systems Management was the first PRISM. And this is an initiative, again, through the Department of Transportation. Precipitating factors here was that there was an increase of carrier – commercial carriers on the interstates, and there was also an increase, with that increase of commercial carriers, in crashes. And so through deductive reasoning, they figured we should probably try to reduce these crashes and address commercial carriers.

And there were also in the industry a lack of assurances that the motor carriers were maintaining good safety practices. So as a result, PRISM was created to reduce the number of these crashes. So PRISM entails a process for targeting the highest risk carriers and a compliance review and roadside inspections for them. So there we have sort of this focus and process. It requires that motor carriers improve their identified safety deficiencies. So there are pretty significant both local, state, and federal sanctions, and that require that once an issue has been identified, that those are addressed.

And then there is enforcement ability. So, you know, if a carrier has been sanctioned and is operating out of service, when it's out of service, there's enforcement; and then those high risk carriers who fail to prevent future accidents, you know, can also suffer enforcement.

And the sort of success here, I think, is that it's really an evolving learning process. So we often talk about the kind of continuous learning system in healthcare, and for this particular – for this particular kind of enforcement and law, you know, there have been quite a few successes here. And I think the best sort of demonstration is that because they're able to identify the high risk carriers, and because they've been collecting data, they've actually seen a discernible reduction in crashes, fatalities, and industries across the board.

So per the Motor Carrier Safety Progress Report, the number of warning letters issued to carriers has been reduced by 75% between 2010 and 2012, and the total reviews performed have nearly halved at the federal and state level. So it's interesting, is that the effort by the DOT to sort of enforce the PRISM rules has decreased substantially, and the number of crashes has – fatalities and injuries has also reduced. So while they're gaining in safety, and they're also, because it's learning, evolving system, they're also reducing effort.

So I thought that was pretty remarkable. And I also thought that what I really liked about PRISM was that it had started as a pilot program at the state level, and those sanction efforts and those efforts in kind of safety efforts were proven, so while that it was – that it was implemented at the federal level. So I thought that was a really – a really interesting one, particularly for those of us who really believe in this learning health system.

In the notes field of the deck, and hopefully that will be available to you, and if not, I can send it out, the stats that I'm citing are available on the – their website, and are really, really interesting to look at.

Another Department of Transportation area of regulation is around motorcycle helmet regulations, and this is a little bit – probably a little bit obvious. But of course, there's a high risk of harm for individuals who aren't wearing properly constructed helmets when on motorcycles. And there were – there were definitely concerns from consumers around the quality of helmets, and enough so that consumers wondered if they would even have a positive impact upon impact.

So the regulations, you know, kind of were focused around both the manufacturing of the helmets, as well as labeling. And I think here, this is, again, a pretty simple one, but because of those assurances, because consumers could easily identify helmets that were high integrity and, you know, there was quality products on the market, and a greater degree of trust, and then the upside, of course, is that motorcycle helmets are 30% effective in preventing motorcycle deaths, and 67% in preventing brain injuries, whereas without them, the results of a crash are almost twice as high without them. So a simple one, but definitely I think shows also the power of labeling when it comes to consumers' need for assurances.

A really interesting one and it's not to say that I think we should go for mass deregulation, but is in the case of the deregulation of the trucking industry. So the Interstate Commerce Commission implemented a while ago, so in the Motor Carrier Act of 1935, regulations that required truckers to seek a certificate of public convenience and necessity from the Interstate Commerce Commission, the ICC. As a result, it became extremely hard for truckers to get certificates. There were a number of tariffs that were imposed, and other sort of complications and difficulties around getting such a license.

And as a result, competition was reduced. Trucking was inefficient. And so in 19 – in the 1970s, and then finally in 1995, there began a phase of deregulation, and then again in 1995, that regulation was abolished by the ICC. So the Surface Transportation Body was created in 1996 within the Department of Transportation, and that kind of stood up different, you know, economic regulatory matters.

But what it did is it took away a lot of the sort of regulations that made the trucking – being in the trucking industry and operating on the interstates so difficult. So the deregulation dropped kind of the rates, those tariffs, as well as improved quality, and it's – the sort of deregulation effect has also made it easier for non-union workers to get jobs in the industry. And LTL carriers – been engaged in predatory pricing since deregulation, so one of the effects of having those high tariffs and a long process to be licensed was that there was predatory pricing in the industry.

