Next Steps and Closing Remarks
Reed Tuckson, M.D.

DR. TUCKSON: Right. So let's do this, then. We are going to finish on time, which is terrific. So let's slow down a minute and look at all the stuff we've got in front of us.

Let me remind us as we consider it, we've got four things that are there. We've got pharmacogenomics, and we've got population studies, so keep those there. That's six. Now, what we did this meeting, my quick list here. I can't believe how much we actually did, it's amazing.

First, the family history project. We are going to get back from the family history project people what all the public education materials that are going out that are relevant to genetics education, and how they intend to connect the family history project to the electronic medical record, and particularly all this HIT infrastructure.

We are sending a letter to the Secretary endorsing the importance of family history as a tool. We are saying to him that we are encouraging to see HHS agencies playing nice together, and that we are encouraging those who are not playing nice, or who aren't involved, to get involved. So that is one set of things which we have done, straight forward.

Number two is genetic discrimination. We have agreed that we are going to compile the testimony from today, including the names of the people that presented, and their congressional districts, and a slew of background materials, apropos McCabe. We are going to put all that together, and then ask to meet with the Secretary to discuss this stuff, as well as to have him convene at the same time the leaders of Justice, Labor, and Commerce, so that we might try to resolve any differences that may exist within the agencies.

EEOC, by the way, is going to analyze gaps in current state and federal legislation. We are asking the Secretary to send this compilation testimony to Congress, focusing on the Speaker, the Majority Leader, and Congressman Barton. We are going to ask the Gene Coalition to send us their membership and analysis, and what it would take from their point of view to solve the problem.

We are asking AHIP for their analysis of what is wrong with the Senate legislation and why they can't get on board, and what is necessary to solve the problem. We are sending a letter to the Coalition for Genetic Fairness requesting clarification on whether they are opposing the use of information for care coordination, or whether they have some other issue that prevents them from getting to agreeing on a consensus.

We are considering bringing either congressional people or senior staff here for the next meeting to see whether or not that will help to try to understand better what it is going to take to get to success. We are considering holding a roundtable discussion to get consensus of key parties at the next meeting, i.e. the Chamber-type people, and the coalition people. So we are trying to think maybe that may be necessary to do at the next meeting.

We need a conference call to discuss the next steps so that we'll know basically how to proceed in this regard. It it something we'll have to do between meetings offline.

The third area was coverage and reimbursement. We are making genetic counseling a priority. We need to deal with the licensure issue and scope of work. We agreed to do a literature review and analysis before the next meeting. Cindy is taking charge of that. Muin is supposed to help.

The National Society and Board of Genetic Counseling are providing their input. As far as the overall reimbursement report itself, we've got a significant more amount of work to do, and they will be sending next steps back to us.

On the intellectual property rights issue, we basically have said that we're going to wait for the final report from the NAS committee, and based on that, how do we deal with the issue of how that affects the protection of the health of the public.

Large population studies we are going to discuss. Pharmacogenomics we are going to discuss.

Man, we did a lot of work. Now, what did I miss, by the way, in terms of what we did?

DR. McCABE: The only thing you forgot on the genetic discrimination is to invite my friends at the Chamber to come and appear before us.

DR. TUCKSON: Done. We'll get that. And then not your mouthpiece, if I recall. So the Chamber gets invited, terrific.

Now, somebody's pet peeve or issue I didn't say. So other than that, what did I miss in terms of what we did or committed to this meeting?

DR. McCABE: I think it was very thorough. I would encourage you, I think it's time for consolidation of what all you have accomplished. Rather than taking on another major topic, pharmacogenomics, or large population studies, I would encourage you to use the next meeting to consolidate and move forward.

I think there is an awful lot on the plate of this committee. You know, I would be concerned that taking on another major topic would be too ambitious.

DR. FEETHAM: Also, as part of the discussion from the reimbursement study, we had talked about the fact, or the reimbursement report, we had talked about the fact of hearing back from the HRSA study, that that may inform that discussion.

DR. TUCKSON: I'm sorry? Say it one more time.

DR. FEETHAM: As part of the reimbursement report, we had talked about the fact of hearing the latest report back from the HRSA genetic services study to see if that would inform that work.

