Update on the Secretary's Personalized Health Care Initiative
Sheila Walcoff, J.D.

DR. TUCKSON: Although I told Sheila she can have as much time as she wants because she really is special. So let me turn now to Sheila Walcoff, who is here representing the Office of the Secretary. She is the Counselor for Science and Public Health of the Office of the Secretary and an extremely important person.

MS. WALCOFF: Well, thank you, Reed, and I'm beginning to wonder if today is "International Complimentary Day." I think we had that a couple weeks ago in our office, and it was a lot of fun.

But I do appreciate the opportunity to return to the SACGHS to update the committee on the Department's work on accelerating personalized health care.

And I will say I did, right away, notice the Reedster bunny. I admire Reed's energy so much, and while that's not consistent with our prevention initiative --

(Laughter.)

MS. WALCOFF: -- it does make me feel like whoever is not here is probably going to suffer the consequences of the bunny sometime later on today.

I have a few slides that I think I'd like to outline.

To reiterate what Reed said a few moments ago, Secretary Leavitt on Friday outlined to the Personalized Medicine Coalition our Personalized Health Care Initiative, and I would like to provide a brief overview of his remarks and discuss the steps that are already underway to develop this important information, as well as steps he's taking to build the foundation for personalized health care and ensure that gene-based medical data and health information technology are used appropriately.

About a year ago, Secretary Leavitt defined 10 priorities on which he intended to spend a significant portion of his personal time and leadership, and those are listed out there for you. As you can see, personalized health care -- we've always put it at the top of his top 10 list, but it's definitely on his top 10.

The Secretary understands that advances in medicine, biomedical science, and technology present opportunities for enabling health care practices to be increasingly patient-specific by taking into account individual differences in health states, disease processes, and outcomes from interventions. The desired outcome is improving effectiveness and safety of medical practices and, as he noted a number of times on Friday, increased value and transparency for patients.

Up here you'll see the Secretary's visions, and these are really the Secretary's words. Personalized health care describes approaches applied across the health care enterprise that place a high value on individual, consumer-focused health by using modern tools, technologies, and information to improve safety and effectiveness. The Secretary often notes that we have a health care sector in the United States, not a health care system, and I know you'll hear later from Dr. Kolodner, and that's one of the key things that the American Health Information Community has been focused on as well.

Our initiative emphasizes a health care system strategy which incorporates new methods of genetic analyses to better manage a patient's disease or predisposition towards a disease and facilitates the discovery and clinical testing of new products. Ultimately, it's about getting the right treatment or preventative approach to the right patient at the right time every time.

Some of our long-term goals -- and the Secretary looks at this as both a long-term vision, the "project of our generation" we sometimes refer to it, and also has very specific short-term goals because he understands -- and I believe we have 666 days left with the Secretary at the wheel of HHS, and we all have countdown clocks. I mentioned them at the last meeting. And we are very aware of the limited time we have to make a very significant difference in accelerating personalized health care and building the foundation for moving forward.

So I'll just talk a little bit about some of our long-term objectives over the next 5 or 10 years. They are to promote connectivity through a national system of health care information networks; assess the need for new policies, technologies, and oversight approaches; develop incentives across the health care system to use genetic information; foster new business models for the pharmaceutical and diagnostic industries; encourage consumer participation in medical decisionmaking, health care management, and prevention through new information-based tools; consulting support and incentives; and establish real-time decision support for disease management strategies using health information technology systems.

Some of the short-term goals, which I'm going to go into in a little greater depth this morning, are to present the AHIC with recommendations for what we are calling a version 1.0 of genomic medical test and family medical history data adoption for electronic health records. We're also looking at developing policies and programs to strengthen consumer and health care provider trust in parallel with infrastructure and technical capacity development; encouraging development of validated clinical genomic testing capabilities, as Reed mentioned also in his earlier remark; and to establish networks of interactive data sources.

You'll see on the slide a diagram which we use pretty consistently to describe the overall vision that we have, and I think this pyramid really captures where we are. At the base is health information technology and knowledge development because underpinning this initiative is the confluence of two powerful global forces that will shape consumer health-based care: information technology and knowledge management. So you see that at the foundation. The full potential of these forces cannot be realized unless the electronic systems, clinical databases, and knowledge repositories currently under development are based on a common set of definitions and standards.

Next, moving up the pyramid, is intervention development and review. There's an increasing need for and value placed on integrated data sets and higher quality information about efficacy and safety outcomes. Using integrated databases, the ability to assimilate and relate experiences is enabling incredible predictive power for outcomes in disease management. As technological capabilities develop across the health care system, better information based on individual differences will aid in future medical product evaluation and postmarketing assessments of safety and efficacy. An expanded set of health measurement tools will foster research and development for conditions where there are currently few successful health interventions or preventive approaches.

