Briefing on the Activities of the Office of the National Coordinator for Health Information Technology and the American Health Information Community
Robert M. Kolodner, M.D. and Jodi G. Daniel, J.D., M.P.H.

DR. TUCKSON: Right on time, look who's here. It's Dr. Kolodner and Jodi Daniel.

Now, the key we have been talking about for many meetings has been how important the health information technology infrastructure is going to be to the transformation of health care and, in particular, personalized care and particularly in the notion of genetics.

So Dr. Kolodner has stepped in marvelously to actually be the leader in coordinating across about 18 different task forces, of which I think I'm on half of them. That's why I really know that Dr. Kolodner is on his game. Believe me.

So thank you so much for joining us and giving us this background. I hope that what the committee will get from this is not only getting the overview of what's going on in HIT, seeing some of these committees, seeing and thinking then about how this infrastructure is available to advance the interests that we have.

And thank you so much, Jodi, for joining us as well.

DR. KOLODNER: Thank you very much, Dr. Tuckson. It's a pleasure to be with you today. I look forward to not the presentation as much as the question and answer afterwards. I'll be doing part of the presentation. Jodi Daniel, the Director of the Office of Policy and Research within the Office of the National Coordinator, will be doing the second part of the presentation.

So as you know, there are multiple challenges to the advancement of the genomics. And we heard about a number of them, the issues of discrimination on the basis of genetic information that we need to protect against, that the genetic information is unique to the individual, is predictive of a person's future health, and is immutable, especially once disclosed. Unique information really does not only affect the information about an individual, but the information about other related family members. And while we had that with family history, it really wasn't as powerful as it is seen with the genetic information itself.

Finally, the challenge, that that genetic information, by then being supplemented with other types of data by non-covered entities, could be relinked, and that we need to do the protection to make sure that sort of violation of privacy does not occur.

Health IT itself, as Dr. Tuckson mentioned earlier on, can really add value to the genomics, both helping to enhance the adoption and utility -- there's a huge amount of information. In order to bring it to the forefront and to the front line clinician so that it makes a difference or to the individual themselves, we need IT to enable that. This issue of trust in the privacy and security of that information is fundamental in order for individuals, you and I and our friends and colleagues, as well as family, to allow that information to be used and to be captured now and into the future.

So there are a number of drivers for health IT adoption, and one of those that is pushing us is that rising cost of health care in the U.S., the fact that in the U.S. health care is double the GDP of any other nation and that, frankly, we're not getting the value of those dollars that we're investing. More importantly, if it continues to rise at the rate that it's going, it will fundamentally undermine our economy into the future, even as now it is challenging the global competitiveness of our corporations.

But there are also positive drivers for health IT adoption. First of all, the fact that consumers and the economy begin to see some of the substantial benefits that can come from it, and there are some organizations in the forefront having shown where health IT can help to improve care.

The administration's leadership, both in the executive branch, the President and Secretary Leavitt, as well as on the Hill, and there's real bipartisan support for the health IT agenda, which is extremely important as we move forward.

And finally, the strong endorsement from industry and commercial leaders who will be able to benefit in terms of their global competitiveness and the fact that so much of our current costs, when we go to market our services and our products overseas, are tied into the cost of supporting health care.

Now, when I talk about the health IT, there are several components that I'd like to address. At the top of the screen, you see the endpoints, the electronic health record, the personal health record, and public health information, public health systems, that are where that information gets used either by providers, by the individuals, or by the community and the nation.

Underpinning that are the standards that we need, standards for data, technical standards, as well as security standards, because without that, we have a Tower of Babel. When we have these isolated islands of standardized information, in order to get the benefit from them, we need to link them together securely, robustly in order to flow that information among the different islands, among the different users in a way that honors the privacy and security of the individual, but also advances knowledge, advances the health of the community. That network is what we talk about as the Nationwide Health Information Network that we're seeking to foster, which is not a single network but, like the Internet, is a network of networks at the community and at a national level.

For those who aren't familiar, the President did issue an executive order in April of 2004 that established the Office of the National Coordinator. The charge to the office was to advance the vision for developing this nationwide interoperable health IT structure, as well as achieving the widespread adoption of the electronic health records, interoperable health records, by 2014, a 10-year goal.

Now, the key role for ONC is then to provide the leadership to achieve this goal and to improve the quality and efficiency of health care, as well as the ability of consumers to manage their health. By that, that's what we mean by the National Health IT Agenda.

But let me emphasize that the purpose of that National Health IT Agenda is what you see highlighted at the bottom there. It's not to achieve technology. It is about the outcome. It is about improving the quality, efficiency, safety of health care. It is about enabling consumers to manage their health.

So health IT is a critical component for a transformation to occur. The transformation is not the adoption of health IT. The transformation is in the individual and population health and advancing that, not just incrementally improving it based on what we're doing today, but bringing about a change in how we support the health of individuals and the nation.

The framework that we have builds from that 2004 charge to 2014 where there will be this widespread use of a variety of things, electronic health records, personal health records, and public health infrastructure, but also that enables other things, home telehealth, and even beyond the home, continuous monitoring of one's health. People talk about the fact that when you pick

up your cell phone and you make a phone call, it's already monitoring your vital signs and using algorithms to be able to determine whether something abnormal is going on and where to record that or who to notify, you or your significant other or your primary care doc, if something is abnormal. It's really a very different way of thinking as opposed to right now where we have this episode where you have to go to a provider and you have that small snapshot where you're getting your care. This allows you to actually have a monitoring of your health in real time throughout the day and night.

We've set up four goals to support this charge that we have, things about informing the health care professional, interconnecting health care, personalizing that health management, and improving population health. Now, you can see that there is a real overlap between the areas that you are focused on as a committee and the activities that we have because the things that you're doing cut across multiple goals there that we are charged with.

We also have a federal advisory committee. It's called the American Health Information Community, and this community, this AHIC, is one that is chaired actually by Secretary Leavitt himself. It's a public/private collaboration and serves to provide input with regard to our advance towards the digital health records and the interoperability.

