



## HIT Policy Committee Privacy & Security Workgroup Final Transcript May 8, 2015

### Presentation

#### Operator

All lines are now bridged.

#### Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Thank you. Good afternoon everyone, this is Michelle Consolazio with the Office of the National Coordinator. This is a meeting of the Health IT Policy Committee's Privacy & Security Workgroup. This is a public call and there will be time for public comment at the end of the call. As a reminder, please state your name before speaking as this meeting is being transcribed and recorded. I'll now take roll. Deven McGraw?

#### Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP

Here.

#### Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Hi, Deven. Stanley Crosley?

#### Stanley Crosley, JD –Director, Indiana University Center for Law, Ethics and Applied Research (CLEAR) in Health Information; Drinker Biddle & Reath, LLP

Here.

#### Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology

Hi, Stan.

#### Stanley Crosley, JD –Director, Indiana University Center for Law, Ethics and Applied Research (CLEAR) in Health Information; Drinker Biddle & Reath, LLP

Hey.

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Adrienne Ficchi? Bakul Patel? Cora Tung Han? David Kotz?

**David F. Kotz, PhD – Associate Dean of the Faculty for the Sciences – Dartmouth College**

Here.

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Hi, David. David McCallie?

**David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation**

Here.

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Hi, David. Gayle Harrell? Gil Kuperman?

**Gilad Kuperman, MD, PhD, FACMI – Director of Interoperability Informatics – New York Presbyterian Hospital**

Here.

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Hi, Gil. John Wilbanks? Kitt Winter?

**Kitt Winter, MBA – Director, Health IT Program Office – Social Security Administration**

Here.

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Hi, Kitt. Kristen Anderson? Linda Kloss?

**Linda Kloss, RHIA, CAE, FAHIMA – President – Kloss Strategic Advisors, Ltd.**

Here.

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Hi, Linda. Linda Sanches?

**Linda Kloss, RHIA, CAE, FAHIMA – President – Kloss Strategic Advisors, Ltd.**  
Hi.

**Linda Sanches, MPH – Senior Advisor for Health Information Privacy – Office for Civil Rights**  
Here.

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**  
Hi, Linda. Manuj Lal? Micky Tripathi? Sarah Carr?

**Sarah Carr – Acting Director – Office of Clinical Research & Bioethics Policy – National Institute of Health**  
Here.

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**  
Hi, Sarah.

**Sarah Carr – Acting Director – Office of Clinical Research & Bioethics Policy – National Institute of Health**  
Hi.

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**  
Stephania Griffin? And Taha Kass-Hout?

**Taha A. Kass-Hout, MD, MS – Director, FDA Office of Informatics and Technology Innovation – Food and Drug Administration**  
Taha's here.

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**  
Hi.

**Taha A. Kass-Hout, MD, MS – Director, FDA Office of Informatics and Technology Innovation – Food and Drug Administration**  
Hi.

**Cora Tung Han, JD – Division of Privacy and Identity Protection, Bureau of Consumer Protection – Federal Trade Commission**

Hi, Michelle; it's Cora Han. I'm here, too. Sorry I joined a little late.

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Thank you. And from ONC do we have Lucia Savage?

**Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology**

Present.

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Hi, Lucia. Helen Canton-Peters?

**Helen Canton-Peters, MSN, RN – Office of Chief Privacy Officer – Office of the National Coordinator for Health Information Technology**

Here.

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Hi, Helen. And Kathryn Marchesini?

**Kathryn Marchesini, JD – Deputy Director for Privacy Policy – Office of the National Coordinator for Health Information Technology**

Here.

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Hi, Kathryn. Anyone else from ONC on the line? Okay, with that I'll turn it back to you Deven and Stan.

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

All right, great. Thank you very much, Michelle and thanks to all of you for making time today to be on our call. We're going to continue with our health big data discussion, having finished the work that we did on the notices of proposed rulemaking and also prior to that on the interoperability roadmap. So we're now able to, as we started on our last call, get back to these health big data discussions that we began in the end of the last calendar year and we really do hope to finish them up.

Our aim today is to review some of the straw recommendations that Stan and I and the staff and our MITRE support team has teed up for all of you. We sent you two documents; one is a sort of working outline, because we are intending to present to the Policy Committee a set of recommendations that...and a real sort of fulsome discussion of everything that we learned or the top issues that were covered in our hearing, what we learned from them, what issues we decided to focus on and then those recommendations. So it's going to be quite a comprehensive document, more than could ever fit on a set of slides. But we will, nevertheless, need sort of summary, higher level slides to present to the Policy Committee.

So what you got was a combination of the issues...the key issues list and the beginning of...beginning text to sort of flesh out some recommendations. So we'll use the slides, but I may refer back and forth periodically to the text that's actually in the draft outline that we sent to you all, because that is a bit more comprehensive. But we just couldn't capture all of that wording on the slide nor did we necessarily think that that was the best way to sort of go through this.

I fully understand that for many of you, probably potentially all of you, you haven't had a chance to read through the outline. That's okay, I don't think it's going to hamper at all your ability to participate in the discussion today, but we will ask as we sort of go forward and try to reach some final state of consensus here, that you do your best to try to read through the outline in between calls and provide us with feedback so that we're continually making sure that we are capturing the discussions adequately in the language that we're actually using in the recommendations. So, with that, let's go to the next slide.

So again we have a meeting today to go over big data recommendations. We're going to have another call towards the end of the month. Our goal is at least to initially present the...our early findings at the July Health IT Policy Committee meeting. I suspect that they...that that meeting will not be the last one where we present the recommendations. We'll...it'll be a good opportunity to get some additional feedback from the committee, which will give us a chance to put some final touches on them for August. But that still requires us to sort of work pretty diligently this month to get some...to get a good working draft set of recommendations prepared for the July meeting.

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Hey Deven, this is Michelle. I just wanted to set expectations. We haven't canceled the July meeting yet, but we did move the June meeting much later in the month...

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

Yeah.

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

So I just want to set expectations that there is a possibility we may cancel that July meeting, so we just have to figure out how we work recommendations. Just wanted to set expectations for that.

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

Okay.

**Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology**

Yeah, so Michelle, this is Lucia. Thank you for saying that and let's get all coordinated and then tell the committee what we're planning to do.

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Yes; it's not canceled yet though, so don't want anybody to be confused.

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

All right, well we'll continue to go...to proceed as planned until we hear otherwise, so; all right. Great. Next slide, please. Okay, so these jump really, it's a really short slide deck, again in keeping with the plan to sort of use the slides as sort of a high-level indication of where the recommendations are headed, but to refer to the draft text that was in the outline that we distributed. We're really focusing on one, two, three, four overarching problems. One is the potential for harmful or discriminatory practices from health big data. We heard a lot about this from nearly every individual who presented to us as part of our Health Big Data hearings.

The second area is the sort of different domains of regulation you have sort of what's covered by HIPAA and the Common Rule. Particularly with respect to analytic uses of health big data and then you have this enormous space that isn't covered by sort of comprehensive rules, particularly around data analytics, but instead is likely to be governed under the Federal Trade Commission's authority and may, in some circumstances, be covered by some state or other laws; but not in the sort of comprehensive way that the HIPAA-governed ecosystem is covered. And yet even in the HIPAA space, we have some...we heard some testimony about the rules, particularly the distinction between operations and when something qualifies as research as potentially not providing the right incentives for the reuse of data for learning purposes...it's just...so that's the third area.

The fourth area is this bucket of issues around de-identification. How well does it work? Do we over-rely on it as a regulatory protection? Is it still worth keeping as an important tool for privacy protection? And what sorts of recommendations would we have to enable continued use of de-identification or anonymization techniques for privacy protection; but how would we strengthen that? And then the last bucket of issues is around security.

So yes, those are big buckets with lots of potential sub-categories within them but in keeping with the request from the Health IT Policy Committee that we try to give them, as much as possible, sort of big and meaningful recommendations in lieu of giving them 30 little recommendations. We've tried to focus on what we think were some of the most important issues that got surfaced during our hearings; we're trying to be parsimonious with respect to the recommendations, although it's very hard to do that in this space because it is quite complex. But basically what our slides do is start to walk us through a set of draft solutions for each one of those areas.

So I'm going to pause here. Stan, did I leave anything out, in terms of how we're going to proceed and what our issues are?

**Stanley Crosley, JD –Director, Indiana University Center for Law, Ethics and Applied Research (CLEAR) in Health Information; Drinker Biddle & Reath, LLP**

No, that was a brilliant summary of where we are and what we're going to be talking about. I think the four issues; I think in particular, kind of highlighting those before we dive in is important. I think we pretty much as a workgroup even prior in the few times we've had to talk about big data; we were clearly focusing on these four areas. So it makes sense and now the hard part is figuring out how to narrow down the recommendations because these are four pretty big buckets.