Finally, translation into clinical practice. The key players in this transformation are health care providers. With new tools, doctors will play new roles. Understanding the unique aspects of each of us as individuals in health care management requires continued advancement in

biomedical research. This is particularly evident in the need for better bridges between research and health care delivery. At this time, we lack the infrastructure and analytical strategies for data management and knowledge development across biomedical research and health delivery enterprises. Barriers exist to standardize formats that can enable information exchange among willing partners in our health care, but we are hoping to create a health care system. We envision a continuum of transformation that builds on knowledge management to support the integration of discovery, development, and delivery in the health care enterprise and paves the way for a more modern doctor-patient relationship where value for the patient is the ultimate objective.

Basically we describe the Secretary's role in this initiative as being two parallel tracks moving along, hopefully, very quickly and together: technology development and the appropriate policies to support that technology.

So up here you'll see an outline of the first set of goals we have, and those are our technology goals, which include establishing the foundation for a networking partnership to enable researchers to search research and clinical data in almost a Google-like search fashion.

If any of you have taken a break from reading the extensive materials that your committee puts together, you'll look in that small document, the President's FY '08 budget, and note that it does include $15 million for the Personalized Health Care Initiative at the Department to begin building and seeding this distributive network which will ultimately link both genomic and clinical data to add efficiencies to therapy development, identify clinical best practices, and provide a better method of tracing adverse events. So we're right at the starting line for that and we're excited about having that money, and that is actually going to be coordinated through Dr. Clancy's office over at AHRQ.

Also, as I noted earlier and I know Dr. Kolodner will give you a much greater perspective on, part of this technology track includes establishing standards for including genomic health information and personal family history and electronic health records. Last year, the AHIC established a special working group for personalized health care to advise the AHIC on these issues.

Our second track is to support the appropriate use of genetic information. Because genomic information is immutable and we know that the American public is concerned about issues of privacy -- it's definitely in the news right now, as well, with the Genetic Information Nondiscrimination Act. But people fear discrimination in health insurance, employment, even public attitude based on the disclosure of their genetic information.

The Secretary has announced a number of times that he supports the passage of legislation to prohibit discrimination in employment and insurance. Just before the Secretary stepped to the podium on Friday, we received word that the GINA bill had successfully been marked up in Energy and Commerce and is, hopefully, headed very soon to the House floor.

In addition, the President has indicated a willingness to sign such legislation, which will provide a level of comfort for those that seek to participate in genomic research, as well as patients who are seeking to improve or inform their health care through genetic testing.

And I think we can not ever go past a discussion on this legislation without turning to Dr. Francis Collins to thank him for his leadership on this. I think, instead of calling it GINA, perhaps calling it Francis would be more appropriate, but we couldn't figure out how to get that acronym to work.

(Laughter.)

MS. WALCOFF: But we did get GEDDI.

Another area of policy focus is analytical and clinical validity of genetic testing technologies, which Reed also touched on earlier. The research and development of new genetic tests is ever-increasing, and the clinical validity of genetic tests should be assessed to determine the test's usefulness in making important clinical medical decisions. Yet, there is certainly a lack of clarity in the regulatory oversight system.

Finally, the initiative seeks to standardize access policies. Research using human genomic sequence databases, supported by public funding, will increase and create many new opportunities that will benefit public health. Currently policies for accessing these genomic databases are inconsistent about who has access to specific information and the time frame in which this information will be made public and the level to which it will be made public. So this initiative is working to harmonize and bring consistency to those policies and move forward effectively and efficiently in terms of that kind of research.

As I noted earlier, the AHIC has established a personalized health care working group composed of a broad cross section of stakeholders, and we've just listed those out for you here so that you can get a sense of where we're going on that. We've recently had a meeting. I think it was about two weeks ago. And I was really encouraged by the comments that I heard while I was there and the extent to which folks are taking this extremely seriously and really putting in a lot of time and effort to work through these issues.

Currently, there's a lack of consensus on policies surrounding incorporation of medical genetic tests and family history information in the electronic health record, and that could impede further systematic and useful adoption of this important technology.

Genetic tests are increasingly being used in mainstream clinical care. However, no standards have been vetted and certified for genetic tests and family history information to ensure incorporation of this important information in electronic health records. So you'll see up there the broad charge and the specific charge and some other issues that this work group is going to be taking a look at over the next two years.