There are more firms on different routes. There's service to small and remote communities. And there's more efficiency, and of course, it's beneficial to consumers. So it might be really interesting to sort of use this particular example as a – as just sort of a – maybe looking at, you know, digging into some of the factors that they considered in more detail, so that we don't necessarily over-regulate ourselves, and that – you know, I think that there are definitely parallels of us wanting to make sure that entrepreneurs and technologists continue to develop in the space of health IT, and there isn't predatory pricing, or that, you know, access to health IT isn't cut off to small and remote communities.

So definitely, even though it's trucking, as I read kind of some of the reasons and eventually the outcomes of deregulation, it oddly enough really resonated with I think some of the dialogues we've been having.

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

Lauren, this is Brad.

Lauren Fifield – Senior Policy Advisor – Practice Fusion

Yeah.

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

Along those lines, can you – can you help me draw the – connect the dots? I'm struggling a little bit to connect the dots of how health IT functions, how health IT is being developed, the kind of entrepreneurial activities in health IT, and each of these examples, the trucking one, for example, that you just went over. Could you – could you connect those dots a little bit for me, please?

Lauren Fifield – Senior Policy Advisor – Practice Fusion

Yeah, sure, so I think in the example of the trucking one, in that particular case, just as you might expect with health IT, and if, for instance, regulation or any approach resulted in really long times to get licensed to, you know, use the interstates, and if that kind of – in this particular example, that certificate of public convenience and necessity became expensive to get, then what kind of happens, and what happened in this particular industry, is that kind of a smaller trucking shop and those – and kind of – the smaller trucking shops stopped entering this market, and then because of the cost and the headaches, most folks who actually did get their certificate weren't necessarily inclined to go to routes of small communities that were underserved, because it was so difficult and challenging to get that certificate. They really wanted to serve areas where they could make that profit, and that having the certificate to pursue that route would be beneficial.

So I think the lesson there in this particular case is really just making sure that anything we suggest and that is done in the future doesn't lead to kind of a similar environment, where cost or time or sort of the regulatory process shut out smaller companies or companies that, you know – a risk here, of course – I think we talk about kind of risk to innovation, but it's also risk to serving communities that, you know, might rely on kind of the little guy or the less expensive guy, or, you know, what have you. So that would be the parallel there.

And I think with the others, again, it's as we think about regulating health IT or suggesting any sort of approach, private or public, it's I think with a lot of the Department of Transportation examples, the use of data and analysis to really finely focus both the regulatory approaches and the industry on specific areas of risk was both effective in terms of promoting better safety, fewer incidents, but also a – having less cost.

In the cosmetics case, I think again we saw post-market surveillance, you know, so kind of mining that data, but also I think we saw that the industry was competing on safety. And so there are ways to sort of have patient safety be a priority in health IT, so much so that it's actually something that doctors and users look for when they're purchasing a product, and that health IT developers are thinking about and take so much pride in, as well as accountability and responsibility for, that it's something that they, you know, actually even want to market as they are looking for users of their health IT.

So again, I – you know, there's never going to be likely a one to one parallel between motorcycle helmets and health IT, but it's sort of just the kind of I think broad parallels, and it comes to creating a regulatory approach, you know, within any industry. So – and I have some takeaways at the end, too, that I can go through.

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

Lauren, this is Matt. One – you know one – there's a whole array of things that are involved if you look at transportation as a system, or just highway transportation. And every time I have a chance to promote a book called *The Big Roads*, it's about the history of the US interstate system, and it is like the greatest book I've read last year, by Earl Swift.

And one of the things in it that just blew me away was that back in 1919, we made a fundamental decision about the structure of our highway system. Was it going to be a federally run system of highways, or was it going to be a network of highways that were connected, but a huge state role in it? Anyway, an organization called American Association of State Highway Officials was formed back in 1919, and this was really the foundation of development of safe road standards. They built something called the Test Road, signals, signs, number, etcetera, where the – and as well as how to allocate money across stakeholders. They're really influential in, you know, this whole array of issues with regard to both the structure and the type of the highway system.

The other I would say is that in – you know, although there are rules around, you know, who can be a carrier, also think about the array of things in place so you can't just jump in an 18 wheeler and drive it. You have to have a license, and that's done – you know, the standards are probably pretty similar federally, but each state has a program to ensure that. And there are safe operation rules. So every trucker has to keep a log book, and there are rules, some of them state, some of them federal, around, you know, how many hours you can drive, and etcetera.

And then there's the whole infrastructure around periodic and regular inspection of vehicles. So whenever you see one of these – you know, the weigh station, that's there to make sure that trucks are safe, even though they've passed initial inspections and their – and their company is allowed to be on the market.