A lot of this is also how we assure the privacy and security of the records and how we enable the market forces because, frankly, in the area of health IT, the market processes did not work. So our role is not to replace those, but it's to set certain boundaries, to set certain targets, to remove barriers, and to provide the incentives in order for the market forces to work, in order for the creativity of the community, of the providers, of the nation to move forward and to advance us so that we achieve that interoperability and that transformation of the health arena.

Our work is done in work groups. So we have a variety of work groups that have been set up. We've been fairly busy. Last year we had over 50 meetings involving over 120 experts and stakeholders. The focus of these work groups is to make the recommendations to the AHIC regarding the policies, technical, business, and social issues so that the AHIC then, as you do, can make recommendations appropriately to the Secretary and to the Department.

We started in November of 2005 by establishing four work groups that had to do with consumer empowerment, chronic care, biosurveillance, electronic health records. Each of them had a breakthrough area. So, for example, the electronic health records established that we want to make laboratory results available to the front line providers, even if that front line provider did not order it, because sometimes that's an issue. We also wanted to make sure that consumers had available a medication profile that they could pull up and make available to whomever they chose to make it available to.

We established two other groups in May of 2006. Because each of those groups identified the confidentiality, privacy, and security issues, rather than dealing with them separately in each of the groups, we brought those together into a group that would discuss and advance those, and Jodi will be talking about that in just a little bit. We also had a work group on quality.

Finally, the most recent work group that we established in October of 2006 was the Personalized Medicine/Personalized Health Care Work Group that Sheila talked about previously.

So of these groups, you can see that there are two that are particularly relevant to the work that you're doing here.

We use the collaboration to advance our agenda, and that term "National Coordinator" is important because my role is to help coordinate the activities. We have public/private initiatives to do so.

There were three contracts that we established. The first two actually are meant to foster the establishment of organizations that will go on and have a regular role to serve the nation. The first is a standards harmonization panel referred to as HITSP. We like to make a lot of alphabet soup as well. This group is looking to take those standards in a variety of areas that exist and harmonize them and identify which ones are we going to be using as we go forward because the problem that we have, as with many standards, is we have so many to choose from. And the problem is if we're going to get beyond the Tower of Babel, we have to decide as a nation which one we're going to be using in order to make sure we're speaking the same language.

Then we have a Certification Commission to look at a variety of products that are out there, electronic health records, both outpatient and inpatient, the network services, and now we're going to be also moving forward on personal health records, in order to provide certification for those.

The reason for certification is twofold: first of all, to help push forward, to drive forward that adoption of the standards that have been identified; and secondly, to help reduce the risk for the front line provider, for example, when it comes to the electronic health record, so that they aren't having to decide does a product meet my needs, does it meet the standards. They will have the certification there to be able to depend on.

In fact, in the very first year, we already have 55 ambulatory EHRs that have been certified, and there's another round. So we expect it will get over 70 by the time we finish the first year. And that represents over 25 percent of the products on the market, but over 75 of the installed base already. Now, that's the good news.

The bad news is that the installed base of really significant electronic health records being used is only at 10 percent of the provider community, whether that's inpatient or outpatient. So we have a long ways to go. We need to help to move that forward, but that is what our charge is.

Now, the final contract is not to establish an organization, but it's actually to foster the development of that network. We started last year by issuing contracts to technology consortia to develop prototypes so that we could look at what does it take, what are the components, and what are the best ideas that we can have. We then drew from that. They actually demonstrated it to the AHIC in January. And our next round is to go not to the technology companies, but to the health information exchange communities that are out there in the regions, local and state, in order for them to then contract for the services.

But we're going to be defining certain capabilities that need to be there, particularly with regard to enabling individuals to control the information that flows over those networks. The reason for doing the latter is not to say that that is the policy, but to make sure that as this technology moves out, that the technology doesn't limit or define the policy, but that it can, in fact, support whatever policies we adopt as we move forward as a nation.

The other collaborative activities that we've been having are at the state level because the state and the communities are where the real action is occurring. It's not going to be occurring at the national level. We can foster certain things such as the development of standards and the

certification, but the true implementations are going to be occurring locally. So we have a number of activities there. Two of them Jodi will be talking about very briefly.

The first on that list is the activity within privacy and security which was a collaboration at the state level to identify where the variations in state laws occurred that might act as barriers to the movement of information.

And the one at the bottom is the State Alliance for eHealth, which is a contract with the National Governors Association and is also a committee, one of those many that Dr. Tuckson is engaged in for the Department. And that's really one that has established the executive level advisory body. It's a connection in to the Governor and to the legislative levels at the state in order to develop the consensus solutions for state policy.

Then finally, another state activity that we had went out through the AHIMA and was to work and identify some of the top, leading-edge health information exchanges out there to identify the best practices and to cull them out so that others that are proceeding to establish the health information exchanges can learn from them and see what issues and strategies were addressed by those early adopters.

Now, one way of looking at this is that health IT supports transforming health care and that, like a tree, privacy, security, and confidentiality are the basis of all the activities that we're doing in transforming health care. And the health IT are activities that feed the roots of the tree. And you see a number of them there, a few of which I've talked about. There's a governance process. In this case, it's the AHIC.

But the real purpose of it is not the tree trunk or the roots, it's the foliage and the fruit of that tree. You see there adding value to patients, achieving high quality, safe health care, adding value for providers, improving public health.

But there are three of them, individuals managing their health in a safer, healthier nation, that really mean that we're not just transforming health care, but we're transforming health and the care. It goes beyond the health care sector itself.

I mentioned the AHIC. We've achieved a number of things over the past year and a half that we have been operating in terms of setting priorities and making recommendations to the Secretary. We have a number of things still ahead of us. That issue of privacy is a critical one in terms of what those policies and what those principles should be. And transitioning the AHIC, unlike what you will be doing, to a public/private entity. So there will remain a federal advisory committee behind, but the real governance will move out to an entity that is a public/private entity in the private sector. And we're in the process of starting that movement.