If standards are not widely accepted, a patchwork of many different systems of electronic health records will impede interoperability and the exchange of useful health information. Initial primary care physician acceptance and understanding of this new medical technology is not keeping up with the rapid pace of genetic research, and this represents the broad and specific charge of the work group and it's something that is very much a part of the Secretary's Personalized Health Care Initiative.

Dr. Downing should also have a bunny with him because he, I don't think, ever sleeps. He's working on all of these issues so hard and is really the string of continuity through the various issues happening at the Department that will promote the Secretary's initiative.

So I'd like to wrap up my remarks with the focus on an area where we believe that the SACGHS could assist us in developing knowledge to support some of the work that I've just referenced. Fortunately, since my system was not working very well last night -- we still have some glitches in technology -- Reed doesn't have this in advance. But I'm just going to go ahead and outline the charge that he referenced earlier, and I'm going to leave a copy with him so that the committee has a chance to look over that and consider whether it would like to take that up on behalf of the Office of the Secretary.

As part of the Secretary's Personalized Health Care Initiative, it's certainly come to our attention that appropriate and clearly defined oversight of genetic testing is a matter of concern for many stakeholders. This is a complex issue and involves a number of departmental agencies.

SACGHS has heard over the last few meetings a range of testimony on this subject and many, but not all, of the HHS agencies involved in oversight of this important technology have participated in the discussions that you've heard. Through this process, the committee has identified a number of unresolved issues concerning oversight of genetic testing technologies. We understand and recognize the importance of this discussion and also see the complexity as the use of genetic technologies expands and plays a larger role in the personalization of health care.

The Secretary is committed to accelerating advances in quality health care and value by enabling appropriate regulation without stifling innovation. And so, as we look back on the committee's work to date, we've been carefully reviewing your work and the work of your predecessor committee, the Secretary's Advisory Committee on Genetic Testing, which is still relevant in today's conversation. In particular, many important topics and recommendations were covered in the July 2000 report, Enhancing the Oversight of Genetic Tests. We agree with the principle stated in this report that the public is best served by ensuring both adequate oversight of genetic tests and the continued development of such tests.

Subsequent to this report -- you're a very, very busy committee, Reed -- in September of 2001, that committee released conclusions about the development of classification methodology for genetic tests. The committee at that point found that the feasibility of categorizing tests for genetic purposes, based on a limited set of elements in simple linear fashion, was not possible.

We've been closely following the information gathered by a broad cross section of stakeholders in forums like this to better understand the issues and to discuss internally how the Department should coordinate oversight of this complex area of public health and science.

To that end, we are interested in the work of this committee and ask you to continue to provide valuable information to inform the Secretary's initiatives. Specifically, we would appreciate your input on a number of questions critical to the Secretary's priority. As I noted in my earlier remarks, the Secretary has announced that the Personalized Health Care Initiative is seeking to better understand the intersecting oversight and regulatory policies concerning genetic tests, to identify the scientific information and oversight needed to assure that tests are being developed and properly used, to encourage innovation and patient access to better genetic tests, and to improve transparency of the system of oversight overall.

To help inform the Secretary's policy progress, we suggest that this committee undertake the development of a comprehensive map of steps needed for evidence development and oversight for genetic and genomic tests with improvement of health quality as the primary goal. We suggest that the map consider and address the following questions. Generally, what are the existing pathways that examine the analytical validity, clinical validity, and clinical utility of genomic tests? What organizations are currently responsible for each of these aspects and what are they doing to address the issues? And what are the potential pathways to communicate clear information to guide test and treatment selection by providers?

We would also like input specifically on both the analytical validity and clinical validity of genetic tests, such as, what evidence of human harm exists regarding genetic tests? Is that harm attributable to analytical validity of the tests, clinical validity, and/or clinical utility? If evidence does not exist, what threats exist that are currently not being addressed in the regulatory

oversight? What distinguishes genetic tests from other laboratory tests for oversight purposes? And what resources, such as standard reagents or materials, are needed to develop proficiency testing requirements? What is currently available in terms of proficiency testing kits for genetic tests, and what information is provided by proficiency testing? What new approaches or models for private and/or public/private sector engagement in demonstrating clinical validity and utility for developing effectiveness measures for use of genetic tests? And what should be considered and why? And finally, if, where, and how additional revised government oversight would add value for patients.

On behalf of Secretary Leavitt, I appreciate your time and attention to these matters, and I look forward to receiving additional input from this committee on these issues and the other broad range of issues that you went over earlier this morning, Reed. You have your work cut out for you. Thank you.

