Briefing on the Status of Genetic Information Nondiscrimination Act
Kristine Bradsher, Michelle Adams and Brian Petersen

DR. TUCKSON: Now, we're going to dial in and that's going to be its own technical issue, but we're going to do that. Members of the committee, try to really be here, you know, like now.

Can you guys hear us on the phone?

MR. PETERSEN: Yes, we can.

DR. TUCKSON: Great. Wow, technology. Well, listen thank you so much and welcome to the committee meeting.

Let me just make sure that I know who we have. Kris, are you there?

MS. BRADSHER: I can slightly hear you. This is Kris Bradsher.

DR. TUCKSON: Yes, Kris. Are you having trouble hearing?

MS. BRADSHER: I've got my ear close by to the phone. So it's a little bit better here.

DR. TUCKSON: You are coming through spectacularly.

MS. BRADSHER: Oh, good.

MR. PETERSEN: This is Brian Petersen. I'm also having a little problem. It's not that you're unclear. You're very soft.

DR. TUCKSON: And in reality, I'm screaming my head off. Let me just ask if there is a technical solution to this. Wait a minute. Our crack technical people are on the case.

So, Brian, I at least now know that you are there. I know that Kris is there. Do I know if Keith is there?

(No response.)

DR. TUCKSON: And what about Michelle?

MS. ADAMS: I'm here.

DR. TUCKSON: Thank you so much.

So while they are trying to boost my voice --

MR. PETERSEN: I think you got a lot louder.

DR. TUCKSON: Okay, well, great because I was getting a headache from shouting. So this is great.

Well, listen, first of all, let me introduce myself to you. I'm Reed Tuckson and I'm the chair of the Secretary's Advisory Committee. You are being very clearly beamed into a conference room

here at the University of Maryland Conference Center. There is a table full of brilliant advisory committee members and an audience full of equally brilliant smart people.

We are really pleased that you've taken the time to give us an update on the Genetic Information Nondiscrimination Act.

For the members of the committee, as you are aware, the enactment of federal legislation to prohibit genetic discrimination in health insurance and employment has been this committee's highest priority since we were established. We monitor congressional efforts on this issue very closely. The Genetic Information Nondiscrimination Act of 2007, GINA, was introduced in both the House and the Senate as H.R. 493 and S. 358, respectively, and many people have been predicting that, after a decade of effort, the legislation will finally be passed by Congress and enacted into law.

There's been an unprecedented amount of congressional interest and activity. This bill has been approved by the Senate HELP Committee and three committees in the House of Representatives. Floor action is anticipated in both chambers very soon.

Our presenters this morning have all been at the center of congressional efforts related to GINA and they are still intensively involved in Hill business this last week before the Easter recess. We are, therefore, grateful that they were able to devote some time to bring us up to date on the bill's progress and prospects for full congressional passage and enactment.

In consideration of their hectic schedules, they're all joining us by phone this morning. So we're going to begin.

And by the way, also to our guests on the phone, somebody who I know you have seen much in this process, Francis Collins, is here with us as well.

We will begin with Kris Bradsher, who is filling in, first of all, because -- Kris is smart herself on this, but also involved with Deputy Assistant Secretary for Legislation, Craig Burton, who we described earlier in the meeting. She will be providing an overview of the legislation and the administration's stance on the key issues that have arisen during the hearing.

So let me just start there, and, Kris, thank you for taking the time.

MS. BRADSHER: You're welcome. As Dr. Tuckson has mentioned, I'm with HHS's Office of Legislation. I work with Craig Burton, and he was called up to the Hill. So I am going to talk on his behalf.

Let me start out with the administration favors enactment of legislation to prohibit the improper use of genetic information in health insurance and employment.

Currently on the Senate side, they're working on some remaining issues.

On the House side, that's where a lot of the action came over the course of the last few weeks. I know our folks from the House can probably tell you a little bit more. On the House side, we're told they will work to reconcile three versions of the bill, with the goal of having one bill sometime after recess. Those three versions are from the House Education and Labor Committee, the House Energy and Commerce Committee, and the House Ways and Means Committee. Each have jurisdiction over parts of the bill.

Last Friday, as you know, Secretary Leavitt had announced steps towards a future of personalized health care. And I understand, Dr. Tuckson, you were there with him as the Secretary outlined a course for achieving personalized health care. Genetics nondiscrimination plays a big role in this top priority for the administration, and the Secretary has made passage of genetics nondiscrimination legislation a top priority this year. And we are working with Congress to make that happen.

Finally, the Secretary is pleased with the progress made by the advisory committee and all the work that you have done so far as we move toward this legislation. We look forward to continuing to work together on legislation and are very happy that you have made this your highest priority as well.

DR. TUCKSON: Terrific, thank you.

Before I get to our colleagues from the Congress, are you able to let us know now whether there is any plan for a statement of administration policy on this issue?

MS. BRADSHER: As you know in the course of the last Congresses, we have made statements. So seeing that as a precedent, yes, I do believe there will be a SAP coming out. I do not know when. We'd like to see what comes out of the House side.

DR. TUCKSON: All right. Well, thank you very much. Will you be able to stand by?

MS. BRADSHER: Sure.

DR. TUCKSON: Great.

Let me turn to Michelle Adams, Legislative Director in the Office of Representative Louise Slaughter. Thank you so much, Michelle.

MS. ADAMS: Oh, yes, my pleasure.