DR. TUCKSON: Good. Thank you. So what has happened is that Ed in his chairmanship-like way has moved us from any errors of omission from my summary of what we decided to analyzing that and saying his conclusion is that we've got a lot on the plate, given that we had these other two issues here, that we did agree that we wanted to get that brief update on the newborn screening, which I think is important, and we wanted to get the briefing on the informatics initiative. So those were two things.

He is saying, I think, then that he is not urging that we bite off the pharmacogenomics or the population study, other than, well, he is saying right now -- let me not reinterpret what he said -- that we bite off those two quite yet. Let me just see if there are other opinions on that.

DR. WILLARD: Just a point of information. I mean, there are two presentations there on newborn screening, and on testing for rare genetic diseases, which are clearly for the information

of this committee, but I'm trying to figure out whether those are in our critical path to get to some action item.

Whereas pharmacogenomics and large population studies clearly are priority issues that we want to at some point weigh in on. If we have to make tough choices, it may to me hinge on whether we have future action items where we absolutely need certain information.

DR. TUCKSON: Let me try it this way, and Hunt, you're terrific.

What I'm thinking is that for the brief informational item ones that just take a few moments to give us a little update, they don't imply another set of work, whereas the pharmacogenomics and the large population studies are saying that there will be subcommittees that will continue and go forward.

Now, the sequential nature of this may be, Hunt, and maybe that's what you're getting at, is that we can at least have some more maturing of those projects, and then put them into the queue, because they'll start to be massaged offline.

DR. WILLARD: Well, that was my sense. If we could devote a certain couple of hours to pharmacogenomics or large population, that would allow the task force to actually jump into action between meetings. Whereas if we skip a meeting, the task force can't do anything anyway. Then we've basically lost four to six months.

DR. TUCKSON: Other points of view?

DR. McCABE: And if you wanted to move one of the topics forward, I think perhaps a little more in-depth briefing on what is going on in HHS might be a way of occupying an hour, but more to keep the momentum going in these directions. I would leave that up to the task force.

DR. TUCKSON: So that would say, and Ed, in that comment, are you saying that both of those have activities going to HHS, or did that sort of imply that you want to sort of get something from HHS on the large population one?

DR. McCABE: Well, I know that there is stuff going ? - I mean, there are plans afoot in HHS for the large population studies. I don't know if there is anything quite so concrete, or something that is easy to get one's arms around in the pharmacogenomics. Perhaps we could be informed.

DR. GUTTMACHER: I would think it might in some ways be close. More equal than you're implying. In fact, I think there are not plans afoot, they are simply exploration afoot. It hasn't really gotten to the point of anything close to plans, I would say.

DR. TUCKSON: Well, let me see if I can take what the guidance is from you and give you one more chance to react to this. I think that what I like from Hunt is that we don't want to lose the momentum of those committees. We don't have to dedicate ourselves to solving both of those issues tomorrow.

What we need to do is to have the committees create at least some time for there to be more discussion and discovery at the next meeting, which then will allow this to go on. By that point, by the end of the next meeting, we'll be ready to start to tackle some of these two. Basically you want to keep sort of both of them alive and moving. It is up to Sarah and I to try to figure out on the agenda how much time we can give to all of this.

If that is your recommendation, let me see how your colleagues feel about that.

DR. WINN-DEEN: Well, just from the pharmacogenomics thing, I think we probably have two or three meetings worth of stuff that we could talk about. So I wouldn't have any problem if we split that up and did a couple of hours here, a couple of hours there, just sort of the latest, hottest things going on.

DR. TUCKSON: Well, I don't see any strong objections, so I think Sarah and I will work hard to get all of these on the agenda and give them the appropriate amount of time. But I think with Ed, I think we are pretty straightforward that we're going to knock out the ones that we've got pretty well mature, get those things really resolved well.

In the interim between the meetings, there are two other things I want to bring up quickly. One is we will send you in the mail a copy of this from the General Services Administration. I really was curious about how you evaluate the quality of a committee like ours. I was very surprised to find quite a very thoughtful analysis that is used to determine whether or not we are worth diddley-squat.

So I want you to see that and keep it in front of you. It does sort of give you a little reality check, as it were, about what we're doing. By the way, I think given Ed's leadership in the past, we'll comport ourselves fairly well in that analysis. But I want you to keep that in mind.