So I think it might be helpful, you know, if we're using transportation as a metaphor, to think about how all of these fit into the broader system, because that's one of the things that we're trying to get at, and – as well as to think about the data collection or learning mechanisms that are in place. And I know that nobody has anything to do over the July 4th, so get Earl Swift's book *The Big Roads* and check it out. Sorry.

Lauren Fifield – Senior Policy Advisor – Practice Fusion

No, that's fantastic.

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

That's helpful. Lauren, as you – as you manage your time in the remaining part of the presentation, I thought a moment ago, or a few moments ago, now, you indicated that Mike Flis was going to make his report on some existing organizations, Continua, and the use of standards in a subsequent call. But we don't have that – we don't have that scheduled, and the schedule is very tight. I mean, that really needs to happen in this call. So if I could ask that we just make sure that we leave enough time at the end for Mike to describe those existing organizations, I think that's an important element to round out. And its part and parcel with the second half of this presentation, of what – of what private can do as compared to – as compared to government.

Lauren Fifield – Senior Policy Advisor – Practice Fusion

Yeah. We can certainly make time. I think he has just emailed me saying that he thought it would fit into something else, but maybe it was just a miscommunication, so I can certainly leave time for him to, you know, sort of describe the different things that, you know, he was going to bring to the table, definitely.

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

Yeah. That's super. Thank you.

Lauren Fifield – Senior Policy Advisor – Practice Fusion

Yeah. Sure. Sure. And again, I think Matt's point is important, too, in that this is sort of, again, a very broad survey. You know books have been written about each of the creations of not just these kinds of individual kinds of highly focused areas of regulation or approaches; but that they operate within a pretty significant infrastructure. And so I think, too, if there are areas where we should dig in more, you know, makes notes of that, and we certainly can – you know, so again, not meant to be completely exhaustive. We would be here for weeks.

But, you know, if there are places where we really should, I think it's interesting, you know, just even kind of hearing reflected back about licensure, we have licensure for physicians, but, you know, and they have to go through training, but at present, none of that is to actually use technology, and certainly not for patients, either. And so it's – I have just found it interesting that there are so many parallels between other industries, but that, of course, there are key differences.

And so – but thinking about that, you know, using physicians and end users as sort of a path forward to greater safety, is another, you know, potential recommendation. So yeah, please chime in. I think it's great. And Matt, if you could email the name of the book, I would actually love to read it over 4th of July.

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

I'm going to do even better. Amazon has a free online version of it here.

Lauren Fifield – Senior Policy Advisor – Practice Fusion

Oh, it's that good?

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

Oh, yes.

Lauren Fifield – Senior Policy Advisor – Practice Fusion

Okay, excellent, so to make sure that we can have Mike – give him some time at the end here, I'm going to keep charging on. So when it comes to the Environmental Protection Agency, so the EPA, specifically in the case of drinking water, there were a lack of standards in place for safe drinking water, and of course, individuals needed to be sure that, you know when they turned on the tap, that it was in fact water that was safe. So in 1974, they created the Safe Drinking Water Act to protect public health in regulation of the nation's drinking supply.

So in the Act, the EPA set national health-based standards for drinking water. The goal was to protect drinking water from source to tap, and so sort of that full distance; and then also created national standards around sound science to protect against the health risks, so enforceable maximum contaminant levels, ways to treat water to remove contaminants, and then requirements for those water systems.

The – I think here, and I'll, you know, try to do better to draw out more parallels, I think we've seen in health IT really the importance of creating standards, and the utility of those. But also that they empower industry to then kind of use those standards in kind of their own innovative ways, and then it came to water standards, kind of the EPA's ability to identify contaminants and run studies and to be able to really precisely identify what maximum levels of contaminants should be I think was really important.

So kind of making that a standard in and of itself. Obviously, in health IT, it's probably more difficult to get to that level of precision, but I think this also points out, you know, if you can – you know, if you can – maybe if we focus on really specific areas, we might be able to have more precision around kind of what we consider to be a risk versus less risk. And there are annual consumer confidence reports on the source and quality of tap water, and there's a public annual summary report of water system compliance with the standards that the EPA has set.

And I think here, the transparency is really, really important. So the general public can know not only about kind of what standards individual water systems are operating at, but also how they comply and how they address compliance issues. So kind of some successes here are the setting of standards, greater transparency, and I think also really helpful for the kind of EPA in this particular area was that they had a very defined goal, the Drinking Water Strategy goal. And so it really I think sort of oriented all of their activities in such a way that all of the things that they measured, all of the standards they set, and all of the reports they produced, are aimed at achieving those goals.