You heard from Sheila about the Personalized Health Care Group and a broad charge there. I'm highlighting here the issue of common standards and the incorporation of interoperable, clinically useful genetic laboratory test data into electronic health records. The specific charge, again highlighting, establishing the standards for reporting and incorporation of these common medical genomic test data into EHRs and providing incentives for that adoption.

Health IT can facilitate knowledge management. It can help us to organize the information to improve the safety, the quality, the efficiency of the health care part. Right now I'm talking about the health care sector specifically. We do this through that establishment of common standards.

Those standards will pervade through not just the electronic health records, but the databases, the repositories that we will be fostering.

We need to be managing the systems to generate that knowledge. It will give us better information on the individual differences. We'll be able to draw that standardized information so that we can do postmarket surveillance, so we can get better evidence development and advance medical knowledge. What we need to do, though, is to figure out how to do that so, again, we honor the privacy of the individuals and do this in a manner that all of us as a society can benefit from.

And we need to, in fact, move from what has been the incentive in the health care arena, which was automating the revenue side, to automating the core activities which are the delivery of care because, as you look across any industry, it's only when you automate your core processes, that you really get the benefits from that automation. And for the last 30 years in health care, we've been automating the edges, the revenue, not the health care delivery.

Health IT, again, is not the endpoint. It is the means to improve health by supporting the physician and the care provider, keeping up to date with medical information; making sure that they have access to that information; making sure they have all the information about an individual so that they can give that better care; improving the diagnosis, having the decision support at their fingertips at the point of care; and being able to know, based on the various parameters, including genetic tests and results, what the anticipated course of that illness might be for that individual.

It supports the researcher by making available a variety of tools and by providing access to a wealth of information that goes beyond what we can achieve with our normal randomized control studies where we have to refine that population in a very tight manner and where most of the individuals that we care for actually have multiple diseases, and we'll be able to draw that information from these databases.

Finally, supporting the consumer, the real beneficiary of all of this, by helping them to receive the best care possible and personalized health so that they get the right diagnosis and treatment the first time, every time.

But as I say, it's really beyond health care itself. It's transforming health and care. So not only do we deal with improving the diagnosis and treatment, the health care delivery portion, but it's really about moving to anticipate and prevent illness and, by that way, really transforming from health care to health.

With that, let me turn it over to Jodi and she will be talking more in detail about the privacy and security aspects. Then we look forward to taking questions at the end.

DR. TUCKSON: So we will do that, and let me just tell you that -- terrific -- Jodi is Director, Office of Policy and Research in the Office of the National Coordinator for Health Information Technology, fondly known as ONC.

(Laughter.)

MS. DANIEL: It used to be ONCHIT, and when you pronounce that out, it sometimes didn't sound quite right.

(Laughter.)

MS. DANIEL: So we shortened it to ONC, and it's not a perfect acronym, but it's better than the alternative.

Good morning, everyone. I am going to just drill down on some of the specific issues related to privacy and security that Rob had touched on in his part of the presentation just to highlight a couple of things that Reed Tuckson and Sheila Walcoff have both said, that privacy is probably one of, if not the most important policy issue that we face with respect to health IT, and that really trust is the key here. If we don't have patients trusting the systems that are set up for sharing information electronically, if providers don't trust that the information is reliable and is going to be protected, then we're going to have a real problem in achieving our health IT goals. So this really is the key policy issue that I face and that we face in trying to roll out our health IT goals and our health IT initiatives.

Two things to highlight. I think the technology clearly does provide some added risks for health information to be disclosed. There's greater ability to aggregate data. There's greater ability if there is an error for a large amount of information to be shared. But it also provides really great opportunities to protect data in a way that's much more secure than in the paper world. You can build in protections that might be administratively burdensome in a paper world. There's ability to identify when there has been a breach of information, where in a paper world, you can't necessarily do that. So there are real opportunities here too, and we're trying to look at how to minimize the risks and increase the protections that are available with technology.

Rob had mentioned the executive order that established our office, and one of the goals that is set forth in that executive order is about privacy and security, that a nationwide interoperable health information technology infrastructure must ensure that patients' individually identifiable health information is secure and protected. This is a key tenet of everything that we're doing and is part of our mission of the office.

One of the things I like to highlight: there's always debate. Do we have to have the policies in place before the technology? Is the technology moving ahead of the policy? I know these are issues that are addressed in medical technology, as well as health information technology. We really see these as having to work hand in hand. These cannot develop in the abstract. The policies have to be built as the technology is being developed. The technology will provide some insights on how best the policy goals can be achieved. For instance, particularly as technology is being developed, you can come up with great policies, but if they're difficult for people to use, people will find workarounds and may, in fact, have less protections than they may have had with a different policy incorporated into the technology.

For example, I know everybody has 3,000 different passwords for every different system you have to log onto and you have to change them every day or every few months. And there are different requirements for making them more and more difficult for people to be able to figure out. But because of that, people always have their little sticky note with their password up on their computer, which in fact is making it less protective than if they had a simpler password that they were able to remember. So there's always that balance with developing the policies and the technology that fits well together.

Rob had also mentioned the NHIN, Nationwide Health Information Network, trial implementations. This is really one place where we're trying to make sure that as some of these technology architecture standards are being developed and being tried out, that we're

incorporating the ability for different privacy policies to be developed and be incorporated in the technology. So we're going to require that the trial implementations have consumer control capabilities in them so that as the policy is being developed, there is the ability to work those into the technology rather than the technology being developed without considering those at the onset.

So where does this all start? I think that when we're looking at privacy and security issues, HIPAA always comes up as the issue and the foundation for everything we're talking about. I think some of the challenges that we face with respect to health IT and genetics -- there are some similarities here based on that HIPAA baseline. The HIPAA privacy and security rules are a very strong foundation for protections. They were the first nationwide protections of health information. There's a federal floor. So they allow for state protections that are greater than those federal protections. Some of those state laws also provide greater protections for specific kinds of information, including for genetic information.