Secondly, I wonder whether I could have your permission to draft a letter that I would send on your behalf, of course you'll write it, that would urge the Secretary to create, and this is not the right word, but sort of a czar coordinative person. Some identified single entity at HHS for these genetics kinds of things. We keep bouncing all over the place with this thing.

Quite frankly, while I am comfortable that before I would take this position that I did talk to the Secretary's office, as I mentioned in my opening remarks yesterday, that this was important to the Secretary's Office, I think that I would feel even better if there was a person that was sort of designated to receive our work, to know that they were on point, and to serve as an official coordinator across the agencies for the things that we're talking about.

I just feel like I would like to make that sort of a little more explicit and more direct. But I open the floor for your guidances as to whether this is worthwhile.

DR. McCABE: So moved?

DR. TUCKSON: Argument? Other points of view?

DR. WILLARD: Would your intent be to circulate that and send it quickly? Or circulate it and have a draft for final decision at the February/March meeting?

DR. TUCKSON: First, great question. Again, just as a point of departure, since there are several things that we're sending to the Secretary as a result of this meeting, I would probably put it in that letter as part of the overall letter and say you know what man, you've got a committee that is working its tail off on issues that are important to the American people. They range in quite a variety of areas. As such, I think we'd like to know that there is somebody who is paying attention to these issues. So it would be packaged into our report to him on this meeting.

All right. I'm not hearing any violent opposition to that, so you'll be seeing that as well. Who on this committee has any further thoughts? Anything that did not get discussed? Miscellaneous? Yes?

MS. HARRISON: I get increasingly concerned that the public doesn't necessarily know everything that we're doing. So in light of that, in a previous discussion that was some talk about putting that vision statement priorities report into at least the scientific literature. If not, even trying to coach it into the lay person's literature, just so again, we could increase awareness about our activities and maybe even get more public comment than we do already from folks that don't traditionally read the Federal Register.

DR. TUCKSON: Barbara, I think you're really on to something there.

MS. HARRISON: And then just one second thing is the testimony yesterday was just so powerful, and again, in this atmosphere of people saying that genetic discrimination doesn't exist and there is nothing in the literature to support that, I think the information that we got yesterday, I'd just throw it out there that possibly we could coach that into something again, that could go into the scientific literature so that people can reference it in the future.

DR. TUCKSON: Boy, those are terrific comments. I was trying in a way, Barbara, also not as eloquently as you, when we had those folks who were testifying, I would sort of say, is there a way in which you can take back to your newsletters and so forth and so on. I think what we ought to try to do is to try to formalize that a little bit, and the major advocacy organizations for the genetic community is to request that synopsis versions of what we're doing, or whatever, are made available to their membership.

I think we should actively, if we have not, Sarah, just formally reach out and say we really would like you to do that. I saw some other hands. Those were terrific.

Emily?

DR. WINN-DEEN: I just wanted to ask if we were going to comment or vote on this draft direct-to-consumer letter. Are we going to give you our blessing to send that? Because it is in the table of packets, but we didn't really talk about it.

MS. CARR: Well, we thought we had your blessing to send it. We had sent it out for comments electronically. As Reed said in the very beginning, we are more than happy to get more comments about it.

DR. WINN-DEEN: I'm just trying to drive it to conclusion. Are we done with it? Are we ready to send it?

DR. TUCKSON: The answer is that you have until the end of this meeting or by the time Sarah gets back to the office tomorrow to send something in. But absent that, it is going out.

But the answer is that you do have time. So if you forgot to read it, didn't look at it, don't remember it, yes, you still have a moment to comment. Other points? These are terrific.

DR. LEONARD: Mine was the same as Barbara's. We are sending the road map to the Secretary, but we had also discussed publishing it. I think that is a very, very important step.

DR. TUCKSON: All right. We'll work on that. Well, listen, let me thank all the members of the audience who have ? - I mean, there are some of you who have been here the entire two days. You are extraordinarily resilient, and we thank you for being part of our little community.

To Sarah and the team, good Lord, my goodness. You all worked something fierce. It is very much appreciated. The support we get is embarrassing.

So thank you very much to everyone. Good meeting.

(Whereupon, at 3:09 p.m., the meeting was adjourned.)