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

Yeah, yeah. Does anybody...now I just got emails that we've been joined by a couple of members who missed roll call; Micky Tripathi and Manuj Lal are both on.

**Micky Tripathi, PhD – President & Chief Executive Officer – Massachusetts eHealth Collaborative**

Yup, hi, thanks Deven.

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

Yup.

**Manuj Lal, JD – General Counsel, Corporate Secretary & Chief Privacy/Information Security Officer –PatientPoint Enterprise**

Yeah, thank you.

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

You're welcome, thanks for joining even if you're not able to stay til the end. So, anybody have any questions about those issues? And you're not...you can also raise others and raise questions as we go through the solutions, but I wanted to give you a sense of sort of where we were headed before we jumped into the solutions part of the call.

Okay, so on the first set of issues, which involves the potential for health big data uses that could cause harm, of which discrimin...potential for discrimination is one particular type of harm, but isn't necessarily the only harm. And we heard about this a lot during the hearings and the text that we've put in the outline really starts to flesh that out, but we...and we provide a couple of examples of potential discriminatory harms. But, there might be other uses that some would consider harmful, like marketing or commercial uses but, we don't have a lot of consensus, from a public policy standpoint, about what...beyond discrimination, what uses would constitute harm.

And people also, in our hearings, expressed some concern about the use of algorithms for decision making about either individuals or sub-populations and the concern that there was not a lot of transparency about those algorithms and little ability for individuals to find out more about that or to challenge the information that informs algorithms or the use of these algorithms. And so we were really scratching our heads in trying to prepare a set of recommendations on this particular issue because it's not one where there are necessarily a lot of really obvious answers yet.

I think a fair amount of agreement that this is a set of issues that could be potentially harmful to health big data and the opportunities because if people don't trust health big data then it could create obstacles to leveraging it for public good on the one hand. On the other hand, again there weren't a whole lot of really obvious answers that necessarily came out. And so what we've sketched out is sort of a need to continually monitor health big data issues, and we do in the next set of recommendations as you'll see, call for more transparency about health big data.

We call on more public inquiry to more fully understand the scope of the issue. More sort of monitoring the use of health big data to identify where there are gaps in legal protections and areas for further inquiry. And we definitely single out the use of algorithms and the need for more transparency there. And here's...and the last piece of this is probably the most specific suggestion that we were able to come up with which is to think about whether there are elements of the Fair Credit Reporting Act, which provides people...individuals with rights with respect to who's accessed their credit report, how their credit report gets used, the ability to identify and try to correct errors in their credit report. Are there sort of elements to that particular consumer protection statute that might be borrowed for a set of protections in the health big data use space?

So I want to open it up for discussion. Is there any particular more specific solution that we missed? Are people comfortable with...

**Stanley Crosley, JD –Director, Indiana University Center for Law, Ethics and Applied Research (CLEAR) in Health Information; Drinker Biddle & Reath, LLP**

Hey Deven, this is Stan.

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

...talking about the Fair Credit Reporting Act as a potential model, but otherwise calling on policymakers and others to continue to monitor this space versus being prepared to identify anything more specific than that at this stage?

**Stanley Crosley, JD –Director, Indiana University Center for Law, Ethics and Applied Research (CLEAR) in Health Information; Drinker Biddle & Reath, LLP**

Deven, this is Stan. The one thing that I was going to say with respect to that first bullet...

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

Yup.

**Stanley Crosley, JD –Director, Indiana University Center for Law, Ethics and Applied Research (CLEAR) in Health Information; Drinker Biddle & Reath, LLP**

...and kind of promote more public inquiry. It was really because the harm that we saw, you know we didn't have a clear consensus. Discrimination, discriminatory practices came up as a clear consensus still a little lack of definition necessarily on what is a discriminatory practice. But in general even beyond that it was very difficult to identify the precise harm that we were then going to try and draft a solution for. So in that first bullet, we're really trying to seek a consensus or seek a position that could enable folks to say, yes, a marketing use is always going to be bad or there is a...there are certain circumstances where this is going to be harmful. So, I think that's where what we're trying here on bullet one, it's just rather unsatisfying.

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

Yeah. Well, I wish we could say more but we're just not sure what else could say.

**Stanley Crosley, JD –Director, Indiana University Center for Law, Ethics and Applied Research (CLEAR) in Health Information; Drinker Biddle & Reath, LLP**

Right. Exactly, but thoughts on those, too.

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

Yup.

**David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation**

Deven?

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

Yeah.

**David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation**

It's David. On number 1, it may not be that it's worth mentioning but I think about the two classes of harm that got called out in the Robert Wood Johnson Data for Health exercise that you and I and some others participated in in that you can have harm to individuals, but you could also have harm at community level...

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

Yeah.

**David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation**

...like redlining and the like. I'm guessing we're not probably being asked to address that broader notion of community-level harm, but it might be just something to think about.

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

Yeah, I think we can flag that. I also think that came up during our hearings.

**Stanley Crosley, JD –Director, Indiana University Center for Law, Ethics and Applied Research (CLEAR) in Health Information; Drinker Biddle & Reath, LLP**

It did and...

**David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation**

Yeah, yeah I mean...

**Stanley Crosley, JD –Director, Indiana University Center for Law, Ethics and Applied Research (CLEAR) in Health Information; Drinker Biddle & Reath, LLP**

...especially with respect to the use of de-identified data that came up but even then there could be a class of harm.

**David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation**

Right and if the only thing we're really calling for is more inquiry, then you might as well enumerate things to go pay attention to.

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

Right, right.

**Stanley Crosley, JD –Director, Indiana University Center for Law, Ethics and Applied Research (CLEAR) in Health Information; Drinker Biddle & Reath, LLP**

Um hmm, yup.

**David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation**

And then I have a second unrelated comment on number 3. I support the notion of algorithmic transparency but I'm concerned a little bit that the technologies that are gaining a lot of dominance in big data work are oftentimes fairly opaque algorithms and they're not something that can actually be explained transparently. They basically learn from the data and presumably spit out what they learn, but you may not be able to explain how it reached a particular decision in which case the transparency would really be around how you validated the algorithm. So it's not so much algorithmic transparency but algorithmic transparency and validation.

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

Okay.

**David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation**

How you tested it, I think that's...

**Stanley Crosley, JD –Director, Indiana University Center for Law, Ethics and Applied Research (CLEAR) in Health Information; Drinker Biddle & Reath, LLP**

The problem...I think one of the problems we have here and even the FCRA analysis or analogy breaks down a little bit in that even the credit reporting data is fairly linear and it's very difficult for us to say that, well we know the three elements that resulted in the issue that you're confronted with. The reason you got denied some service was because of your...you had a late bill paid to the gas company on January 7, and that's what they do with FCRA, they explain why it is that you have the score you have and the steps that you could take to do something about it. And it's just not that linear with this health data stuff, but...so isn't that the great example of how it's not the same.

**David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation**

Yeah.

**Stanley Crosley, JD –Director, Indiana University Center for Law, Ethics and Applied Research (CLEAR) in Health Information; Drinker Biddle & Reath, LLP**

But at least it's a step toward it, right? If you have to try and at least point to factors maybe, is there a factorial approach that says these factors went in, even if you can't explain the algorithm?

**David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation**

Well, even...I mean even that could be limited; it's quite popular to literally throw thousands if not tens of thousands of features into...

**Stanley Crosley, JD –Director, Indiana University Center for Law, Ethics and Applied Research (CLEAR) in Health Information; Drinker Biddle & Reath, LLP**

Yeah, right.

**David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation**

...a training mix and you may do some printable component reductions and reduce it to hundreds of features but those hundreds of features will be linear combinations of the thousands of features so you're still stuck with thousands of features...

**Stanley Crosley, JD –Director, Indiana University Center for Law, Ethics and Applied Research (CLEAR) in Health Information; Drinker Biddle & Reath, LLP**

Yeah.

**Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology**

So this is Lucia and I kind of like the suggestion David made about validation. And I have the lawyer brain, but what it makes me think of is the way that we require people who are making sort of large scale decisions in their workforces and stuff like that to have their employment criteria validated as not having an impact we otherwise won't accept in America. And I think that that...it ties in nicely...that idea of validation ties in nicely with what's identified in the earlier slides which is, every one of our testifiers kind of identified this as a very important problem. Nobody had a specific solution to latch on to, but we can kind of learn when we can take a deeper dive than the policy workgroup is capable of doing, it should be possible to look at pieces that are helpful in other environments and then construct something that works for this environment. So, a combination of transparency, validation and maybe things you're not supposed to do or outcomes that are not supposed to be generated by these valid and transparent algorithms.