There are still more contaminants that need to be addressed, and so I think that's also an interesting parallel to health IT. We might not be able to boil the ocean and address all potential areas or all potential even instances of risk, but that maybe we focus on highest priority ones first, or even just a set first, to sort of move the needle. And certainly there's also cost of research and analysis. So the EPA conducts quite a bit of research to get different contaminant levels, to monitor different systems, to conduct those reports and publish them. So definitely cost involved there that would need to be addressed.

And then there's also a good degree of expertise that's needed. So the EPA has, you know, standards even around the research that can be conducted. And so I think really making sure that an agency is armed with a really high degree of expertise in an area is helpful, and certainly potentially a challenge. So – and I think for health IT, we also understand that. But it is so complex in that each different type of software or app or whatever it is can be so complicated that trying to figure out what is meant by expertise might also be an important area for us to address.

So moving into the financial sector, we have the Dodd-Frank Act. There has been much written on the Dodd-Frank Act, but precipitating factors here, financial crisis in the US led to quite a bit of outcry for change in the financial sector. You know, folks felt like there were no assurances of trust or integrity, and a lot of risk for both individuals and companies. So the Dodd-Frank Wall Street Reform and Consumer Protection Act was created in 2010 with some really big goals, to strengthen the economy, stabilize the housing market, end 'Too Big To Fail,' and streamline the regulatory process.

The Dodd-Frank Act created an advanced warning system, more transparency and accountability for organizations and individuals to comply, protections for investors, and again, more kind of transparency and accountability rules for credit rating agencies, and then really aggressive enforcement. A bureau was created, so the Consumer Financial Protection Bureau and the Financial Stability Oversight Council was created. There was a – quite a bit of data collection and publications for market transparency was implemented. Financial safeguards were put into place. And, you know, some different requirements for companies to sell products like mortgage-backed securities, to retain some of that risk.

I think what's really interesting about the Dodd-Frank Act is almost just inherent in its goals. And I think for me the takeaway was as we're thinking about our recommendations and as we're thinking about what we might recommend for health IT, you know, having too big a goal can be – can make for regulation that doesn't necessarily get the job done. So the Dodd-Frank Act is complex, but it didn't reform the entire system. Instead, it was sort of a very complex layer on top of the system, so sort of a complex banding, as opposed to actually going and creating something anew.

And so the kind of complexity on top of the system I think was difficult, and made for sort of productivity of the bill a challenge. And it was incredibly costly. There were obviously a lot of data collection and analysis, different bureaus, councils created. It sort of overwhelmed the industry. And it's definitely led to more information for regulators on American derivative markets. But I think this is just I think a great example of taking on too much with any one approach, rather than really focusing narrowly on specific problems.

So I'm sure there are many more articles and much more to say on this particular one, but I think the parallel for us is trying to think about really focused goals, and not taking on too much, because I think as with the financial industry, healthcare is obviously an enormously complex industry. And sometimes I wonder, as we're thinking about risks of harm to patients and sort of other risks, that some of those may be inherent in healthcare anyway and not necessarily related to health IT. And so, you know, just being sure that we're not trying to correct everything wrong with healthcare, but that we're trying to make sure that anything that could go wrong with health IT, we can avoid where possible.

And we're almost through here with the government sector, but we have Sarbanes-Oxley. And so this was something that was enacted in 2002 to sort of mitigate and in reaction to corporate and accounting scandals. Enron is a sort of famed example. And the legislation created a number of different reports, types of analysis, disclosures, responsibilities for organizations, different sorts of processes for organizations, and then a Public Accounting Oversight Board.

You know, the law was not broad enough, so this is sort of, you know, trying to get the porridge just right, in contrast, of course, to Dodd-Frank. And the private sector was sort of asked or called upon to increase their level of responsibility, so CEOs and CFOs were forced to certify the validity of SEC filings. So I think an interesting here is really the sort of government calling on private industry to step up their efforts in both the regulatory process, and then I think also kind of having their internal controls be improved.

I think we probably – a close parallel might be in some sort of quality system process, but I thought was interesting, too, about this was that it was calling on the individual, so not just the – not just the sort of type of development, but the sort of individual – those efforts. And truth be told, and I think this is another thing that we can – is analogous to healthcare, with Sarbanes-Oxley, it was hard to determine the success of the act, because there was no baseline established about the numbers of fraud. And I think in healthcare, too, we've cited several times that we don't necessarily have great baselines when it comes to patient safety or adverse events that derive from paper workflows, or from workflows that are not necessarily – that are not necessarily affected by health IT alone.