DR. TUCKSON: Well, thank you very much. First, again -- and I won't belabor it -- we really appreciate your personal leadership, Greg's, and the attention of the Secretary.

So in the spirit of the almost always true dictum, be careful what you ask for, we asked for an assignment. I think we've gotten one. We got a pretty big one, a pretty powerful one.

What we will do is -- and I am well aware of the anxiety that goes with someone trying to present a report on Sunday night and your computer doesn't work and you're running around with the senior people at the White House and HHS trying to get the computers to work at 6 o'clock on Sunday night to get something in. That's always no fun.

We will take a copy of what you have here or what we're able to get here, and I'll have it xeroxed for the committee and we'll return to this issue tomorrow. Then we'll start to think about it.

I think that this charge is important. Now, again, I want to just quickly, while we have Sheila here because I know she's got to get back downtown, say that I'm comfortable and excited by the charge especially because I think it is important that the committee understands the context of the charge. And I want to have Sheila comment on this specifically because it's not good enough for what I say. You have to hear it from her.

I, through a series of meetings, am convinced that HHS understands the importance of protecting the public and that they are doing their work to coordinate the federal agencies and are looking carefully themselves at what CLIA and CMS and what FDA and what FTC and all that are supposed to do. So I want the committee to be confident that as we look to take on the assignments that we have, that it is within a context of an overarching activity at HHS.

MS. WALCOFF: Well, that's exactly right, and in that overarching activity is the Secretary's initiative. It's one of the policy areas that we identified pretty early on, and there are a number of folks here that are very, very engaged in this from the Department's perspective. But it's something that we think, in the next two years, we'd really like to move forward on and try to establish some clarity and consistency so that the area of personalized health care isn't stalled. We continue to promote innovation, always with an eye out looking at that issue of public trust.

DR. TUCKSON: Actually, you ended exactly where I wanted you to end -- where I was hopeful that you would end.

One of the things that impressed me about the Secretary's comments in this whole area of personalized care and particularly HIT has been his realization of the public's anxiety around privacy and confidentiality. That's the sister, as it were, of this issue of trust of oversight. I think that it's pretty clear to me that this movement is not going to go very far or very fast if the public is not assured that there's confidentiality and trust, there's anti-discrimination, but this idea of trust on the regulation side has to be addressed. So I do see that as being keenly important.

MS. WALCOFF: Well, thank you. Also, too, I know that Dr. Kolodner will talk more about what the AHIC is specifically doing in the area of privacy and security, and it's certainly something that is moving along as part of that track I spoke about earlier, right along with technology and the other policy areas that we're trying to develop.

DR. TUCKSON: One other thing. Then I want to give the committee members -- I'm buying time for your computer brains to figure out the question you want to ask Sheila. But let me also say that this is the second meeting now that Sheila has come before us and mentioned "the clock." Again, one of the things I like about the way that the Secretary does his business is that he's keenly aware that he's only there for a certain period of time. So he's not interested in a lot of yama, yama, yama. He wants to see something happen.

So we're going to have to think carefully about what things we can deliver to him in time for his watch in these areas and as that committee process goes forward. So maybe through Greg Downing, we can have a way of continuing to keep track of -- you know, maybe help us, Greg, to think about, as we try to organize ourselves to respond to some of these challenges, what the timeline is for us on this. So it's something that we have to consider.

MS. WALCOFF: Well, we really look forward to continuing our work with you, and I know that I also have an assignment because I'm going to have to go back and prepare the Secretary for not one, but two quizzes. So I might have to start traveling with him on his overseas travel so that I can have some flight time to do that.

I'm happy to take any questions before I need to head back to Washington, if anyone has any.

DR. TUCKSON: Does anybody? Yes, Joe?

DR. TELFAIR: Good morning and thank you for the presentation.

If you could just speak briefly, if you can, on the initiative. If you can say a little bit about financing and access issues, one, and secondly, consumer and public education and engagement as it relates to the rolling out of this involvement. I know that on the committee you have listed some of that, but in your presentation, you didn't discuss it that much. And I was just seeing if you can say a little more about it.

MS. WALCOFF: Sure. I think you're asking specifically about reimbursement policy and education, if that's right.