**David F. Kotz, PhD – Associate Dean of the Faculty for the Sciences – Dartmouth College**

This is David Kotz; this is smack on, I think these issues are really challenging. I think it was David is correct in saying that most of these machine-learning based algorithms involve hundreds or thousands of factors that are input and can't indicate why they came to some conclusion. They just learned patterns and then they, in the future, given new data, predict a similar outcome. And one of the chall...so I guess I would want to know what transparency means, if you use it in a document...

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

Okay.

**Stanley Crosley, JD –Director, Indiana University Center for Law, Ethics and Applied Research (CLEAR) in Health Information; Drinker Biddle & Reath, LLP**

Right, exactly.

**David F. Kotz, PhD – Associate Dean of the Faculty for the Sciences – Dartmouth College**

...like this because you're not going to get the companies to disclose their algorithm, literally, line for line because that's a proprietary secret of theirs usually. And if it's not technically feasible to reverse engineer the algorithm, a decision to say these are the reasons why you were denied credit or given a higher insurance premium or what have you, then that avenue for transparency is not possible. One thing that I fear about validation, although I think it makes some sense to call for validation, is that you can have a perfectly valid algorithm model that says that people with certain ethnic backgrounds or racial backgrounds or what have you, actual preferences, are more susceptible to certain conditions or certain outcomes. And that's a valid result and yet, as Lucia said, might not be acceptable in our society for us to make discriminatory decisions based on factors like that.

**Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology**

Yeah so...

**David F. Kotz, PhD – Associate Dean of the Faculty for the Sciences – Dartmouth College**

So being valid is not sufficient, maybe, as a policy point.

**Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology**

Right, that's what...this is Lucia; thank you David. That's why I think it's sort of a combination of transparency, validity and, you know I have no idea what the prohibited results, outcomes, behaviors might be; but one can imagine some kind of consensus being developed about what's prohibited. It's absolutely true that people with certain diseases cost more, but that doesn't mean we treat them differently because we made public policy decisions to do that, to treat them the same.

**David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation**

Well, and this is David, the other David; that's why we have to focus on harms, but I guess we're backing off from that because we can't actually figure out how to do that.

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

Well, I wouldn't say we're backing off...

**David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation**

I mean, you could have a 100%...

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

...from it, we're...

**Stanley Crosley, JD –Director, Indiana University Center for Law, Ethics and Applied Research (CLEAR) in Health Information; Drinker Biddle & Reath, LLP**

Yeah, we're not backing off...

**David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation**

Well...

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

...saying, time period that we had, we didn't...we recognize it's not consensus yet on harms, there's not even probably full knowledge about what those harms are today much less what might be...

**Stanley Crosley, JD –Director, Indiana University Center for Law, Ethics and Applied Research (CLEAR) in Health Information; Drinker Biddle & Reath, LLP**

Right.

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

...uncovered in the future. And that makes it really hard to have a concrete set of recommendations at this stage to say, you know people just shouldn't do "X" with this data, because we...and that's the part about transparencies, we don't always really even know when an algorithm is used for decision making purposes, much less...

**David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation**

Right but my point is, to echo the previous point is the algorithm could be 100% accurate and highly validated and still be used to cause discriminatory behavior, so...

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

Yeah.

**David F. Kotz, PhD – Associate Dean of the Faculty for the Sciences – Dartmouth College**

Exactly.

**David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation**

...the transparency and validation doesn't guarantee good outcome, it just says the algorithm isn't being misrepresented for what it does.

**Linda Kloss, RHIA, CAE, FAHIMA – President – Kloss Strategic Advisors, Ltd.**

This is Linda and I wonder if one dimension of transparency that we could agree on is transparency of the sources of information used for big data.

**Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology**

Do you mean...Linda, this is Lucia; do you mean the data in the data set or do you mean...

**Linda Kloss, RHIA, CAE, FAHIMA – President – Kloss Strategic Advisors, Ltd.**

Right, right.

**Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology**

You mean the data in the data set.

**Linda Kloss, RHIA, CAE, FAHIMA – President – Kloss Strategic Advisors, Ltd.**

Exactly.

**Stanley Crosley, JD –Director, Indiana University Center for Law, Ethics and Applied Research (CLEAR) in Health Information; Drinker Biddle & Reath, LLP**

The source of the data?

**Linda Kloss, RHIA, CAE, FAHIMA – President – Kloss Strategic Advisors, Ltd.**

Yeah.

**Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology**

Or sources, right, it could be multiple sources.

**Stanley Crosley, JD –Director, Indiana University Center for Law, Ethics and Applied Research (CLEAR) in Health Information; Drinker Biddle & Reath, LLP**

It'll be...hundreds.

**David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation**

I mean, some of that may be considered proprietary by some vendors, depending probably on the space that you're in but I think it's something to consider. The other thing...

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

Well...

**David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation**

...that as I recall, doesn't the Fair Credit Reporting Act give you some kind of recourse to challenge the data...

**Stanley Crosley, JD – Director, Indiana University Center for Law, Ethics and Applied Research (CLEAR) in Health Information; Drinker Biddle & Reath, LLP**

It does, yes.

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

Yes.

**Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology**

Yes.

**David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation**

...and get it corrected? Do we go that far here? Can you challenge...

**W**

But you can't do that if you don't know where it's come from.

**David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation**

Exactly, that's why...

**David F. Kotz, PhD – Associate Dean of the Faculty for the Sciences – Dartmouth College**

You can still claim that it's incorrect, even if you don't know...

**Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology**

Yeah, yeah.

**David F. Kotz, PhD – Associate Dean of the Faculty for the Sciences – Dartmouth College**

...or maybe if they don't know where it came from.

**Stanley Crosley, JD –Director, Indiana University Center for Law, Ethics and Applied Research (CLEAR) in Health Information; Drinker Biddle & Reath, LLP**

This is Stan; the frameworks that I'm working on right now in the private sector are dealing with the same types of analysis that you typically do with data, but it's touching on each of these things. It's the source, the data type or data category, you know is this data that the user has provided? Is this machine-generated data? Is it device data or electronic health record data? And then it's, what's the proposed use and what are the protections that are involved; it's all of these factors that are coming in, but if we're talking about the 6.1 is addressing harm. And so what we're hearing is that harm might be tied to use, it might be tied to source, it might be tied to transparency.

**Gilad Kuperman, MD, PhD, FACMI – Director of Interoperability Informatics – New York Presbyterian Hospital**

This is Gil; just along these lines one...a comment I was going to make, and I don't know exactly where it fits, but all of this kind of rests on a presumption of data quality and if you've got poor quality data, the model could be wrong and so there could be harms if you're trying to predict who's going to have a disease or not have a disease. If the model was created based on poor quality data the model could be wrong or the model could be good but if the input data are wrong...faulty or poor quality, then you could get a kind of a poor prediction for that particular thing. So, I don't know exactly where it goes, but to me, I think...and this did to me come up on some of the calls was that the quality of the data is still a challenge around use, big data approaches.

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

Yeah, we can...so, I mean I think we obviously can flesh this out to reflect the more sort of nuanced set of circumstances here, but do people think it's still worth calling for some transparency even while acknowledging that it may be a challenge with many types of machine learning. But certainly having some transparency about the data sources, and spelling out exactly the kinds of protections that the Fair Credit Reporting Act provides, as part of a recommendation to sort of consider applying that to a broader set of circumstances than it currently applies to. So...

**Linda Kloss, RHIA, CAE, FAHIMA – President – Kloss Strategic Advisors, Ltd.**

Yes, I would support that.

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

Thanks, Linda.

**Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology**

This is Lucia; the other thing I wanted to say just to the workgroup as a whole, I think our biggest constraint is actually being concise and precise. But one thing for you to think about, and I don't know, I got to listen to all of the listening sessions which was 10 hours, maybe not everyone could participate. But one thing we can certainly do is identify or focus on with transcription citations, core ideas and things, you know we shouldn't shy away from saying that experts presented ideas to us without weighing in...without necessarily evaluating those because I think part of what we're doing is helping separate the ideas that are wheat from those that are chaff for the people for whom this report is being prepared who couldn't listen to the 10 hours of testimony we did.

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

Yeah which Lucia, it's Deven; I mean I'm fine with doing that. I don't like to say anything is a recommendation from the workgroup until we've vetted it, but certainly in the sort of more comprehensive document that we're working with the MITRE folks to prepare, we can raise...we can cite to the transcript and speak...and talk more specifically about what people recommended to us.

Okay, let's move to the next slide and the next category and see what progress we can make on that one. So this relates to the sort of uneven policy environment where certain health big data uses are going to be covered and others...by comprehensive laws, particularly around analytic uses, HIPAA and the Common Rule being two of them, not the only ones. And then in the non-HIPAA covered space, again we've talked about the authority of the Federal Trade Commission to have oversight over and crack down on unfair or deceptive trade practices. But it isn't the same sort of level of sort of comprehensive regulation that would apply in the HIPAA and/or Common Rule space.

