

**Remarks by the Secretary of Health and Human Services**  
*Michael O. Leavitt*

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MS. AU: I will turn it back to Steve and Rick for a little bit. Ms. Phelan is going to talk after the Secretary does his thing.

DR. TEUTSCH: As all of you can see, we are extremely fortunate today to be joined by Secretary Leavitt. As many of you know, the Secretary has shown enormous initiative in the area of personalized health care, for which we are very grateful.

This Committee, Mr. Secretary, has been working very diligently for a long time, and we are really grateful that the report and efforts that we have done have reached your office and are getting the kind of scrutiny that we hoped they would. We really appreciate your leadership.

For those of you who aren't aware, the Secretary was formerly governor of the State of Utah and born and bred in Utah, so it is a particular privilege for me to introduce you to the group. We look forward to having your thoughts. Thank you.

SECRETARY LEAVITT: Steven, thank you very much for your leadership of this group. I had a chance to meet with Reed Tuckson a couple of months ago at the interchange, and I didn't have a chance to publicly thank him but I want you all to know I appreciated his service. I expressed it to him directly.

Thanks for indulging my unscheduled visit. I did want to just come and thank you for your service. This is an area of quite particular interest to me. We are struggling with so many different issues where there is a need for balance and finding that place between fostering innovation and, at the same time, giving people the sense of confidence that they need.

It is so seldom that we are ever close to the curve or ahead of the curve, and I think many of the issues that you are dealing with are on the leading edge of the curve. There is a good possibility we will be able to stay somewhat ahead in terms of the policy decisions.

I was very pleased and appreciative of all the work that went into the passage of GINA, and I want to acknowledge my great admiration for Francis Collins. As I'm sure all of you know, he is not only going to be leaving the panel but also HHS. He is going to go on to do great things and we will all have a chance to see him and be involved with him.

Francis, I just want to tell you how much I have valued our relationship. I have told you that a number of times privately, and I want to say it publicly, too.

DR. COLLINS: Thank you.

SECRETARY LEAVITT: Thanks for all your contributions.

I will just mention, in the same spirit of staying ahead of the curve on these policy issues, today it just happened on my desk landed an FDA release. The U.S. Food and Drug Administration has approved a novel genetic test for determining whether patients with breast cancer are good candidates for treatment with the drug Herceptin.

We are going to see a lot of this. We [need to] have the capacity to stay ahead of the policy issues related to it, and there are so many still to be dealt with. I have spent a lot of my time as

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Secretary dealing with what I think is going to be a convergence, a convergence of information available electronically that we can use to provide patients with unparalleled information about the quality and the cost of their health care. I think that will lead us into an era where we will be able to make judgments on the effectiveness of drugs and effectiveness of different procedures.

I was in Singapore a few weeks ago and saw a collaboration that is going on there with NIH. We were looking at the various generations of being able to sequence and essentially lay out an individual genomic profile. It again called to my mind how rapidly this is changing. We talked about the speed with which that could be accomplished over the course of just a few years.

It is evident to me that at some point this will be very common. If we don't have the ability to manage this information in a standardized way, if we don't have the capacity to protect the privacy of those, that there will be a great opportunity lost.

I think we are ahead of this curve, and so I want to thank all of you for being willing to struggle with these quite significant dilemmas. It is of great value to me as Secretary, and it will be to future Secretaries.

Steven, I didn't want to disrupt the meeting too much. If there are subjects that your colleagues would like to inform me on directly --

[Laughter.]

SECRETARY LEAVITT: This would be a very good time to do that. If they have a question or suggestion, I would love to interact a little with your group.

DR. TEUTSCH: Please do. Comments or questions? As you can see, the topic is of great interest. We have a standing room crowd. Please take advantage of this opportunity to engage the Secretary.

SECRETARY LEAVITT: In this kind of a crowded council generally there is a fight.

DR. TEUTSCH: So far so good.

[Laughter.]

DR. TEUTSCH: Julio.

DR. LICINIO: Yes. I have a comment. I'm Julio Licinio from the University of Miami. As we have seen, particularly in today's meeting, there has been a lot of advancing genetic information being made by the private sector directly to consumers. The special academic health centers and the more traditional side of medicine have been a little more hesitant. The two sides look at each other with some degree of suspicion.

Do you have any ideas or thoughts of how we can move ahead with 1) the direct-to-consumer approach, and 2) the traditional medical approach?

SECRETARY LEAVITT: I won't resolve that today.

[Laughter.]

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SECRETARY LEAVITT: But I do think that that is the type of question I was talking about. How do you give people the sense of security they have, at the same time allowing innovation to go forward. I believe that if people are given information that is high quality and that is consistent they will use it in a way that will drive their own interest and, in doing so, will drive the quality up and the cost ultimately down. I think having the capacity for consumers to have access to it is going to be of enormous importance.

I don't want to weigh in on either side of that today except to just acknowledge the struggle and to say I think it is a positive struggle because it is in the tension between those that both sides of the debate will ultimately be improved.