So as we're looking at privacy and security policies, we need to not only be looking at federal policies, but also some of those state policies and how those two can work together. That's why we're doing so much work with the states, as Rob had mentioned, to make sure that we're looking at both levels, both the federal and state level, to address those issues.

There are some things, though, where health IT may pose additional privacy or security risks that may or may not have been considered by HIPAA, and those are some of the things we're looking at now. Again, as I had mentioned, there are opportunities for greater data sharing. There are opportunities for greater aggregation. So these raise questions as to do we have the right policies based on these greater abilities to share information and to aggregate information.

There are also new entities that have entered the market in the realm of health IT, as well as with research and genetic technologies. We have new health information exchanges that have developed, regional health information organizations and the like, that are not necessarily covered directly by HIPAA. They may be covered indirectly through contracts with those entities that are covered, but they raise questions when those entities are sort of holding a lot of information or aggregating a lot of information. Does that raise new challenges? Does that raise new policy questions that we need to think about in order to make sure that the information is private, is secure, and that there is trust that consumers have that information flowing through those will be safe?

Same thing. Sheila was mentioning the ability to aggregate a lot of genetic information and have genetic databases. Again, these entities that are holding this information may or may not be covered directly by federal or the state laws that currently exist. And so there are new opportunities and challenges to look at those areas.

Some of these issues are being raised by the privacy and security solutions contract at the state level that Rob had mentioned. There are also things that we're looking at internally and that we've been talking with the Office for Civil Rights about. The Office for Civil Rights at HHS enforces the privacy rules. And as we're getting some new information from the states, both at a state and federal level, about some challenges that they're facing, we're taking those to heart and we're looking at how we can best develop policies to address those concerns.

So at the state level, as Rob had mentioned, we have the Health Information Security and Privacy Collaboration. This was an effort to look at a state level at the state laws. We have 34 states and territories that are working within their state but are collaborating across states as well through some regional and national meetings to look at their state privacy laws and their business

practices, get folks from various stakeholder groups to identify how things really work in the real world with respect to privacy and security policies and practices. We've learned about many misconceptions about certain laws. We've learned about entities that are much more protective than those laws. We've learned about variations in those laws. And those states are each identifying variations in policies and practices and laws looking at state solutions and developing implementation plans within their own state to address any legal or policy barriers that they have at a state level with respect to privacy and security.

Where we're going with this is we now have 34 states that have been looking at these issues and they've had some cross discussions through regional and national meetings. But what we want to do in the future is to try to find opportunities where there are issues that are overlapping across the states to bring those states together to have some regional or multi-state collaboration to look at some of these challenging issues that come up at a state level or an organizational level, but that really do require collaboration across jurisdictions. As we all know, patients don't stay within state jurisdictional lines. They often will cross over to different states. People travel. People might travel to specialty hospitals for care. People from rural areas may be going outside of their state to go to cities and the like. And so we want to make sure that we don't end up with 50 state stovepipes but, in fact, that we have collaboration across those states on some of the privacy and security policy issues and legal issues.

Because the HISPC had identified this need for this cross-state collaboration, it was one of the drivers for the State Alliance for eHealth. This is an effort by the National Governors Association working with the National Council for State Legislatures, the National Association of Attorneys General, and the National Association of Insurance Commissioners to try to build consensus by state leaders. The State Alliance itself is made up of governors, legislators, attorneys general, insurance commissioners, folks from their health agencies and the like, as well as technical advisors, including Reed Tuckson, to look at these issues that are coming up in various different manners and to try to see if there's some consensus that can be drawn across the states and promoted across the states so that as the states are taking on these issues, they have a baseline to work from, they understand what other states are doing in this area, and there's some harmonization of those policy discussions and decisions.

Particularly with respect to privacy and security, there are three task forces that are providing information up to the State Alliance. One of them is the Health Information Protection Task Force, and this one really is focused on the issues of privacy and security at a state level. They will be taking some of the information from the Health Information Security and Privacy Collaboration work, as well as doing their own work and research and testimony to try to identify where there are issues and opportunities for cross-state collaboration on privacy and security policies.

Then at the federal level, one of the biggest sources of policy development we have is the Confidentiality, Privacy, and Security Work Group of the American Health Information Community that Rob had mentioned. The broad charge of this work group is to make recommendations to the community regarding the protection of personal health information in order to secure trust and support appropriate interoperable electronic health information exchange.

The specific charge is really related to those breakthrough areas that Rob had mentioned. This work group was formed by a recommendation of the first set of work groups that were focused on the breakthrough areas, the Electronic Health Records Work Group, the Chronic Care Work Group, and the Consumer Empowerment Work Group, who all identified privacy and security

issues with respect to their breakthroughs. They were replicating the same discussions in all of those work groups, not necessarily having a means of coordinating them and not necessarily having the experts at the table who really understood these privacy and security issues. So they made the recommendation to have a specific work group focused in this area.

We started up this work group in August of last year. So they've been operating for about seven months at this point. So far, they've come up with recommendations on patient identity proofing. They had five recommendations for how entities would identity-proof a patient and make sure that the patient is who they claim to be. Those recommendations were advanced by the American Health Information Community to the Secretary based on their January meeting.

They're trying to now go a little bit broader and look more at some of the privacy focused issues and are looking at the implications of having some entities within health IT and electronic health information exchange being covered by federal and state laws, whereas others that are new and emerging that are not covered by federal and state laws, and trying to figure out what the implications of that are, how to make sure that there are appropriate protections that will ensure consumer trust and the like. We've just started down this road at our last meeting a few weeks ago and will continue in our next meeting to have some more hearings on this topic this month.

The other thing that they're very focused on and interested is personal health record privacy policies. There are a lot of personal health records where the consumer can put their information in a health record that they control as opposed to the doctor's health record, and many of those personalized health records are not necessarily covered by federal or state laws because, again, they're new entities.

So the Consumer Empowerment Work Group has focused on these and has identified this as an area to focus, and the CPS Work Group will be working with them to look at privacy policies for personal health records.