And so we've got a number of recommendations here; one is the sort of better education set of points around best practices. And we had a bunch of those recommendations that were part of the notice of proposed rulemaking for Meaningful Use Stage 3, and I think that we can point to them again as part of this process, without completely rehashing them. And they were all adopted unanimously by the Health IT Policy Committee.

But we also could recognize that policymakers and Congress could do more to consider Fair Information Practice-based policy protect...legal protections for data that's outside of the HIPAA space, but certainly for now, voluntarily adopted codes of good conduct for people who voluntarily agree to abide by them could be enforced by the FTC against those entities where they have jurisdiction. And HHS and federal partners could help in sort of participating in the establishments of these codes of conduct or providing advice for them.

It's actually framed in the outline more as an advisory role versus that we've asked the agencies necessarily to develop rules of the road. Certainly if Congress were to act, there would need to be some rulemaking that would need to be done there. And that the...what the code should really focus on are some of the transparency and lack of transparency issues that we talked about. The right of individuals to be able to access data about them, accountability for how data are used and use limitations in terms of...and this, I think relates to the harm and discrimination points that we raised earlier.

The third category involves the re-evaluation of existing rules around particularly when we want to leverage data to make contributions to the learning health system and making research rules maybe more efficient and providing some incentives to adopt more privacy-protecting architectures like data enclaves. And then the last point here is strengthening existing rules on patient access to data and this could be part of an examination of the HIPAA rules and guidance under those rules, in terms of the patient's ability to access data under that regime. And also creating patient right of access in the non-HIPAA covered space.

So those are the four sort of overarching spaces where we've got some draft recommendations that we've begun to sketch out. So what do folks think about this category and where we are, at least in draft, headed? Hello, are we still on the line?

**Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology**

I think we're all still here, Deven.

**Micky Tripathi, PhD – President & Chief Executive Officer – Massachusetts eHealth Collaborative**

...I'm here.

**Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology**

I think people are all looking at their...going, what, it's not regulated?

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

No, I don't think they are Lucia, I think everyone on this call knows that.

**David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation**

Yeah, I think we're thinking, boy, I wouldn't have to write those rules.

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

Yeah.

**Stanley Crosley, JD –Director, Indiana University Center for Law, Ethics and Applied Research (CLEAR) in Health Information; Drinker Biddle & Reath, LLP**

Well, and this is Stan; and I am...there are actually a number of private projects going on right now with a number of kind of cross-industry players. I know of at least four separate activities that are going on where they're trying to figure out this...these self-governance codes because everybody's calling for them. The FTC has been very...in calling for self-governance codes. So I think we're going to see some of these, it just it makes sense that HHS and some other agencies would be involved in trying to help shape these as much as possible because for the near-term, this may be the only governance mechanism.

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

Yeah.

**Micky Tripathi, PhD – President & Chief Executive Officer – Massachusetts eHealth Collaborative**

Deven, this is Micky.

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

Yes.

**Micky Tripathi, PhD – President & Chief Executive Officer – Massachusetts eHealth Collaborative**

So I don't know, I mean, the second one just concerns me, maybe it's just because I'm watching what's happening with the 21<sup>st</sup> Century Cures...

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

Oh...

**Micky Tripathi, PhD – President & Chief Executive Officer – Massachusetts eHealth Collaborative**

...and then scares me more and more, perhaps just confirms...

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

Right.

**Micky Tripathi, PhD – President & Chief Executive Officer – Massachusetts eHealth Collaborative**

...the sense that I've had of anything with Congressional action can go many ways, only one of which might be the best way or even a good way. The fourth...I'm just wondering on the fourth one, what would constitute strengthening existing rules? I guess I don't fully understand that, what would strengthening mean, is that through regulatory statutory processes or what does that mean?

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

Well, so that's a good question, Micky, and not one that we've spent a lot of time as a workgroup fleshing out. Certainly in the testimony for the hearing outside of the HIPAA space, there's not a clear right for people to be able to access data that's collected about them. And this...these debates about this have sort of surfaced most recently in the press with respect to devices, like Hugo Campos and his pacemaker and wanting to get...

**Micky Tripathi, PhD – President & Chief Executive Officer – Massachusetts eHealth Collaborative**

Um hmm.

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

...the data from his pacemaker and not being able to because that's not a space where HIPAA provides him with a guarantee that he can at least have access to that data under those rules. So, and it could be that maybe we as a workgroup are prepared just to speak to that particular piece of it, because we did not have a lot of discussion about sort of what, if anything, we would do to HIPAA's basic access rights.

In the non-HIPAA space, they look pretty darn good, given that it does provide for a right of access in the former format that the patient wants, as long as it's producible by the entity in that format. It's...the entity has 30 days to produce it, could take a bit more time if they need to go off-site in order to get those records. There are very few exceptions to that general rule and so it does cover a lot of space. So it could be that we just...we, as a group have not had a lot of time to sort of talk about that access right. It may have been...it may have sort of seeped in here, admittedly because of the conversations going on around the Meaningful Use Rule, which isn't about the HIPAA rule, but there have been a lot of sort of blended discussions about the patient's right of access as a result of the proposed change to Stage 2.

So, I mean I'm amenable to whatever the workgroup feels most comfortable recommending at this stage. Patient access did come up in our hearing.

**Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology**

Deven...

**Micky Tripathi, PhD – President & Chief Executive Officer – Massachusetts eHealth Collaborative**

Yeah, no and I think its fine as a general recommendation, I was just wondering if we had further thought on that.

**Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology**

So, this is Lucia; just one more thing to point out about that. Again, this is in the context of big health data so this isn't quite exactly moving it from one provider to another provider or moving it from a provider to your individual PHR, but this is about how this...the set of reports here about big health data, all those things that we observe about big health data might also be issues, concerns or opportunities in other electronic health information-driven activity as well.

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

Anybody else have any thoughts about any of this? So keep in...on the Congress point, Micky, it's...in the language that we've got in the outline that the text says, Congress could address this through legislation but voluntarily adopted codes of conduct are un...

**Micky Tripathi, PhD – President & Chief Executive Officer – Massachusetts eHealth Collaborative**

Right.

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

...can be enforced by the FTC for entities who are subject to their jurisdiction and adopt it. So it doesn't even actually say Congress should, it says Congress could.

**Stanley Crosley, JD –Director, Indiana University Center for Law, Ethics and Applied Research (CLEAR) in Health Information; Drinker Biddle & Reath, LLP**

Yeah and I actually, yeah, I actually agree with Micky here on the congressional action thing does kind of frighten me a little bit, but I'd want to be much more specific if we were making a recommendation on what we are asking for.

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

Okay. Are people though comfortable with acknowledging that this is something that Congress could address?

**Stanley Crosley, JD –Director, Indiana University Center for Law, Ethics and Applied Research (CLEAR) in Health Information; Drinker Biddle & Reath, LLP**

Yeah, no, I think that's right.

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

Okay.

**Gayle Harrell, MA – Florida State Representative – Florida State Legislature**

This is Gayle...

**Micky Tripathi, PhD – President & Chief Executive Officer – Massachusetts eHealth Collaborative**

But I think its worth...it is worth pointing out that the FTC does have some enforcement authority...

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

Yup.

**Micky Tripathi, PhD – President & Chief Executive Officer – Massachusetts eHealth Collaborative**

...even if codes are voluntarily adopted.

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

Yes.

**Micky Tripathi, PhD – President & Chief Executive Officer – Massachusetts eHealth Collaborative**

That's...point out.

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

Yeah, I heard Gayle.

**Gayle Harrell, MA – Florida State Representative – Florida State Legislature**

Yeah...

**Linda Kloss, RHIA, CAE, FAHIMA – President – Kloss Strategic Advisors, Ltd.**

And Linda...

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

And Linda. Okay, Gayle then Linda.

**Gayle Harrell, MA – Florida State Representative – Florida State Legislature**

Okay, I'd like to agree with Micky; I really feel a little uncomfortable. The "could" would be much better than the "should."

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

Okay.

**Gayle Harrell, MA – Florida State Representative – Florida State Legislature**

And we want to make it very clear that we are not directing that this happen, you know if they look at it as we are volunteering system of this sort would be much more preferable and...some monitoring of that. But, I don't know that we want to tell Congress they should go and do something; you never know what's going to come out of that.

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

Okay.

**Micky Tripathi, PhD – President & Chief Executive Officer – Massachusetts eHealth Collaborative**

And Gayle, just for the record, we love individual legislators, it's just when they get together at the national level, they seem to do crazy things.

**Gayle Harrell, MA – Florida State Representative – Florida State Legislature**

As a lawmaker I can tell you, I know what happens.

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

Linda.

**Linda Kloss, RHIA, CAE, FAHIMA – President – Kloss Strategic Advisors, Ltd.**

Yes, thanks. The NCVHS privacy, confidentiality and security subgroup just held a hearing on application of HIPAA and the exclusions for financial institutions under 1179.