And I think with Sarbanes-Oxley, there is board – there are board failures that are still common. So, you know, it could be potentially worth figuring out kind of more of those failure points, if we're looking for things not to do. And then we'll go – oh...

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

Lauren, if I can, I just want to...

Lauren Fifield – Senior Policy Advisor – Practice Fusion

Sure.

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

We have to – we have to manage the time. So there are really three segments when you're done that we need to cover. We need to cover the public, which should be about ten minutes. We need to cover Mike's portion, which should be about ten minutes. And I do want to make sure that we give people on the committee time to discuss this. So are you able to wrap this up in the next say two minutes in order to give folks a chance to start talking and let in the ideas exchange?

Lauren Fifield – Senior Policy Advisor – Practice Fusion

Yeah, sure, absolutely. So I'll just actually flip through these, and so – and just sort of call them out. So this is sort of private sector approaches. The precipitating factors are mostly similar to those that I cited in the public approaches to either risk of harm or need for assurances. But the High Trust Alliance, I definitely encourage you all to go back through these. It's a private sector group that creates – establishes standards, harmonization between different laws, the federal and local level. Again, use of analysis and industry data. And then also creates ownership of the industry.

The Joint Commission has been around for quite some time, and deals in healthcare, but is, you know, something that we could potentially draw on for a private sector approach to accreditation or assuring the quality of a system, and that's specific to healthcare. So there could be some interesting parallels. Again, standards for industry are important there in defining what is meant by quality.

The Good Housekeeping Seal of Approval is also commonly known. It's for evaluating products and issuing consumer reports. Sort of a long history here, but allows consumers to really reliably trust in the products that they're going to purchase. And I think what's interesting here is that there's, again, that trust, but also accountability. So if someone is a seal bearer and there's a limited warranty associated with that, and again, high quality and reliability, and that's, you know, a private sector implementation.

Florida Orange's Seal of Approval is, you know, the private sector – this is a little bit more about market competitiveness and using quality and high integrity processes as a competitive advantage, and I think something that I could easily see done in the health IT space. The American Podiatric Medical Association created a seal of acceptance for footwear to allow consumers to understand what would be really, really quality. So here, awareness and education played a large role in kind of improving the experience of consumers and improving safety. And then they had really strict processes in place around obtaining seals. So another interesting way that private sector saw that there was a consistency and integrity issue, and addressing that.

So here's a summary of takeaways. In most cases, before there was any sort of regulation, the industry had some chance to self-regulate or mitigate risks on their own. Standards were incredibly important, and allowed industry to be competitive, both in the promotion of safety and trust and integrity, as well as sort of finding kind of ways to innovate on those. Focused regulation seemed to be the most successful, both in terms of using data to identify areas where regulation would best serve, and not kind of taking on goals that were so broad they were sort of drowning. Reporting and collection of data was really important. Transparency to both the public and within industry had a really positive impact. And then, you know, sort of, again, regulations that were too big generally failed, again, because harder to respond to, less targeted, and definitely more expensive.

So these are the questions that I had for us to consider, and I guess we could have Mike go first, and then get to discussion.

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

Yeah. I think that makes a good flow. Mike, if you wouldn't mind, you know, taking up to ten minutes to describe some of those existing activities, and then we can go into the discussion questions.

Mike Flis – Roche Diagnostics

Well, thank you for the opportunity. I apologize. I don't have any slides to walk you through, and I'll attempt to be brief. Certification processes have been used within the medical space in lieu of regulatory body involvement to provide confidence to public, government authorities, and industries. The certification processes tend – rely upon consensus standards as building blocks, and I'm glad to have heard Lauren mention standards as something that in other aspects of the economy are commonly used as building blocks.

In our particular case, we can look at a handful of standards that already exist, such as ISO 14971, which relates to assessing risks associated with medical devices. There's an IEC standard 62304, which describes the processes for developing, verifying, and commercializing software, and then life cycle managing it through all of the changes. We have an IEC standard 62366, which describes the proper way to go about establishing a usability engineering program, which would be applicable to software products as you're trying to optimize the user – excuse me, the interfaces.

And then most recently, the American Association of Medical Instrumentation decided to cooperate with FDA and Underwriters Laboratory and sponsor several workgroups to look at creating new documents that would pertain to mobile technologies and the interoperability of medical devices. So the work that they create can be relied upon by industry and the public and the government. And in fact, when these workgroups come together, all three of those parts of society are represented, so that the documents that they produce don't just represent industry's perspective, but they represent the needs of all three so that they can be not only approved, but they actually are put into force. They're implemented.