So this is just sort of a summary of how all of these things work together. Underneath everything that we're looking at, all of our privacy and security policies, is the legal framework that we're focused on. We have the CPS Work Group, and then we have what we're calling phase II, which is how does the work of the CPS Work Group fit in with other activities that we're doing.

The dotted lines are sort of informational and the solid lines are sort of more of a direct link. But we see the work of the CPS Work Group feeding our certification activities for electronic health records and for networks. We see it providing some input to the State Alliance where there are state-level issues that are raised. We see a direct link with the NHIN trial implementations as we said. As there are policies that are developed, we want to make sure they're incorporated into the technology and we'll be requiring those contractors to look at those policies. Clearly, their work will infect our federal policy development and our thinking on how to protect information from a federal perspective. And then it will help with standards efforts as the HITSP group is looking at standards for privacy and security and will feed other AHIC work groups. So we see them working closely with the Consumer Empowerment Work Group, the Electronic Health Records Work Group, as well as the Personalized Health Care Work Group, and we have met with the Personalized Health Care Work Group, and I've spoken at that group as well to talk to them about the CPS Work Group and some of our activities. And Greg and I are in constant dialogue on how we can make sure that those groups are working together.

Then as Rob was saying, the goal here isn't just to have all of these activities, but really to make sure that we end up with a nationwide health information network that brings together the policies

and technologies and make sure that they're incorporated together. As we start moving, we hope to see these circles get closer and closer together and eventually have a direct overlap with one another so that the privacy policies and the technologies are in harmony.

And with that, we'll take your questions and comments. Thank you very much.

DR. TUCKSON: Well, this is terrific. Thank you.

So as my colleagues begin to think about their questions, I just want to reemphasize for those of you that don't live in the world day to day of AHIC, again, the reason that this stuff is being presented to you is, from where I sit, I can't think of anything that is currently more transformative in the real life of health care delivery than what's going on in these committees. I mean, this is absolutely fundamentally redefining the mechanisms for the infrastructure of care delivery at every level. This has all the stuff that's going into an electronic record, everything that will be standardized expectations for how the electronic record will work, not only collecting information but providing the prompts for information, evidence-based scientific guidance that will affect care at the point of delivery.

So all the things on the task force's agenda around how do you educate physicians and other professionals to know how to keep up with all of the developments in genetics around appropriate stuff -- this is one of the vehicles to dump that kind of information into a point of access care record delivery. It's how we're going to evaluate physicians' performance around are they doing the right stuff. That's what's going on in this space. It's the personal health record for the patient. It's how they're going to accumulate family history and how family history and genetic-based information gets accumulated in a way that a patient can take that from one care setting to another across the fragmented health care delivery system. That's what this stuff is essentially all about. So I just want to sort of keep in your mind that this is transformative.

So I guess the questions that I would have, as my colleagues begin to think through, are two things. One is how can we influence or at least ascertain that genetics is, in fact, a priority in the electronic record committees, in the patient health record committee. And I don't mean that pejoratively. Is it only or specifically through the Personalized Health Care Work Group that we ought to be following up? But how do we sort of say, okay, genetics is actually -- you know, because the committees are making decisions every day about what they can do and what they can't do. Certain things are more important than others on a timeline, so that this committee may need to sort of understand, all right, well, where are we on the line, our interests are where on the line.

Secondly, if you can remember a second one after that long first one, is for us to start thinking and trying to understand better the privacy and confidentiality and just the natural linkages that occur between our interests in anti-discrimination. What I'm trying to get to here is -- so try to keep both of these in your head. I know I'm killing you here. The concern around discrimination is one thing, legitimate and real. On the other hand, of all the people in health care that will require an infrastructure of support for coordination of care, it's going to be people with genetic disease. They're going to have complex illnesses requiring lots of interaction with the health care system. So the ability to have information about that person put forward into the health care delivery system in a way that allows the coordination across care settings, having that protected but used and then not discriminated, if it ever got out, are fundamental issues.

So I put both of those before you. Then my colleagues will ask you from then on.

DR. KOLODNER: Well, thank you very much. I'll take the easy question, the first one. I'll leave the hard one to Jodi.

We're balancing a lot of priorities as we move forward in this agenda. The AHIC has a lot of things that it's identified and is starting to move forward. The good thing about that is everybody's particular interest is number one. So we have a few number ones.

This, however, because it is part of that transformation of health care and health, has to be built in at the foundation as well. So the Personalized Health Group is certainly the main vehicle for connection, and Greg Downing helps to foster that as he does this one and is a direct link.

In addition to that, as with your meetings, all of our meetings are broadcast and widely available. Whether it's monitoring the AHIC meeting itself or reading the transcript, which may go faster than just listening to the meeting, or the work groups which also are broadcast, where there are issues -- you can see what we have for an agenda, and if there are issues that you think either touch on your area of interest here or should touch on the area of interest, then first of all, through Greg, you can make sure if it should touch but it's not clear from the materials that we send out ahead that it has, you get the message to Greg, and that is something that puts it on our plate at the time of the meeting. But by monitoring those things, you can see where we need to add and pay attention to something that we may not be paying attention to.

So I encourage you to kind of use all of those means, but you do have a primary channel in. The AHIC will be considering those things.

The other thing that you have is for the next 666 days, if that's the right date -- and I didn't check the calendar this morning before I came in -- Secretary Leavitt has this as a top priority. So you have an advocate both as the chair of the AHIC and in the separate hat, because it is a separate hat, in his role as Secretary for those interests.

DR. TUCKSON: Great. Well, as Jodi gets to my other question -- again, we've got time for my colleagues to be able to query you as well -- I'd like to make a specific request.

First of all, I do want to acknowledge Greg who spends a lot of energy making sure that our staff is updated on these things.

Number one is I would like you, as you consider new candidates for the Personalized Health Care Work Group, to consider someone from this committee formally to be on it. Again, I understand how complex it is populating those committees. So if you'll notice the careful way in which I phrased it, I'd like you to consider someone from this committee to be on that.