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

Ahh.

**Linda Kloss, RHIA, CAE, FAHIMA – President – Kloss Strategic Advisors, Ltd.**

And one of the things we learned was how different the regulatory environments are across industries and it seems to me that one of the areas, like for example, patient access to data; that isn't a whole cluster of regulations that exists at all in the financial institutions. So I'm wondering if one of the recommendations might be that the HIPAA standards apply, even as if healthcare data is being combined with financial or other kinds of data, what trumps? And it seems to me we need to be held to at least what is now the na...the current highest standard...

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

Are you talking about...

**Multiple speakers**

(Indiscernible)

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

Are you talking about for patient access, Linda?

**Linda Kloss, RHIA, CAE, FAHIMA – President – Kloss Strategic Advisors, Ltd.**

Right, right, right.

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

Okay.

**Linda Kloss, RHIA, CAE, FAHIMA – President – Kloss Strategic Advisors, Ltd.**

So if you think about that, we can expect in big data that this isn't just merging a lot of health data, that it's health data sets with a lot of other kinds of data sets, you know what regulation applies in those circumstances? And I think we could probably speak to that issue.

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

Got it.

**David F. Kotz, PhD – Associate Dean of the Faculty for the Sciences – Dartmouth College**

This is David.

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

Hi, David.

**David F. Kotz, PhD – Associate Dean of the Faculty for the Sciences – Dartmouth College**

So I was wondering, maybe this is a naïve question, do we have a definition earlier in this document somewhere about what is health data? If we're calling for policies or regulations related to non-HIPAA covered health data, then it seems like we would need to define health...

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

Yeah, so I believe, although it's worth checking in the outline and it wouldn't have been actually in the pieces that we shared with you.

**David F. Kotz, PhD – Associate Dean of the Faculty for the Sciences – Dartmouth College**

(Indiscernible)

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

But from the very beginning of these conversations, I think that where we have landed is that we want "health data" to be your sort of obvious candidates of health and wellness data, but any data that then is collected about an individual that might not be health data on its face, but...

**David F. Kotz, PhD – Associate Dean of the Faculty for the Sciences – Dartmouth College**  
Uh huh.

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**  
...then is used for a health purpose.

**David F. Kotz, PhD – Associate Dean of the Faculty for the Sciences – Dartmouth College**  
Okay.

**Stanley Crosley, JD – Director, Indiana University Center for Law, Ethics and Applied Research (CLEAR) in Health Information; Drinker Biddle & Reath, LLP**  
And infer health status...

**David F. Kotz, PhD – Associate Dean of the Faculty for the Sciences – Dartmouth College**  
Yeah, I'm sure it gets pretty gray at the edges there, but...

**Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology**  
David, this is Lucia; I think there was a lot of testimony about data that's about people's health, while it might not be PHI in the HIPAA sense, is still data about their bodies and their minds. And secondly, we know...here at ONC we know that people think things about health data in general that may not be true. They think HIPAA applies when it doesn't, they think it doesn't apply when it does; like there's a whole universe of that confusion that this is just another symptom of.

**David F. Kotz, PhD – Associate Dean of the Faculty for the Sciences – Dartmouth College**  
Oh, I believe all that and I just wondered if we...where do we draw the line if we have a policy, you know. And so...because all that is health data, but there's for example, behavioral information is very interesting and not necessarily about your health, but it can be used, obviously, in health.

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**  
Yeah. Well and we talked about...we never had testimony specifically from the folks that Fair Isaac, but the development of a prescription, the score that they came up with for predicting which individuals would be likely to take their prescription medications...

**David F. Kotz, PhD – Associate Dean of the Faculty for the Sciences – Dartmouth College**  
Uh huh.

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**  
...is likely not informed by health data at all.

**David F. Kotz, PhD – Associate Dean of the Faculty for the Sciences – Dartmouth College**

Right.

**Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology**

And we do have testimony that who eats which kinds of food and in what quantities is data about health, even though it's retail consumption data.

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

Right but...

**David F. Kotz, PhD – Associate Dean of the Faculty for the Sciences – Dartmouth College**

So, do we...

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

...depending on how it's used.

**David F. Kotz, PhD – Associate Dean of the Faculty for the Sciences – Dartmouth College**

...just want to say based on its use? Okay.

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

So we generally say at the beginning that we wanted our recommendations aimed at the health and wellness data both in the HIPAA space and outside the HIPAA space, but also data that might not on its face look like health data at all, but when it's used for a health purpose.

**David F. Kotz, PhD – Associate Dean of the Faculty for the Sciences – Dartmouth College**

Okay. Fine.

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

But it's worth emphasizing. Other thoughts? Okay, we got some good feedback on this; we'll re-evaluate the text that's on there and come up with a refined set of recommendations based on the discussion. Let's see what we can do with the next category, which is on de-identification; next slide, please.

So here we've got, and Linda Sanches no intent to put you on the spot here, but we do have some language in the report that...or in the draft outline that calls for some more regular review of the HIPAA de-identification standards and more regular guidance, beyond the guidance that was fairly recently issued around de-identification, to make sure that the methodologies remain robust. And acknowledging that it may be helpful to have assistance from third-party experts like those at NIST to sort of keep up with the latest on what's going on with state of the art de-identification methodologies and re-identification techniques.

**Linda Sanches, MPH – Senior Advisor for Health Information Privacy – Office for Civil Rights**

I enjoyed those recommendations when I read them.

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

Okay, good.

**Linda Sanches, MPH – Senior Advisor for Health Information Privacy – Office for Civil Rights**

I wonder if Congress will actually provide us some funding for those efforts.

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

Yeah, well that would sure be helpful.

**Linda Sanches, MPH – Senior Advisor for Health Information Privacy – Office for Civil Rights**

Yeah, but yes, depends on a lot of new information in this space.

**David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation**

Deven?

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

They're thinking about...we considered that actually as a workgroup. David, go ahead.

**David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation**

Deven...

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

Yeah.

**David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation**

The only thing that I might suggest you add to this, and maybe it's incorporated in one of these and I just haven't parsed it carefully enough is, the use of the data haven notion where you have data that is de-identified but if it was data in the wild you might actually be able to re-identify it because of the ease with which you could combine it with other external sources. But if it's in a data haven so that you can't get at that, you get the effect of essentially being de-identified even though it might not have been impossible to reverse it in the wild. So, I was impressed by the several people that talked about the effective use of data havens...

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

Yeah.

**David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation**

...which to me strikes me as a little bit different than just the de-identification methodology per se.

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

Right, so what we've got is somewhat reflected in the last bullet, although maybe imperfectly so, in the text of the outline it says, consideration should be given to risk-based de-identification requirements and the re-identification risk when data is held by entities or in environments where re-identification risk is lowered by the way that the data is held. So like a data enclave...

**David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation**

Yes. Yes.

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

...or another sort of data repository that meets strong security requirements, for example.

**David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation**

Yeah, I see it now; thank you. I just...I was...data enclave is a phrase I meant to use and I just wasn't focusing...

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

Data haven, data enclave, data mart...

**David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation**

Yeah, no, but that's what I meant there is that you assess the overall risk of the system which may mean that you take a different approach to the de-identification because you have certain other things in place to guarantee the data's not available for combining with external sources.

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

Right.

**David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation**

Because I don't think you can really de-identify anything if you can combine it ad lib.

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**  
Right.

**David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation**  
You have to have something like this.

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

Yes. So in addition to noting that, we also do expressly talk about whether the safe harbor methodology its use should be more limited to the circumstances where the safe harbor has been tested previously and found to be robust, which according to the testimony that we got from one of our experts, was when the data is a large random sample of the population, the safe harbor tends to work relatively well. But that presumes that you're not going to be combining that data with other types of data or that in fact the circumstances that govern the data collection do sort of meet the criteria that make the safe harbor work better.

Re-evaluating de-identification status of a data set when context changes; this is the issue of the mosaic effect and the potentially changing re-identification risk when data sets are combined. Developing or encouraging programs to objectively evaluate statistical methodologies that are used for de-identification. And whether those that turn out to be promising in certain types of data sets ought to be given sort of safe harbor status in that context, which is much more desirable from a legal risk standpoint, to have some degree of sort of certainty if you're using something that's been proven and vetted and that it's been granted some safe harbor status.

And then, of course, here we do mention Congress here, so we should talk about whether we still want to take a hands-off approach to that, but there isn't a way for regulators today to, through regulation, sort of prohibit re-identification or making...or being sloppy, at least outside of HIPAA, with how you de-i...how you...what sorts of methodologies you use to claim you've got data that had been appropriately de-identified. You know, we did have some testimony about contractual approaches to prohibiting re-identification, which certainly we know people today, data holders today sometimes use to reduce re-identification risk. But you don't have this sort of regulators can come after you if you're re-identifying data sets that are supposed to be de-identified. Nobody has that power today, from a policymaker standpoint. Folks, what do we think of these?