And the documents have the appeal that they're not just a domestic document. They tend to become international, acknowledged by the manufacturers in many countries and the authorities in many countries. As I look into the future for innovation in health IT, I think of mobile applications and cloud solutions, I envision companies located – whether they're – I believe Brad's in Scotland today – they could be in Scotland, Taiwan, or Northern California, they're creating a product which they want to commercialize globally and have only one set of regulatory requirements or expectations to fulfill. And if each of the health authorities is looking at the same international standards, and they contributed while they were being written, this could really work well.

Now back in 2006, there was an organization formed, and it's called Continua. They – let me pause. They – it's an international nonprofit open-industry alliance of healthcare, technology, and medical device companies and providers working together to improve the quality of healthcare through the use of interoperable devices, services, and systems for Tele-health, personal connected health, mobile health, and independent living. It's envisioned that these services will empower information-driven health self-management and facilitate the incorporation of health and wellness into the day to day lives of consumers.

Continua is a pioneer in establishing standards-based guidelines and security for connected health technologies such as smartphones, gateways, remote monitoring devices, disease management services, and electronic health record systems. Continua has developed five design guidelines and released those over the course of the past seven years. The most recent is posted in 2012, and as a follow-up to this meeting, I'll provide you their web address, so that if you wish, you can take a quick look at it.

Continua has – although they've only been around since 2006, they've already established relationships with many of the USA federal agencies, such as the Veterans Administration, the Department of Defense, National Institute of Health, and they've also worked in conjunction with authorities in other countries such as the International Standards Organization, the United Kingdom's National Health Service.

So I wanted to bring this to your attention to show that the concept of building up some type of certification process that could be used in lieu of having to work with a health authority, a regulatory body, in order to commercialize the device, the building blocks are already being put in place. A lot of it is being driven from the United States, but it's being built to facilitate the commercialization of health IT internationally.

And given that so much of this idea is being driven from the United States, and know that our innovators want to create products that they can commercialize here and in other countries, I'm hopeful that this FDA/SAA working group can take advantage of these standards, this one – this particular body, Continua, and the concept of relying on certification testing bodies rather than having to go through a regulatory body for all forms of health IT. Now I hope that was helpful and what you were looking for.

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

Mike, it is, and I'll give people a chance to ask questions. I mean, if I can just sort of draw this, you know, to a point, the reason what Lauren did was so terrific, I think, and so helpful, and Mike's description of the standards organizations and certification bodies, is our task, this regulations sub-workgroup's task, is to at the end of the day propose to the full working group some regulatory specs, elements that the regulatory system ought to have.

And I think, for example, Lauren's review of kind of what the collective US experience has been with different regulatory systems – well, public regulatory systems and private oversight, and the conclusions – some of the conclusions that she drew sort of gives us a roadmap for the exercise that we've been asked to do, coming up with those regulatory specifications. So that's the context for this information and how we might use it.

So with that as background, what do people think? What – you know, as you listen to Lauren and you listen to Mike, what takeaways do you have from it that would be relevant to our ultimate recommendation as to what the regulation of health IT ought to look like? Anyone draw any conclusions that they want to share with the group?

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

So this is Meg Marshall, and first of all, I would like to thank Lauren for that fantastic job. I think you went above and beyond, and I know that that was quite a bit of work, to put together that overview. So bravo and thank you.

So I suppose, Brad, and I'm auditing, you know, as a member of the full workgroup, of course, but my thoughts are that there are multiple failure points to be concerned about, and it looks like there's different levels of government intervention, and they all seem to be central around the concept that private industry is ideal to provide the solution, and that government intervenes and that ideal solution isn't met. So I think that we have the opportunity to recognize the multiple failure points, that there are multiple opportunities across all of these agencies to provide some mitigating factors. And I think that the workgroup as a whole is going to be challenged to try to harmonize across those approaches.

So – and then just one final comment is that I think consistent across what we heard is that failures still happen. So even with the best intended plans, there's still opportunity for failure, and to recognize that the process of notification when the failure happens, of enforcement, of any processes that were violated prior to the failure, but then certainly the recognition that this is an opportunity for learning and evolving and growing, and all of us in the technology field recognize how challenging that is. So those are just a few of my takeaway thoughts, but again, thank you to Lauren and thank you to Mike.

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

Great, appreciate those comments. Other insights anyone wants to share?