Secondly is I'd like to have, as a standard part at least for our next meeting and perhaps several to come, a formal update from the Personalized Health Group, either a member of that committee to come and brief us or staff function. However, you best decide, Robert, in your role. But somebody would come and brief us as to exactly what's going on. We will certainly monitor. My thing is I think you gave the right answer, Bob, but unfortunately, these folks are so darned busy on this committee here, with their regular lives, that I think they just need to have that going forward. So if we could do that.

I see Marc --

DR. WILLIAMS: You're too late. There are two of us that are already on the Personalized Health Care Work Group: Steve Teutsch and myself. I can't speak for Steve, but I am going to speak for him anyway.

(Laughter.)

DR. WILLIAMS: But I think we would be most interested in formally liaising with this committee and doing that.

DR. TUCKSON: I wasn't too late. I was prescient.

(Laughter.)

DR. TUCKSON: No, that's great, Marc.

So why don't we do this then? We've got a committee of the committee. You are connecting it. So we will hear from you as a team report.

I think that what we ought to do then is -- Sarah, if you could remind me -- when we get to the discussion about next steps tomorrow, let's see if we can't give our team a little sense of guidance about at least what we see as some of the issues. I think this needs to now become one of our strategic goals, and since it's basically one we can claim, since we're already doing it, we're in terrific shape.

DR. KOLODNER: We'll be glad to put the check mark next to the recommendation. It's nice to have that.

(Laughter.)

DR. KOLODNER: But there's another one that just has the box instead of the check mark, and that is, that it might be worth having the same connection to the CPS Work Group, to the Confidentiality, Privacy, and Security, so that there's somebody particularly sensitized to this area on that committee. And we would certainly entertain that if there is another member who would like to sacrifice their time and be on multiple committees as well.

DR. TUCKSON: And then I'll just sort of telegraph specifically I'm sort of interested in the connection between this stuff and the electronic -- the Certification Commission for Health Information Technology and the connection with the personal health record crew because I think those two are very important.

Jodi, in terms of my quick question on the confidentiality and privacy.

MS. DANIEL: Sure. As Rob had mentioned, if we would be open to including more folks -- and actually, I have talked with Greg Downing trying to find somebody who has sort of a research in genetics background to join that work group. We haven't identified a particular person. So we would be at least open to suggestions.

In addition, internally Greg and I have been talking a lot about how to make sure that genetic and privacy issues, as well as health IT and privacy issues, are both considered simultaneously. As I had mentioned, the CPS Work Group is starting to look at some of these issues, you know, the landscape of having some entities that are not covered and some entities that are covered, looking

at some of these entities that are aggregating data from a health IT perspective, but I think there's also the same thing happening with respect to genetic information and these databases. I think there are some very similar issues that are being raised. So we've been talking, but we would definitely be open to any input on how to integrate those together.

DR. TUCKSON: Great. The thing I want to just explicitly tee up for later discussion, especially when we get to the genetics and the anti-discrimination legislation stuff, again, it really is this extremely sensitive and specific point, that there are lots of effort being done to have information that allows you to coordinate care for chronically ill, complex people. And then the genetic discrimination stuff is clearly trying to make sure that you're, again, not able to harm or misuse that. So there's a dynamic tension, though, between how do you solve that equation. So I just want to keep that in front of the committee as we go forward.

Let's take other questions. I'm looking for hands. Yes, Francis.

DR. COLLINS: So thanks for a very interesting presentation, obviously a critical topic for the future of all of medicine and particularly for personalized medicine.

I just want to ask, in terms of the charge to the Personalized Health Care Work Group, which you outlined, it seems very heavily focused on the use of genetic laboratory tests as a means of making sure that that information is properly standardized and incorporated into the electronic health record so that it is possible for all of the communication priorities to be achievable in terms of physicians and other health care providers having access to interpretable information and using it to benefit health care.

It was a little surprised, though, not to see any reference in that charge to family history, given that family history at the present time is a very strong driver of whether a genetic test is ever going to be conducted. And of course, it is an independent predictor of potential future risk and, at the moment, probably the best genetic test we have. Plus, it's free. It's poorly collected, however, and certainly poorly represented in any kind of electronic form in most medical records. So there's a great opportunity here to optimize that part of personalized medicine.

Many efforts have been underway by several groups over several years to try to provide the kind of tools that would make that possible, including the work that's been going on with the Surgeon General and the family history tool and the work at the CDC.

So I guess I'd like to be reassured that the charge here, by focusing so specifically on genetic tests, is not missing out on the opportunity to do something that could really be quite spectacular, both empowering providers and empowering patients to take advantage of the use of family history in a much more effective way than we currently do.

DR. KOLODNER: Fortunately, the work group, like many federal advisory work groups, isn't limited by their charge. One of the first activities that they looked at, as we identified what are the areas to focus on, family history is one of those areas that they are focusing on, and I expect that we'll have a recommendation coming forward on that which, the way that we flow, will then form the basis of a scenario of what we call technically a use case, which then we give to the standards group to identify what are the standards that should be used, which then can be put into the certification process. So the work group has corrected that shortcoming and will be moving that forward.

DR. TUCKSON: The list we have is Kevin, Marc, Chira, Joe, and Muin, and let me start with Kevin.

DR. FITZGERALD: Great. I'd also like to thank both of you for the presentation.

I'd like to thank you too for your emphasis that both of you gave on the idea that for any of these public health benefits to occur, there's going to have to be public trust. I understand that we certainly want to reassure the public that there aren't going to be any harms coming out of this.

At the same time, I'm just wondering. In order to get this public trust, we're going to have to also engage those segments of our population which, unfortunately but perhaps justifiably, already don't trust the system or the sector, however you want to put it.

So instead of just reassuring people they're not going to be harmed by this, how can we engage them in such a way as to say this is actually going to give you greater empowerment, greater control both on a policy level and also on a technology level, you know, an empowerment and control that they don't presently and haven't in the past experienced?

DR. KOLODNER: That's an excellent question, to which I can't say that I have the answer.