**Gayle Harrell, MA – Florida State Representative – Florida State Legislature**  
This is Gayle; can I jump in?

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**  
Yeah.

**Gayle Harrell, MA – Florida State Representative – Florida State Legislature**

I am very reluctant to put things in the hands of Congress, but...or any, being a legislator, any legislative body to go into something quite as complex as this. However, in a situation where if there's no current law that really comes to the level...needs to be, where technology has gone; if law is so far behind when it's possible technologically, then you're opening up a whole new arena. And that takes some significant thought before you go down the legislative road.

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

Right.

**Gayle Harrell, MA – Florida State Representative – Florida State Legislature**

So before you ask for laws to be passed, I would certainly say that maybe we need to have HHS or OCR or someone really do an in-depth study as to what the specific problems are? What issues have developed with de-identification? And have very specific examples and how you would solve that legislatively. You don't go into an arena such as this without really taking that in-depth look. We scratched the surface on it with our hearing and really opened some doors to thinking on it, but I would say we really need to have maybe OCR or HHS or someone take an in-depth look at this and bring back specific recommendations as to what you would do to...what you could do legislatively to prevent the de-identification.

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

Hmm. That's, I hadn't really thought of that, Gayle. There's been so many reports that have come out of parts of the administration, not OCR to the best of my knowledge, but the President's Council for Advisors on Science and Technology...

**Stanley Crosley, JD –Director, Indiana University Center for Law, Ethics and Applied Research (CLEAR) in Health Information; Drinker Biddle & Reath, LLP**

Um hmm.

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

...for example, the JASON Report to provide another example...

**Gayle Harrell, MA – Florida State Representative – Florida State Legislature**

Yes.

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

...of people saying, de-identification doesn't work, but nobody really doing the sort of in-depth analysis of just really what the HIPAA de-identified data re-identification risks are, beyond the testimony, of course, that we got...

**Gayle Harrell, MA – Florida State Representative – Florida State Legislature**

Correct.

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

...in our hearing from the experts that we heard from.

**Gayle Harrell, MA – Florida State Representative – Florida State Legislature**

And how do you prevent it?

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

Right.

**Gayle Harrell, MA – Florida State Representative – Florida State Legislature**

Not just...you don't want...you want the analysis, but you also need to say, okay, realistically, what can you do to prevent it and, you know...

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

Well that is the sort of data enclave, data haven sort of issue that we do raise.

**Gayle Harrell, MA – Florida State Representative – Florida State Legislature**

Right.

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

It isn't a prevention but it's another sort of risk reduction strategy.

**Gayle Harrell, MA – Florida State Representative – Florida State Legislature**

Correct, so you need to have those recommendations in place when you go and say, yes, this is something that should be addressed or needs to be addressed.

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

Right.

**Gayle Harrell, MA – Florida State Representative – Florida State Legislature**

You know, have a plan in place before you go and throw a problem up against the wall.

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

Yeah. Fair point. We will not ask Congress to...so it's like we're not ready for that.

**Gayle Harrell, MA – Florida State Representative – Florida State Legislature**

I don't think... would be ready for that.

**David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation**

Deven?

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

Okay. David?

**David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation**

Deven, this is David. It's David; unfortunately I have to leave to go to another meeting that I don't get a chance to get out of, so, thanks and sorry miss the tail end of the conversation.

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

Well thanks for the time you were able to give us, David.

**David McCallie, Jr., MD – Senior Vice President, Medical Informatics – Cerner Corporation**

I enjoy it; thanks. Bye, bye.

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

Anyone else on this issue of Congress and re-identification on Gayle's set of points?

**Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology**

So this is Lucia. And if we're going to accurately capture the testimony that was provided, that was definitely within the testimony that was provided as were the techniques of enclave and the techniques of contract that people can prohibit re-identification by contract and doubts about the long-term strength or adequacy of that. So all those things are things that our witnesses said, and I guess my question Gayle is, are you comfortable with us describing that as things the witnesses said without necessarily us endorsing one of them?

**Gayle Harrell, MA – Florida State Representative – Florida State Legislature**

Oh yes, I think all that information needs to be put forward, very much so. And as potential ways of dealing with the problem, to what the definition of the specific problem is and that should definitely be put out there. As far as saying what the legislation needs to look like, I think we're a long way from that; but those kinds of issues need to be there.

**Stanley Crosley, JD –Director, Indiana University Center for Law, Ethics and Applied Research (CLEAR) in Health Information; Drinker Biddle & Reath, LLP**

...this is Stan. Linda would it help if we were talking...consider those recommendations that we're talking specifically about the re-identification of...under HIPAA of data that has been previously de-identified under HIPAA, under the safe harbor? Maybe if we narrow what it is we're talking about as accountability for that attempted re-identification, is it narrowing what we would look at or part of that?

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

Well I just had a sense that Gayle and maybe some potential other members of the workgroup who haven't had a chance to chime in yet are...just sort of feel like it's premature to say definitively that we need Congress to pass a law...

**Stanley Crosley, JD –Director, Indiana University Center for Law, Ethics and Applied Research (CLEAR) in Health Information; Drinker Biddle & Reath, LLP**

Right.

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

...on this.

**Stanley Crosley, JD –Director, Indiana University Center for Law, Ethics and Applied Research (CLEAR) in Health Information; Drinker Biddle & Reath, LLP**

Right. Okay, yeah. And I think it...I agree, and this is Stan; I agree that it's in the broadest sense...this...if we were to narrow it into further buckets maybe, but I'm fine with that.

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

I do, I think we can...what we can do is just talk in the report about, as Lucia pointed out, and this wouldn't be in the recommendation section. This would be earlier in the report about what people recommended to us to resolve this, you know dealing with the residual re-identification risk is ultimately going to be important, but we also have a good set of recommendations to try to reduce that risk, which is an important set of accountability mechanisms that stop short of criminalizing or creating civil penalties for re-identification. And we, you know as I think Khaled's testimony pointed out to us, we actually don't in the HIPAA space have a lot of evidence of re-identification going on, at least that we're aware of, so...

**Stanley Crosley, JD –Director, Indiana University Center for Law, Ethics and Applied Research (CLEAR) in Health Information; Drinker Biddle & Reath, LLP**

Right.

**Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology**

Yeah, I mean there's a lot of let's just call it chatter about that amongst the statisticians, but you're right, I don't know that we have prohibited re-identification that's been definitively investigated.

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

Yup.

**W**

Right, I mean I know you've heard me say this before but no one has come to us and we haven't seen reported any HIPAA de-identified data set that has been re-identified.

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

Yeah.

**W**

I'm not saying it hasn't happened, but it would be great to have something we could actually chew on.

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

Yeah. It's never good to try to regulate a problem that may, in fact, not exist yet.

**Gayle Harrell, MA – Florida State Representative – Florida State Legislature**

And once you start regulation you put all kinds of reporting requirements in, you see increased cost of compliance with things that perhaps didn't need to happen to start with, wind up making things very difficult to do.

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

Yeah. Okay, any...we're making really great progress on these; any other thoughts on this sort of set of...we've got some massaging to do here, too clearly, and we will do that in advance of our next call. But any other thoughts on the de-identification piece?

**Linda Kloss, RHIA, CAE, FAHIMA – President – Kloss Strategic Advisors, Ltd.**

This is Linda and do we want to put in a recommendation on education here? I think this is an area where there's just so much misunderstanding and myth and it is one where everybody needs to get a little wiser. So maybe this is you know in the OCR vein of the interoperability roadmap that there's an educational piece here.

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

Around de...and...HIPAA or sort of generally.

**Linda Kloss, RHIA, CAE, FAHIMA – President – Kloss Strategic Advisors, Ltd.**

Around...generally. Generally.

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

Yeah. Okay. Anybody...sounds like a good idea to me; Stan, anybody have any objections to that?

**W**

Nope.

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

Education is always a good recommendation.

**Stanley Crosley, JD –Director, Indiana University Center for Law, Ethics and Applied Research (CLEAR) in Health Information; Drinker Biddle & Reath, LLP**

Yeah and along with it, maybe just a little more context around the re-identification risk, too...

**Linda Kloss, RHIA, CAE, FAHIMA – President – Kloss Strategic Advisors, Ltd.**

Yeah.

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

Okay, great. Thank you Linda. All right, so the last sort of recommendations deal...next slide, please, deals with the issue of security. And here we had an entire sort of half-day; we had several persons come to talk to us, this was actually in January, I believe. We didn't have a lot of testimony in our December hearings about this so we went back and asked several people to come and talk to us about the...and we heard from them that there was a need for really a sort of end-to-end kind of secure environment for health data, which is particularly a challenge to do because you...we don't regulate in the US based on the data. And so no single actor within the data ecosystem is really responsible for the end-to-end aspects of this.