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

This is Anura Fernando from UL. Again, I'd like to applaud the efforts of both the presenters. I just wanted to mention, you know, this – the issue of harmonization, international harmonization in particular, seems to be a very key point in all of this. Mike mentioned the AAMI and Underwriters Laboratory's, you know, combined efforts and so forth for standards development. We currently have members of ISO and IEC also involved in that effort, and see that as an integral piece moving forward, just because from a technology perspective also, you know, telecommunications infrastructure, etcetera, it binds the globes together, and it crosses geographic boundaries.

And so as healthcare starts to cross those same boundaries, ensuring interoperability and assurance of safety has to be harmonized as well, so that we don't have people traveling across boards who are put in jeopardy as they cross borders, potentially.

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

Very useful, thank you, are there other comments? Well, before we go to public comment, let me go back to Lauren, because I kind of hurried her at the end. We have – you know, we have five minutes if we want to use them for more discussion, if there's anything that you omitted that you'd like to cover before we need to go to public comment.

Lauren Fifield – Senior Policy Advisor – Practice Fusion

Sure. Thanks, Brad, and thanks to those who had feedback. So I think I have two other points. One is to thank my intern, Jordana Cowen, who's been working on this project. I think her family thinks that I'm a slave driver. But she did an incredible job, and so I'm grateful to her.

And second, I think the one last thing I'd say is that as I was kind of going through all these, and as she and I were discussing, we realized that regulation worked really, really well. So I think we might have even gone in with a bias towards not, but we realized it worked really, really well when there was a clear failure of industry to address something, and when that either risk of harm or that need for trust was really well identified. And I think that's true in the private sector as well.

And it – that really started to break down when it was sort of a general concern about risk of harm or a general need for assurance. And so I really think, particularly because there – what we are tasked to consider and then provide recommendations for is so broad, I can't – I can't stress enough for us to find all the ways we can to really, really finely focus in on areas where we do think an approach, whether it's regulatory or not, is important. And otherwise, try and find some way to kind of let industry or let time or more data and insight kind of show us where an approach, regulatory or not, is necessary. So that's my last two points, and thanks again.

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

Well, I just want to echo the other expressions of gratitude, Lauren. You and your team obviously put in a tremendous amount of work, and so we're very grateful for you doing that on behalf of the whole working group.

With that, I want to make some remarks about the next few meetings, but I think that maybe is best done at the end, MacKenzie. Should we go to public comment, and then – and then all I want to do is kind of script out what the next couple of meets are, about what the agendas are.

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

Sure.

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

Can we do public comment at this juncture?

Public Comment

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

Yeah. We can do public comment first. Operator, can you please open the lines for public comment?

Caitlin Collins – Project Coordinator – Altarum Institute

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

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

Okay. Thank you. And I'll continue to make the offer that I have, I think, at the end of most of these calls. If someone thinks of something later and they want to send me an email, I'm very interested in getting additional insights.

So let's just talk about the meetings over the next week, because there are a lot of them, and in part, I need, MacKenzie, your help understanding the schedule of the full committee. Do we have full committee – full working group, I should call it – full working group calls tomorrow, Thursday, and next Tuesday? Is – am I reading my Outlook calendar correctly?

Lauren Fifield – Senior Policy Advisor – Practice Fusion

Yes.

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

I'm pulling up the list. Someone just said yes, so they beat me to it. But the full workgroup, we do have a call tomorrow, Thursday the 27th, and then July 2nd, July 26th, August 1st, August 13th.

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

So I'm struggling a little bit. I haven't seen what the agendas are to be, but MacKenzie, you've heard what we're doing. We're doing, you know, these series of calls that are mostly learning. We're gathering data. And on Monday, we really roll up our sleeves and start the discussion and then, you know, forming the consensus recommendation. I don't have anything particularly to report on behalf of the working group, the sub-working group, tomorrow. What are we expected to do in the call tomorrow?

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

So Kate, are you on the phone?

Kate Black, JD – Office of the National Coordinator

Yes, I sure am.

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

Have you heard anything back from David yet regarding tomorrow's agenda? I know you've reached out to him.

Kate Black, JD – Office of the National Coordinator

No, I sure have not.

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

Okay. So we'll circle back with David for the agenda tomorrow. I know there is also a planning call that there is a pull-out for, Brad, where we're going to get the subgroup chairs together with David to talk about the meetings and what we're going to be planning for each of them.

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

Okay.