But as we move forward and ferret out what our policy should be and how that policy evolves over time, I think we need to think about our experience in other realms, and specifically let me raise the issue of the Internet and the use of credit card information on the Internet. On any issue that we have, we have the early adopters who take risks and we have the people on the other end who may never adopt that technology or never trust it and certainly are more risk averse. We need to figure out how to allow the population to develop that trust and for them to choose when to be a part of it and how fast we move it forward.

I think those are the challenges with the policy development because, on the other hand -- and this gets to things that are labeled as opt in/opt out. Do you opt in to allow your information to be a part of it, or do you opt out if you don't trust it? And there are pros and cons to each of those that we'll be exploring and discussing in great depth in a variety of fora.

But this issue of recognizing that there are different levels of trust, there are different levels of risk-taking, and also the fact that no matter how much reassurance I give or the Department gives today, there are people who are going to take a long time to develop that trust. And how do we address that? What sorts of policies do we do in the meantime?

MS. DANIEL: If I could just add also. I think the personalized health records can go a long way in gaining that consumer trust because it is a place where the consumers can gather their own health information and have greater control of how that information is disseminated. And that is something that's new where now a consumer's health information is basically held by their health plan and their health care provider and not by them. So I think that that could be one big driver of consumer trust and consumer involvement that can help us.

A couple of other things. We're very much including consumers in all of our different collaborative efforts, our consumer advocacy groups, both in our work groups, as well as in the work of the Health Information Security and Privacy Collaboration at a state level. We've had consumer advocates come and talk to the states about how to engage consumers, and we've required them to engage consumers and consumer advocates in their approach. So we are trying to get that consumer engagement up front as the policies are being developed.

Many of those projects have recommended consumer education and that is part of some of those state implementation plans, which I think can be helpful. And as Rob had mentioned, again, there are some opportunities for consumer control so that if folks are comfortable with sharing some information but not others, there may be opportunities to create policies in that area. Again, we don't have specific policies at this point, but there are opportunities there to get more consumer engagement and consumer trust based on a lot of the different activities we're doing.

DR. TUCKSON: So here's what we're going to do. We're going to do real quick questions and real quick answers. This has been terrific but we've got to get a break in, and we have to be back in here at 10:15 because we've got all these important people calling in for the next part.

So, Marc.

DR. WILLIAMS: Brief comments. Just to reinforce what Francis said, we are moving ahead on family history and actually already have a draft use case to take that forward. Since that information is already available, unfortunately in unusable form in electronic health records, we're trying to say can we convert it into something useful.

The second point was the interaction between the different work groups. I think the use cases are really an excellent vehicle. As I've begun to review some of those that have come out of other work groups, I can see where pieces of what our charge is would fit into others. So I think using those as a point to be able to interact and suggest that perhaps we could include something from our work group into this that would enhance that use case could be quite powerful.

And the third is just relating to the tension that Reed mentioned about the harm from privacy violations, which for most cases, still represents a theoretical rather than a tangible harm, against the tangible harms that are resulting from the inability to use the information that we have. Again, just to take it back to the family history, this information is already in the medical record. It is already available for anybody who wants to look at the medical record. But if we could actually take that information that's there and put it into a usable form, we can prevent tangible harm that is occurring because we don't know the information.

DR. TUCKSON: Let's make sure we come back to that, Marc, in the discussions to come. I think that's very important.

Chira?

MS. CHEN: Thank you for your presentation.

I would like to find out how these electronic records are being kept. A provider A and a provider B, they are from different, separate systems, where a patient goes to two different providers and how they could be connected and how they are being protected.

DR. KOLODNER: That's at the heart of our agenda, that is, first of all, standardizing the information so it is usable within each and not just textual information, and then developing a network that is secure, how do we authenticate the user, how do we know that they are authorized to receive that information, and how do we move it across so that the systems themselves can receive the information and incorporate it as part of the thing. That is actually what we're challenged with doing. And we have examples where that is happening on a small scale, and what we're looking to do is how do we foster that widespread use.

MS. CHEN: This especially will be important for a patient that does not have insurance, that just goes from provider A to provider B just for a specific treatment and that's it, and how these are going to be connected and how they're going to be followed through.

DR. TUCKSON: So you absolutely got to the heart of the matter. You've spoken right to the heart of the issue.

DR. KOLODNER: One thing just to mention is we're working with HRSA to make sure that we don't increase the gap, but that we actually address safety net provider needs and rural and underserved.

DR. TUCKSON: That's key. That's key.

Joe?

DR. TELFAIR: Since I have to keep it short, I'll cut down on the number of questions that I had and others do too.

DR. TUCKSON: Sorry.

DR. TELFAIR: That's all right. You're the boss.

(Laughter.)

DR. TELFAIR: Just on two things, and this is an area I asked earlier. The first is if you could speak to the maintenance and sustainment of the system itself, how you anticipate that that will occur. It's a long-term issue because you have a development piece, but when you are done with the development piece, now what? How do you maintain that? That's the first question.

The second one then is also what do you have in place at the current time that addresses issues related to monitoring the policy and work group process because you have a lot of those. I know every group always has goals and objectives and that sort of thing, but how do you get a sense that they're moving in a direction that's consistent with the overall intent of the effort itself? Because that to me will have a lot to do with your outcomes.

DR. KOLODNER: With regard to the system, what I mentioned is is that our focus is to enable the market forces to work so that it isn't that we're developing a sustaining system, but we're fostering the development of that. So the electronic health records have to be self-sustainable within the provider setting.

The personal health record which, as Jodi mentioned, may in fact be the great disruptive technology, may be the thing that, when the consumer gets it and understands the value of it, may take off faster than the providers are adopting the electronic health records. It may actually push that forward. We'll see whether that happens, but it's certainly possible.

Right now there's a number of efforts, employer-based, insurer-based, or individual-based types of personal health records. Each of those will be self-sustaining. They need to occur, and then what we need to look at is how do we have a governance process. That's why we're looking and having the AHIC move into the public/private process that will oversee and foster that. There are other examples where the networks are not sources of profit but actually are byproducts.