Certainly entities that are covered by the HIPAA Security Rule need to adopt protections within their environment, but the data that becomes health data may be popping in and out of that environment on a daily if not hourly basis, depending on the type of data and the circumstance. And so we just don't have that and in addition we, while the Federal Trade Commission certainly has a set of security expectations and with the authority that they have, they have health companies accountable for lack of good security protections for consumer data. We don't necessarily have a sort of comprehensive set of security requirements that would hit all of the different actors in the ecosystem. And so we've got some recommendations here sort of calling on ideally a desirable end-to-end security network, but acknowledging that the policies don't quite measure up. And so while we don't call on Congress specifically here, we do have this sort of vague, admittedly vague, calling on policymakers to, we said enact comprehensive legislation; I guess that's got to be Congress, so we'll have to think about how...what we want to say here about the lack of a comprehensive environment.

It could be that we want to, as I'm thinking about this, get back to the voluntary codes of conduct that we talked about earlier. That recommendation actually isn't necessarily reflected here and perhaps it could. Do we have enough incentives to have entities using the sort of privacy-enhancing technologies and architectures that are both about protecting privacy, but also have good security attached to them.

And then we also had some recommendations that the Tiger Team developed back in 2011 that we circulated to you, actually I think it was several weeks ago, where...it was back in December of 2011, the Tiger Team had been asked to take a look at the HIPAA Security Rule and compare it against a number of other security frameworks, including ones that apply to the Federal Government, as well as some voluntary security frameworks like HITRUST, for example, and sort of take a look at how it measured up.

And we did not put ourselves in the position of evaluating or judging one framework to be better than the other, but we did call for the need for a flexible and scalable framework, given the different resource levels for the different actors in the space. But also calling for education and guidance as well as a consistent and dynamic process for really updating policies as circumstances change and the threats change and the need to be more...to place priorities around security in different...on different types of protections or on different types of threats that arise as circumstances change.

And so this doesn't...this is...we were trying to sort of provide for some recommendations that could help create the end-to-end type of security environment that's desirable. But acknowledging that we're hamstrung by our general approach to regulating on a sectoral basis and by sort of, again, we have some laws that cover some entities in this space and not all. Wo...this is another area where we can do more to sort of pull in from the testimony that we heard from some of the security experts that spoke to us and we would do that in the body of the report.

**Stanley Crosley, JD –Director, Indiana University Center for Law, Ethics and Applied Research (CLEAR) in Health Information; Drinker Biddle & Reath, LLP**

(Indiscernible)

**Gayle Harrell, MA – Florida State Representative – Florida State Legislature**

This is Gayle again; I'm going to jump in on this, too.

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

Okay.

**Gayle Harrell, MA – Florida State Representative – Florida State Legislature**

Okay, I think the recommendations that the Tiger Team did back in 2011 are still very, very valid.

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

Okay.

**Gayle Harrell, MA – Florida State Representative – Florida State Legislature**

We have seen many breaches since then, so I think those recommendations need to be reiterated and very strongly so. The scalability and flexibility of security needs to be there; technology changes on a daily basis and you've got to be able to do that. You also...I think there's so much that can be done within guidance and the encouragement of the different department where if it doe...if it falls out of HIPAA, what else can be done? HHS has...and OCR has the ability to offer guidance without getting into specific law changes.

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

Um hmm.

**Gayle Harrell, MA – Florida State Representative – Florida State Legislature**

And I think, and perhaps I don't have an in-depth knowledge enough to know what guidance has already been issued, but perhaps you could give us an indication of that or maybe our staff could, as to do we not...has HHS not really taken any steps to look at this and what they already have out there and what more they could do, under guidance?

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

Right, in the HIPAA space.

**Gayle Harrell, MA – Florida State Representative – Florida State Legislature**

In the HIPAA space or even beyond HIPAA space, you know what other entities, is it OCR that would be the guiding force behind that? Who else would be able to offer guidance?

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

Well I think in the, you know, the Federal Trade Commission...

**Gayle Harrell, MA – Florida State Representative – Florida State Legislature**

Okay...

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

...and the work that they do to have some oversight over privacy and security in consumer-facing space.

**Gayle Harrell, MA – Florida State Representative – Florida State Legislature**

Okay, so what kinds of guidance do they have out there and what are their...what provisions and ability do they have to look at this space, the healthcare space and say, we need to perhaps beef that up a bit?

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

Oh yeah, no, they have some, they have authority and they've been doing...I'll certainly let out FTC reps on the phone speak to this, but they have been talking about health and health technologies and health data in a number of different reports and white papers that they've put out over the past several years.

**Gayle Harrell, MA – Florida State Representative – Florida State Legislature**

Um hmm.

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

So there are definitely some things out there, I'm not sure everyone's aware of them, though.

(Indiscernible)

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

In fact I know that earlier we just didn't sort of bring over the voluntary code of conduct recommendation that we had in the other section and it might also fit very well here, too.

**Gayle Harrell, MA – Florida State Representative – Florida State Legislature**

Yes, I think it would; absolutely.

**Manuj Lal, JD – General Counsel, Corporate Secretary & Chief Privacy/Information Security Officer –PatientPoint Enterprise**

Hey Deven, this is Manuj.

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

Hey Manuj.

**Manuj Lal, JD – General Counsel, Corporate Secretary & Chief Privacy/Information Security Officer –PatientPoint Enterprise**

Hey. There were some NIST standards that were released in 2008, I believe, for implementing the security rule, the HIPAA Security Rule. I know in my circles at least, folks put a lot of weight behind what NIST does and...

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

Yeah.

**Manuj Lal, JD – General Counsel, Corporate Secretary & Chief Privacy/Information Security Officer –PatientPoint Enterprise**

...understand that HITECH obviously put a lot of weight behind it as it related to encryption. I think it would be really great if we saw NIST take on a more active role and maybe taking one degree beyond kind of this type of document that I'm referring to, the implementation guidance and update it for the new challenges we're looking at today like beefing up things like data transfer among non-affiliates and things like that. I would love to see that happen and I think it would be a really great resource for people to look at.

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

Thanks, Manuj.

**Manuj Lal, JD – General Counsel, Corporate Secretary & Chief Privacy/Information Security Officer –PatientPoint Enterprise**

Yup.

**Cora Tung Han, JD – Division of Privacy and Identity Protection, Bureau of Consumer Protection – Federal Trade Commission**

And this is Cora, I should just hop in here and I can point some people towards some resources on the FTC's website but we have data security business guidance and also a few guidance pieces aimed at security practices in the connected space that went along with our Internet of Things Report. And we also have some guidance for mobile App developers, which I think would be applicable in this space. And then we also did a seminar not too long ago on Consumer Generated and Health Data, and you can find all of that info on our website and I'd also be happy to direct people to it.

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

Thank you, Cora. That would be very helpful; we can include that.

**Gayle Harrell, MA – Florida State Representative – Florida State Legislature**

Would you e-mail that around, the link?

**Cora Tung Han, JD – Division of Privacy and Identity Protection, Bureau of Consumer Protection – Federal Trade Commission**

Sure. Yes, I'd be happy to; I'll e-mail a set of links to Deven and then she can circulate them.

**Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology**

Actually Cora, if you could just send it to Michelle Consolazio, then we can distribute it without taking up Deven's good time.

**Cora Tung Han, JD – Division of Privacy and Identity Protection, Bureau of Consumer Protection – Federal Trade Commission**

All the better, great.

**Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology**

Sorry to volunteer you Michelle, or me.

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

No, thank you, Lucia.

**Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology**

This is Lucia; the other thing...Cora's...exactly right but the think to really understand is, a couple things. I think most of our witnesses were very clear, if they knew about the relative roles of the FTC and OCR, other federal agencies, they were aware of this thing which is, the FTC doesn't actually issue regulations.

So, they can give best practices and they publish a lot of really informative stuff on their website and of course when they...when an investigation or enforcement action that is generally publically known as well. But they're not a regulation-writing agency, so they don't sort of undertake the same activity that OCR or other Health and Human Services divisions might undertake in terms of giving regulations as a, here's how you should do it sort of thing that's a requirement.

**Cora Tung Han, JD – Division of Privacy and Identity Protection, Bureau of Consumer Protection – Federal Trade Commission**

Right, that's right. I just added certain context...have done regulations, but Lucia is absolutely right, that's sort of generally under our Section V is we don't issue regulations.

**Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology**

So you have to understand that guidance has a bunch of different meanings; so sometimes guidance really has the effect of a requirement, which is when it comes through regulation, and sometimes it doesn't. It's just a good idea, it may be a really good idea, but it's not enforce...it's a good idea.