I don't have anything beyond that to offer except to say the struggle is good. It will create a positive outcome because both sides have legitimate interest and legitimate points of view. I think that it is often the case that consumers are underestimated in terms of their capacity to sort through these things, and I think there is often a sense of well intended protection that we want to provide that sometimes can constrain progress. Somebody needs to be pushing the envelope a little, and yet, at the same time, someone needs to have the brake on just enough to keep us on the road.

DR. COLLINS: Mr. Secretary, can I ask you a broad, overarching question? First of all, thank you for your very kind comments a moment ago. It has been an absolute privilege to be part of this Department and to serve under your leadership. To have someone as the Secretary who has such an interest and such a fund of knowledge about personalized medicine has been just truly gratifying, and I think I speak for all the people on this Committee in saying so.

SECRETARY LEAVITT: I have had great teachers.

DR. COLLINS: One of the reports this Committee put out was on reimbursement for genetic tests. I think as we are both excited about the potential here of personalizing prevention, we are also wondering how that is going to get implemented in a circumstance where, at the present time, our medical care system seems to be more devoted towards reimbursement for actual disease than it is for covering the possibility of prevention.

At the same time, I think many economic models would say we have to change that if we are going to do something to rein in what is otherwise a really scary curve of what proportion of our GDP is going to go to health care.

So, from where you sit, can you project at all what the opportunities are here for taking the science, which is putting us in a position to do a better job of prevention, and actually putting that into an economic framework that will enable implementation across the board, not just for people who have a lot of their own personal resources to invest in this with their own pocketbooks but as a more general public health strategy.

SECRETARY LEAVITT: I will just say it has to happen. It is just a function of, really, when people are confident enough in the science and we have an economic model that will demonstrate the capacity for this to provide long-term savings.

I'm aware of this issue. I get lots of mail about it.

[Laughter.]

SECRETARY LEAVITT: I suspect some from people in this room.

I know CMS is still wrestling with this. I had a briefing and a conversation not long ago where they laid out what they saw as the competing considerations. But it must have happen, and it ultimately will. I just think it is a function of when are we confident enough with the science and when does the economic model warrant it.

One of the things that gets into this discussion that is unfortunate in my mind is the way the federal government scores its budget. We don't score prevention very favorably. We don't give credit in the development of budgets in the scoring model for good, thoughtful, preventative measures. I believe that has to change across the board, and that will be part of what happens. It is not likely to happen in the next 197 days, but I think it will happen.

DR. TEUTSCH: Paul.

DR. BILLINGS: Mr. Secretary, thank you for your work on GINA as well. I was going to ask you how this Committee can be optimally useful to you in your last months of tenure and how you think we might be ultimately useful to the incoming Secretary.

SECRETARY LEAVITT: The report about the oversight of genetic testing, that is a very useful tool. It helps very much for a secretary to have a place where he can toss a difficult question and say "Give me the best solution here." I think you can expect that the work of this panel will just increase. There is an endless number of thorny, difficult policy issues that I believe I and future secretaries will be addressing to this group for solutions.

So I would just say what you can do is just show up and give your best advice, because there is going to be a lot of it required.

DR. TEUTSCH: Muin.

DR. KHOURY: As a fellow federal employee, we probably haven't met, Mr. Secretary. I'm Muin Khoury from the CDC National Office of Public Health Genomics. I just wanted to thank you for your leadership the last few years. I was going to follow up a bit on the oversight report since the Committee has really worked hard over the last few months and gave you that report. There is lots of good information.

It is befitting that you would show up in a session that we are talking about personal genomic services because the field is moving so quickly. As you started saying, we need that balance between innovation and also, at the same time, high quality information to the consumers and the need for oversight and the federal government to do just the right thing, not too much of one thing versus the other.

I was wondering whether or not there is going to be any movement on that report during the next few months.

SECRETARY LEAVITT: The places that it helps the most are in the debate we just talked about where you have money decisions being made based on the movement of science. There is little question in my mind, as I suggested, that we have to ultimately deploy a model where we can use these tools in prevention. The issues really will boil down to when does the science reach the point that we can reliably depend on it and when can we get government policies aligned with it.

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I don't know how close we are to that delta because there is a lot of thought being given to it other places in the Department. I don't want to either bias or, for that matter, improperly inform about it. So I won't say more except that I do want you to know that the report is both useful and being used and moving us toward the point where those cross in making that determination.

DR. FITZGERALD: Thank you, Mr. Secretary, for coming and being with us today. A quick question, somewhat logistical, very practical, but I think one that is becoming more and more important to this Committee as we do exactly what you say, which is to try to address the multiplicity of issues.

Logistically, in the past our responses have tended to be focused on these larger reports, which I'm sure are very helpful to you if you have insomnia.

[Laughter.]

DR. FITZGERALD: But it might be also useful if we focus on perhaps more brief responses, more directed responses, things that might have to be done in between our semi-annual meetings.

The question that we have been wrestling with a little bit yesterday and we will wrestle with a little bit today is, are there other ways in which we could get information to you in a timely manner, perhaps in a more focused way. Would that be helpful?