If you look at how much we spend in health care today and how inefficient it is, if we were to take just a small portion of that, that would more than sustain the infrastructure, but we need to make sure that market forces are there so there's actually a movement of those dollars in so that we can get the value for our dollars spent.

DR. TELFAIR: But that is actually my point. There's a utility issue in regards to the actual application of this process. So I'm wondering whether or not any of your groups are actually developing a set of concrete, adoptable recommendations about them. There's the wish side of we hope this occurs. There is the side that history may play itself out. But then there is the aspect of will they actually get this done, given what we know about the way that our health care dollars and decisionmaking around those dollars are actually spent and how that information is influenced.

I guess I'm just trying to get to the point that this is a very good system. And this is for both of you all. This is a very good system, but it always falls apart when the rubber hits the road, particularly around those who are trying to assess this. And if you're talking about working with states and localities, that is pretty much what they're real concerned about.

So I'm just wondering, given everything, do you have any groups that are focusing on concrete, usable recommendations for both sustainment and then for assessment of that process?

MS. DANIEL: In almost all of the contracts that we have with the standards folks, Certification Commission, with even the State Alliance, and others, we've asked them, as part of their contract, to identify sustainable business models. With our NHIN prototype contracts, one of their requirements was to develop sustainable business models that could be used to sustain a nationwide health information network. They presented those at a public forum that we held for them to display what their prototypes were, as well as the business models for sustaining those networks.

So it is something that we're incorporating into a lot of what we're doing. We understand that that's one of the biggest challenges that we face and we're trying to make sure that as folks are looking at the technology and looking at the policy issues, that they're looking at those as well.

DR. TUCKSON: Also, I think, Joe, you've got to realize that a lot of this stuff -- and it may be a model that we need to think about or that challenge we got from Sheila a moment ago around public/private partnerships. It's going to be very difficult for a software vendor to be able to put forward a product that does not have CCHIT certification in it. It's just going to be hard to do business. So I think there are certain things that are being built it. But I think your question is appropriate.

Let me do this as I get to Muin, and Steve had his hand up. Here's the deal. This committee is in training. We're in shape. We are an in-shape committee. And I think that we can probably manage to know, you know, you need to slip out quietly to do a bathroom break or grab a cup of coffee. And we don't need no darned breaks anyway a lot of times --

(Laughter.)

DR. TUCKSON: -- because this is a hard core committee.

So since we've got four important people about to call in at 10:15 on genetic discrimination, which we have to be in for because we asked these people to stop their work to do it, we're not

going to worry about the break. We're going to keep asking questions until 10:15. So that way, we get Muin in and we get Steve in. So you're in shape. It's all right. You don't need a break.

Muin, go.

DR. KHOURY: Reed, I admire your firm leadership on this. So I'll try to be very quick. But thank you very much for both of your presentations.

Actually the ultimate utility of personalized health care resides probably not only in establishing standards for how you put the stuff in the records, et cetera, but trying to connect the providers and the patients so that patient care and disease prevention can be achieved.

So in terms of genetics, there are the three areas that we alluded to: genomic tests and genetic tests; family history, which is very, very important; and then a third area which touches upon Reed's early comments about our initiative called GEDDI, Genetics for Early Disease Detection and Intervention, which goes along with this.

So right now, for example, there are many people with familial hypercholesterolemia that are missed in the medical system. I mean, these are people with very high cholesterol. They may have a family history. They have other signs and symptoms, things like hemochromatosis where people show up with chronic fatigue and maybe elevated liver enzymes.

So I think the ultimate utility of this stuff is the ability to meld in the results of genetic tests with the results of family history with the results of prompts of signs and symptoms that together will allow the health care provider to make early disease detection and then intervene in a much more effective way.

So I think the plug I have is, in addition to genetic tests, family history, add a way to code and allow for signs and symptoms to come out through the medical records, but I didn't see that here. So that's one question.

The other is aside from transmitting the results of these things -- you know, you have a family history, a positive test -- the ability of decision support by the physicians and the health care provider to figure out what these things mean. So when does a positive family history mean anything? So, for example, in our family history initiative at the CDC, we have a classification of average, moderate, and high. So if these things can become part of the coding behind it so that you will see not only a family history, but a family history of sufficient magnitude to allow sort of a prompt to refer for genetic testing, perhaps that could be it.

So these two things are questions and maybe they're too much detail at this point. But I would encourage you to explore them, and if you have any comments on these right now, feel free.

DR. KOLODNER: Just a brief comment and that is, I absolutely agree. First of all, the linkage between the personal health information that an individual might have and the provider, bi-directional exchange is critical. That's why the PHR is really just another node on this network, and it's up to the individual how much they choose to share or not share.

But the functionality that you're talking about within the electronic health record, both for the provider, as well as for the individual, because at least certainly from my experience in VA, we're now starting to give the same reminder prompts to the individual so they can be an active part of their own health care, is important. And what you're really identifying is the edge of what is their

knowledge and where can we, in fact, put those prompts. They're relatively sparse right now but will increase. We need to make sure that the functionality is there.

So that would be something -- and I suspect it will be at the next round or two for the Personalized Health Care Work Group -- that beyond family history, they may start to do a use case having to do with some prompts that would be in the clinical decision support area.

DR. TUCKSON: And one second from Steve.

DR. TEUTSCH: Yes, very briefly. We talked about trust at the individual level. There's also trust at the group level. As this information gets used for population health interventions and population health, clearly we need the trust of these groups and how will it be protected and what will be the mechanisms because, obviously, it can create lots of population-oriented concerns as opposed to those just at the individual level.

DR. TUCKSON: All right. We're going to go ahead and dial in on the phone.

Let me just say this. One thing the audience and members need to know. It's good to slip out quietly, whatever you've got to do to take the break. These damned doors are going to kill me. So if you can, let's maintain good door etiquette.

Thank you, Bob and Jodi. We really appreciate it. This is a great relationship we've established. Let's keep this going, and I really appreciate your effort today. Thank you so much.