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

Okay. Well we'll be sure to beef up the sort of guidance best practices points here as opposed to the congressional points, I think we don't have consensus that Congress should be specifically acting here. So we'll work with the...with both what we did back in 2011, but also the suggestions that we've gotten on this call.

**Gayle Harrell, MA – Florida State Representative – Florida State Legislature**

And Deven also...it's Gayle again; if you add that education piece that we previously mentioned...

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

Right.

**Gayle Harrell, MA – Florida State Representative – Florida State Legislature**

...I think making sure that there is an education component to this as well.

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

Right, right.

**Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology**

Hey Gayle, this is Lucia; just a point of clarification. Are you talking about education for the businesses that do this activity or education for the consumer who's data is at play in the data or both...clear, 1, 2 or both.

**Gayle Harrell, MA – Florida State Representative – Florida State Legislature**

Both, absolutely both.

**Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology**

Okay.

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

Okay. Anyone else? Okay, well why don't we go ahead and pull up the instructions for public comment and pause for a moment and allow Michelle and Altarum to announce the upcoming public comment period.

**Public Comment**

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Caitlin or Lonnie, can you please open the lines?

**Lonnie Moore – Meetings Coordinator – Altarum Institute**

If you're listening via your computer speakers, you may dial 1-877-705-2976 and press \*1 to be placed in the comment queue. If you are on the telephone and would like to make a public comment, please press \*1 at this time.

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

Okay, great. So while we wait for anyone who's interested in making a public comment to queue up, I want to sort of...we've gone through all of the recommendation areas in the slides that we had created for this call. Is there anything that people had hoped to see in our big data recommendations that we didn't talk about and that we haven't...that we need to find a home for or have a discussion about and include as we go back and revise what we've done of these recommendations and come up with a set that we intend to present to the Policy Committee?

**Gilad Kuperman, MD, PhD, FACMI – Director of Interoperability Informatics – New York Presbyterian Hospital**

Deven?

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

Yes, Gil.

**Gilad Kuperman, MD, PhD, FACMI – Director of Interoperability Informatics – New York Presbyterian Hospital**

Gil Kuperman here; this may be kind of a rhetorical comment but, and I think the recommendations are terrific and great work and thanks to you and Stan for doing this. The observation I have is, you know, I wonder how much of this is really related to big data per se and how much of this is just kind of recommendations going forward that are germane, even to the current environment. I think there's a couple of things around the algorithms and the transparency and maybe some of the stuff around the de-identification issues maybe; but in general, just some of these things seem kind of germane to...

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

To lots of different things.

**Gilad Kuperman, MD, PhD, FACMI – Director of Interoperability Informatics – New York Presbyterian Hospital**

...yeah, to lots of things. So I didn't know if that's kind of something to be considered or mentioned or thought of or not; so I just wanted to mention that.

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

Yeah, no, I mean I think it's, Gil, I think it's kind of a fair point. It's...we sort of, and I don't think it's necessarily accidental and I'm not sure that it's necessarily a bad thing, in part because I think we were aiming at trying to build trust in uses of data. And maybe we didn't just focus solely on analytic uses...

**Gilad Kuperman, MD, PhD, FACMI – Director of Interoperability Informatics – New York Presbyterian Hospital**

Um hmm.

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

...but we, in our discussion of sort of what builds trust, I think we have surfaced a lot of issues that are...may not be relevant just to big data at all and are really about sort of just uses and disclosures of health data or data related to health generally and not just in the analytic space. I mean, it's a good point, it could be that when we present these, we will need to emphasize those that are sort of more about data analytics and learning and others that have...that certainly would have an impact on data analytics and learning, but are protections that are not just about those particular types of uses. I mean I don't...

**Gilad Kuperman, MD, PhD, FACMI – Director of Interoperability Informatics – New York Presbyterian Hospital**

Yeah, you know, I didn't know if that may be...might be a question that you might get from the Policy Committee.

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

Oh, we might.

**Gilad Kuperman, MD, PhD, FACMI – Director of Interoperability Informatics – New York Presbyterian Hospital**

Yeah, but one of the things I think is that you know, the way we kind of defined big data at the beginning, the volume, velocity, variety, etcetera, you know, that those kinds of issues I think increase the urgency with which some of these lingering issues, which are already present in the environment that even though it may not identify anything new per se that the urgency will be increased as we move into the era of big data. So, it may be just kind of amplifies what may have been kind of lingering concerns...

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

Right.

**Gilad Kuperman, MD, PhD, FACMI – Director of Interoperability Informatics – New York Presbyterian Hospital**

...might be one way to say something about it.

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

Yeah, that's a good point. Other folks on that issue or any issue that we haven't discussed? Okay, Michelle, do we have any public comment?

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

We do, Stephanie Hoelscher. As a reminder, we have 3 minutes for public comment. Please go ahead Stephanie.

**Stephanie Hoelscher, BSN, RN, CHISP – Nurse Manager, Chief Clinical Analyst - Texas Tech University Health Sciences Center**

Yes ma'am, thank you. My name's Stef, I'm a nurse and a Chief Clinical Analyst from Lubbock, Texas; this is my first time on an ONC call. I appreciate it and I think it's very well run. I did want to discuss a little bit just very quickly on 6.3 with your discussion of de-identification and re-identification. We are potentially in the future going to use it for big data pooling, but we're actually de-identifying an entire EHR domain right now for the purpose of the Simulation Center.

So the use of de-identified data has become very important; we've brought in some live data and are in the process of scrambling and there's not a whole lot of literature out there on that right now, so I'll be curious as to what everyone comes up with. We have tried to adhere to the HIPAA data point standards, so that's come in really handy. And with re-identification of patient data later for data extraction; that should come in real handy as well. So I'm interested in the ONCs development with EHR big data extraction that's been very helpful today.

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

Terrific. Thank you, Stephanie, I hope you...

**Stephanie Hoelscher, BSN, RN, CHISP – Nurse Manager, Chief Clinical Analyst - Texas Tech University Health Sciences Center**

Thank you.

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

...participate in more of our calls; your comment was very helpful.

**Stephanie Hoelscher, BSN, RN, CHISP – Nurse Manager, Chief Clinical Analyst - Texas Tech University Health Sciences Center**

Thank you.

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

Thank you. That...any others Michelle?

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

No, that's it.

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

All right. Well, I want to thank the working group for a terrific and very efficient call. We clearly have some work to do in incorporating your suggestions and recommendations into the outline. Anything else you want to send us offline, if you haven't had a chance to sort of read through the text yet and you have a chance to do so and want to send us some more thoughts, please do. Otherwise, you can expect a revision coming your way and we'll have a chance to talk about it at our next...on our next call later this month.

**Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology**

Hey Deven, in terms of input from the committee members who haven't...the workgroup members that haven't been...this is Lucia; closely involved in the actual day-to-day work, is there a time limit on which it would be helpful to get their comments for incorporation in the next round?

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

That's a good question. So we have our next call on June 22...

**Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology**

So maybe June 18 or June 17?

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

I'm just trying to pull up my calendar so I can see what dates those are.

**Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology**

June 17 is the Wednesday, so that's 10 days from today.

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

Yeah, that would be great.

**Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology**

Okay, so close of business Eastern on June 17.

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

Yeah, but we'll...

**Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology**

And if you get them to me or Helen or Kathryn or Deven or Stan, we'll make sure they get circulated.

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

Right, although it occurs to me, Lucia that in the meantime we probably will just start to revise this...

**Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology**

Exactly, I don't...we're not going to wait, it's just that would be the drop dead, like earlier is better everyone.

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

Yeah.

**Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology**

In all your spare time.

**Deven McGraw, JD, MPH, LLM – Partner – Manatt, Phelps & Phillips, LLP**

Right, right. And in the meantime, if we're able to get you a revised draft out sooner, and we always try to give a coup...a few days...for people to take a look and give us additional comments on even a more recent draft. But, still would be helpful to have comments on what we've done so far if you...additional ones, beyond the ones that you've...the input that we've had on this call, which has been great, if you can. Okay, well with that, I hope everyone has a terrific rest of your day, look forward to talking with you again in a couple of weeks.

**Stanley Crosley, JD –Director, Indiana University Center for Law, Ethics and Applied Research (CLEAR) in Health Information; Drinker Biddle & Reath, LLP**

Thanks, Deven.

**Lucia C. Savage, JD – Chief Privacy Officer – Office of the National Coordinator for Health Information Technology**

Thank you, Deven.

**Michelle Consolazio, MPA – Federal Advisory Committee Program Lead – Office of the National Coordinator for Health Information Technology**

Thank you, Deven.

**Gayle Harrell, MA – Florida State Representative – Florida State Legislature**

Thank you, Deven.

**Gilad Kuperman, MD, PhD, FACMI – Director of Interoperability Informatics – New York Presbyterian Hospital**

Thank you.