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

In terms of just in general with the calendar appointments, I know we like to get them on the calendar in advance. That doesn't mean after the chairs talk, the subgroup chairs talk, that if one isn't needed, we could always cancel it. It's just best to have them on the books, with everyone's busy schedule. So it's basically to be determined at this point. But I will circle back with David regarding tomorrow.

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

Well, you know, I know Julian is on vacation, and I'm here at Continua meetings over the next few days. And as I said, you know, and please, anyone, you know, express a point of view; I don't know what we have concrete to report. We can report the fact that we just did what we did, but we wouldn't go through that in any sort of detail, I wouldn't imagine, with the whole group. So I'm just not sure we would do tomorrow. So let me know what the agenda is.

So let's talk about what we're doing, though. So this really concludes the series of meetings that we have scheduled that were, as I – as I referred to a moment ago, kind of data dumps, where we collect a lot of information about existing regulatory and non-regulatory schemes, and share it with the other members of the subgroup. And I sent out an email, I think it was last Friday, trying to, you know, rather clearly and probably bluntly announce that transition, that we're moving from, you know, presentation format meetings to really discussion format meetings. And so I tried to put in the email what the agenda is for next Monday, the July 1st meeting of this group.

And, you know, I don't have – I mean, I can recap that when we start the call on Monday, but I don't have more than five or ten minutes to really say. It's just a matter then of turning it over to all of you to say, okay, now that we've done that data dump, what nuggets are you extracting from all of that data in – with regard to the questions that were listed on the agenda? So that's the call on Monday.

Then the call on Wednesday, so it looks like we have a call every day next week if we go forward with the full working group as well, but the call next Wednesday is a call that's focused on two specific agenda items. That is, we wanted to call out the issue of reporting separately, and we didn't want to do it on Monday, because quite honestly, Julian, that's his first day back from China, and I wanted him to lead that discussion, because he's knowledgeable and passionate about it. And then we're going to talk about the ambiguities. So that is the Wednesday call.

And then on the 8th, which I don't know what day of the week that is, the following Monday or something, Tuesday, that's when we have Joe Smith leading the discussion about conceptually new ideas for how to regulate health IT. That is, kind of looking at a blank page of paper and saying, if we could – if we could conceive a system for regulating HIT, what should it look like, without kind of, you know, focusing too much on the – on what is, focusing on what it should be. So that's the 8th.

Then from there, we roll up our sleeves and we start writing whatever our collective recommendations are going to be, and we've got the two meetings – two conference calls, rather, schedule to do that. So that's the choreography of the subgroup, anyway. And as I say, we have to figure out how to time that or how to connect up with what the full group is doing, and I don't – I don't currently know what that is. But that's the agenda. Comments, questions, concerns about that path forward? Okay.

Well, then it's ten till. I have nothing else on my end. Anybody else have anything before we adjourn?

Jared S. Quoyeser – Intel Corporation

Brad, this is Jared. I guess just a question for MacKenzie, more than anything. MacKenzie, do you think that it – the possibility of actually cancelling tomorrow's call is real, or should we definitely plan on being online?

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

As of now, plan on being online, I'm going to try and send an email around to all of the involved parties to see if we can sort that out, but for now it's still on.

Jared S. Quoyeser – Intel Corporation

And I guess I would like to ask other members if they feel that there's merit in having a full FDASIA call tomorrow when we have another one planned for early next week.

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

You could probably tell from my question that I didn't – I didn't under the value of it.

Jared S. Quoyeser – Intel Corporation

Oh, no. No. I clearly know where you're coming from. I just want to know if the others are in agreement.

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

I'll shut up.

Unidentified Speaker

Totally.

Unidentified Speaker

Completely, absolutely.

Unidentified Speaker

Yes.

Unidentified Speaker

I say all FDASIA, all the time.

[Laughter]

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

So in my – this is MacKenzie. In my email to David and the rest of the federal staff, I'll just put that – the sentiment of the workgroup or the subgroup, which is all workgroup members anyway, in the email. So if it's not needed for tomorrow, we can always post – just cancel tomorrow's and have the standing one for next week on Tuesday on the books, so –

Mike Flis – Roche Diagnostics

But MacKenzie – this is Mike Flis. The opinion could change if we saw an agenda for tomorrow's meeting.

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

I hear you. I'm working on it, and I'll get you any information I can. So right now, it's on the books, and if anything changes, I'll let you guys know. But I will share your – I will share your thoughts with them.

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

Thank you very much.

Unidentified Speaker

Thanks, guys.

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

Take care, everyone.

Unidentified Speaker

Bye.

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

Bye.

Lauren Fifield – Senior Policy Advisor – Practice Fusion

Thank you.