[I would just] say, too, Rick and Greg have been wonderful in giving us direction from your office and helpful advice on how we could best serve the Department of HHS.

So I'm just wondering, is that something that we should be looking at more or are these reports really the way we should be focusing our efforts?

SECRETARY LEAVITT: Let me be truthful about this. The executive summary of a report is the most important thing to me.

[Laughter.]

SECRETARY LEAVITT: I don't wade through the depth of things I don't understand. I do find the summaries very useful.

To be honest with you, where I turn is to Rick and Greg, who are very much involved in helping me have the information I need and in some cases defining the questions I need to ask. So let's pose that to them.

[Laughter.]

DR. CAMPANELLI: The question was are the longer versions of these things or are there more targeted things. I think right now I would say that for our tenure here that we have a lot to chew on in the report that you have given us, and we are chewing on that.

But I think it is a good question looking forward. I think we certainly have the kind of relationship developed that we have where we could come to you directly with particular questions, and in the past sometimes we have. We have targeted more specific questions.

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From my perspective, and Greg, I don't know if you would want to say anything more about that, we really would avail ourselves of both of those methods if it was convenient for the Committee to look that way.

SECRETARY LEAVITT: I would be interested to hear Greg's response, but while he is coming up near a microphone --

[Laughter.]

SECRETARY LEAVITT: I have found that these larger reports often anticipate questions that haven't yet been posed, or at least they are not mature or ripe yet in terms of policy. Generally, I will end up with a policy question that frames up an issue, and it is very helpful to have one of my colleagues to say "We had a very thoughtful group look at that. The SACGHS has actually examined it and here is what they said." They may then extract some thoughtful piece from that report and I get it in a two-pager and they write it at a level I can understand it.

So I don't think you should assume that because it is big and thick that at some point in time the essence of matters related to direct policy don't find their way to the Secretary. They do.

DR. DOWNING: Now you have revealed all of the secrets about how it works.

[Laughter.]

DR. DOWNING: I think the one part that is not told is the community that develops within the organizations and across the agencies. This forum, this leadership, and your vision I think has created, at least in my 15 years of public service, a very unique opportunity to share not only the science and the technology but the human elements of what these important challenges present.

It is still a little fuzzy sometimes as to how the decision processes ultimately work, but I think that what we have tried under this initiative is some new ways in which the confluences of the challenges that face every agency, and in many aspects the corners of the Department that I didn't even know of, collectively get to a common place.

Our first conversations that we had with you almost two or three years ago now really were all about that, and the visit to the mountain, and how to bring the community to a new place of understanding. It won't be the happy place that everyone envisioned in their own dreams but the aspects of getting there collectively. That journey is a really important part of the story.

I think we have valued this forum as an important way to ask critical questions and learn from all of you and to help us keep in front of everything that is coming. I think in your role [as] the Secretary to convey that to those who follow, that will be an important asset for that challenge of science and technology and the aspects of human health.

SECRETARY LEAVITT: You referenced the mountain. When I was governor of Utah, Steven, out behind the state capital there is a peak. It is called Ensign Peak. You know well, then, that it is a favorite place for people to hike. At lunch often, for my exercise, I would leave the state capital and hike to the top of this peak. It was about a 45-minute forced march and your heart was pumping pretty good by the time you got to the top.

But it wasn't just the exercise I enjoyed. It was being able to be up high enough that you could see the entire expanse of the valley in the Salt Lake City area. You could see freeways and

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schools and universities. You could see hospitals and houses and playgrounds. You could just see the way all the forces of a society have to come together to make a community. It felt like a great place to think because you could just see so much of the way things interact.

I would say that has been the significant privilege of being governor of a state or being Secretary of Health. It has allowed me to see enough of the confluence of different things that a picture of how this is going to unfold begins to form in one's mind.

I can see this, and I know you can, too. It is a much different future than we now live in, but it is happening one dot at a time. The key is figuring out how to connect them all. We spend a lot of time with electronic medical records. Why? Because it is the electronic medical record that allows us ultimately to have the quality information and the ability to provide the personalization that will ultimately use this tool.

Moving all of these along in parallel isn't a neat, clean process. It doesn't happen in an orderly way. But you can begin to see it form up. Having the capacity as you come to a point where you have to connect two or three of these dots, having a group like this to be able to not just have a place to toss questions but to have a body of thinking that can inform various parts of it as it comes together, is a very important thing.

I think my message here is don't think you are just responding to a question from the Secretary. What you are doing is creating a body of information and thinking that will connect a lot of different parts of this system as we move into the future.

I'm disrupting your meeting longer than I had intended to.

DR. TEUTSCH: Thank you so much for coming, Mr. Secretary.

SECRETARY LEAVITT: Thank you.

DR. TEUTSCH: It is a privilege, and we do appreciate all your leadership and support of all the agencies. You should know that the staff that support us is equally terrific.

SECRETARY LEAVITT: Thank you, thank you.