DR. TELFAIR: Well, reimbursement policy is one thing, but also literal access to whatever comes out of the work itself by those it directly affects. So it's more than just the reimbursement policies actually because what I'm speaking of is the education as engagement. In other words, it's one thing to be aware. It's another thing to be educated. It's another thing to be involved. So I'm speaking with that part of it, which I know is an outcome of the work, but has there been a

discussion for that? Have there been some thoughts around that so far? I mean, I realize it's just getting started.
MS. WALCOFF: Sure, and absolutely, we started actually about a year ago with this initiative. The Secretary came to me and asked me to take a look across not just my portfolio, which is science and public health, but really across the Department to try to figure out what we could do and what he could do as a focus of this initiative. In that, we looked at a pretty big vision, a long vision, a generational vision, and then tried to narrow it down to some specific areas where we thought he could have direct leadership over the next couple of years. Absolutely, in those discussions, we talked about transparency, education of not just providers, but consumers, researchers in terms of the spectrum of stakeholders, reimbursement policies. That list that we have on the AHIC slide is really kind of a brief snapshot, I think, of a broader number of issues that will certainly touch on this and are worthy of discussion as we continue to go through.

We haven't identified some of those as our priority issues mainly because we know we have limited time and, to some extent, limited resources, although I really don't think Greg Downing ever sleeps. But I can let you know that we are engaged in those kinds of discussions and that we continue to seek input and information on those because they do inform our other policy processes, as you noted.

DR. TUCKSON: Terrific.

Any last questions? Oh, yes, Andrea.

DR. FERREIRA-GONZALEZ: Thank you so much for a great presentation.

We really appreciate the Secretary's coming to provide us some charge to specific issues of oversight. Since I haven't seen the charge in detail or have had some time to look it over, there are a couple of things I would like you to go further on or a little bit more explanation. If you cannot do it today, maybe at a later time, as we go more down into the charge, you can provide us with more detail of specifically what you're looking for.

In the area of oversight and the role of the states and the federal government, could you tell us a little bit more about that? Do you want us to actually look at the role of the federal government and the states and the private sector in oversight of genetic testing?

MS. WALCOFF: We left the charge, in some respects, purposefully broad because we didn't want to create an expectation of anything specific. We really wanted to get the best look, a broad spectrum look from the variety of stakeholders that represent this committee.

I think that our focus certainly would be more on the federal side because that's the area we have the ability to impact. But we would like an understanding of the intersection of what the private sector is doing, certainly public/private partnerships, and your views of where the federal government is on this would be extremely informative.

I think in terms of state regulation and state issues, I know that there's been some work done by the committee in the past, and we will be looking at that. But I think we would be looking at a more broad federal look so that we can try to identify some specific areas where we can take action.

DR. FERREIRA-GONZALEZ: And with regard to the analytical validity and the clinical validity and utility, if you can provide us more specifics of what the Secretary is looking for.

MS. WALCOFF: Sure. As I said, this is our first outline of the charge, and I very much anticipate us continuing to work with you all as we move forward on this. I think those kinds of discussions will come out as we move forward, and I'd like an initial look at how the committee feels about the charge and I think we can further develop it from there and have some more specific discussions.

DR. TUCKSON: I think, Sheila, what we probably will do then is -- Greg, are you going to be around for much of this meeting?

DR. DOWNING: The whole time.

DR. TUCKSON: The whole time. Oh, wow. Unbelievable. Great.

So what we'll do is when we get to the discussion in the agenda on this topic, we will have a chance to engage at that level of granularity and sort of negotiate out a little bit in terms of how much of this we can get done on the timeline that is available.

I think this idea of the relationship between the public and private sector is one that has particularly engaged me intellectually. I think this is one that we are uniquely able to do something with, and I think that's going to be important.

I think your question really was important in terms of helping them to understand better -- if I understand, the charge at this level is really clearly trying to understand, when it comes to analytical or clinical validity, whether there is evidence of harm or what are the threats. What is it that we really are concerned about? I think that's really what the charge sort of speaks to, as I understand it. So we'll drill into those things.

All right. Amazingly, it's like 1 minute of. Gosh. That's why I'm going to call the question here and just say thank you again for this. And we look forward to responding back to you and the Secretary with the results of this meeting's deliberations, and we'll shape the expectations between our committee and the Secretary's office within the next couple of weeks and have something firm and a real work plan and a real sense of expectations by timeline. We'll negotiate all that out I think, hopefully, within the next two weeks.

MS. WALCOFF: Well, that sounds great, and I thank you again. While I didn't specifically mention timeline, I did leave that for a little bit of a more granular discussion. But our clock is ticking. So we are anxious to put you on a fairly accelerated timeline for this. Fortunately, you all have already done a very good amount of work on this to date. So I think focusing in on some of those specific questions that can help us in our policy process will be extremely useful.

So thank you very much and don't eat too many bunnies.

DR. TUCKSON: Well, we're all about the deliverables. So, again, thank you very much.