Just to reiterate, I think most of this has already been covered, but we had three committees of jurisdiction in the House and all three have finished their business as of Friday, marking up the bill and reporting it. All three, Ed and Labor, Ways and Means, and Energy and Commerce, ultimately passed the bill out of their committees by voice vote. So now we're going ahead to reconcile the three different versions before it comes to the Rules Committee, and we're hoping for floor action shortly after recess.

DR. TUCKSON: Great, thank you. If you'll stand by then and let me turn to Brian.

MR. PETERSEN: Sure.

DR. TUCKSON: By the way, Brian, Deputy Legislative Director of the Office of Representative Judy Biggert.

MR. PETERSEN: I think Michelle has covered most of the issues here in the House. I just wanted to say that we continue to push forward with a strong bipartisan effort on this in the House with Ms. Slaughter's leadership and my boss working on this legislation and trying to work in the most bipartisan way possible to get a bill, not only to the Senate but to the President's desk, that can be signed into law. So we're happy with the progress we've made so far on this.

Obviously, a lot of work has been done in the House so far, and this bill has been around a long time. So we're hoping to move it forward and get it out of the House soon.

DR. TUCKSON: Great.

By the way, again, if either of you could just give those of us who are not experts in this sort of thing -- so once it comes out of the House, what then do you see happening in the Senate, and then how do you sort of get the two of those things together?

MR. PETERSEN: Michelle, would you like me to or do you?

MS. ADAMS: Either way is fine.

MR. PETERSEN: Okay. Just for a second, obviously, after it passes out of the House, the process is one in which the Senate has two options -- actually, I guess three options. Number one, they could pass their own version of the bill and insist on a conference with the House, in which case we try to work out the differences between the House and the Senate version in a caucus between the House and the Senate. Another option would be that they could take up the House bill and pass it as is, which would send the bill directly to the President's desk. Or a third option would be they could take up the House version of the bill, make a number of changes, and send it back to the House to see if we would agree to those changes.

Michelle, hop in if you see other options than those, but those were the three legislative opportunities that we'd look for.

DR. TUCKSON: Michelle, let me just ask you then, given that you've described that the bill has gone through a variety of committees in the House -- I know it's gone through Education and Labor, Ways and Means, Energy and Commerce.

MS. ADAMS: Correct.

DR. TUCKSON: What, if any, significant changes to the original bill have been made, or did what went in come out?

MS. ADAMS: There have been a few changes mainly because, you know, this bill has been around for 12 years.

(Laughter.)

MS. ADAMS: So some of the things that we did were actually updating, so for example, the definition of family member would be consistent with HIPAA, which wasn't around when my boss introduced this bill 12 years ago. So we've made a number of changes like that to bring it up into current standards.

In each instance, the committee folks have been working with my office and Brian's office very closely, and I think trying to merge the three different versions on the bill won't be too bad because as it's gone through every committee, we've made more and more improvements, but it's kind of been consistent with what the previous committee did.

DR. TUCKSON: So actually, other than this sort of fundamental HIPAA stuff, it sounds like you're saying, if I hear you, that there are no significant changes. Let me then ask if that's true? And maybe, Brian, you could comment.

Is there any significant concern about the bill? Who's fighting against it? Is there opposition to this bill that's going forward?

MR. PETERSEN: Sure. Michelle, would you like me to handle that one?

MS. ADAMS: If you want to.

MR. PETERSEN: Sure, that would be fine.

I would say that a lot of the changes that you've seen in the three different committees, as Michelle has said, are not that big of changes. Usually it's a situation where the changes are slightly different in each committee. So, obviously, that presents some minor problems as far as getting one version of the bill that is consistent.

As far as opposition, I would just say that the bill is widely supported by, I think it is, over 140 different groups, and there still remains what I see as some reluctance on the part of some insurers that stand behind and support this legislation. But in the past, over the last few years, I think we've seen statements from them that show this bill not only would work as intended, but would not cause problems to the way in which they manage health care.

So I'm not sure what, at the end of the day, it will look like as far as groups in opposition, but I think that it does say something that the bill in the last few years has passed the Senate unanimously twice. We have over, I think, 90-some Republican cosponsors and I think over 120 Democratic cosponsors in the House. There's just wide, wide, wide support, and I think that's kind of the message to take away, that while there might be a group here or there that we could point to that doesn't like a certain piece of it, I think to a large degree, a lot of the opposition has been muted to the bill.

DR. TUCKSON: Well, we're going to turn now to some of the members of the committee who have questions, and we're going to start with Marc Williams, then followed by Francis Collins.

DR. WILLIAMS: Thanks for the opportunity to comment.

One of the issues, as I read through it and was asked to comment, related to what I know has been an extremely thorny issue over the years and that is the definition of what constitutes a genetic test. In reading through the language, it refers to, of course, DNA and RNA, but also, I believe the language is analysis of proteins and metabolites that would also "allow detection of a genotype." That, I know, has caused some concern as that could be very broadly interpreted in terms of what do you mean by detecting a genotype. So could a cholesterol test or could a blood pressure measurement be interpreted by some as detecting a genotype?

I didn't know if that had received any attention in the markups and how that was addressed and whether that can be further clarified in rulemaking or whether it will ultimately come to a test of case law once the bill is out.

MR. PETERSEN: I guess I'll make a brief comment on that. I think I would kind of at least like to hear Kris' opinion on the regulatory side of things as it relates to that.

Number one, in the committee, you did see an effort by a number of Republicans, Mr. Stern's amendment I think being the highlight, of an attempt to narrow the scope of the definition of genetic test in such a way that I think would be rather problematic. In Mr. Stern's amendment, they attempted to amend the definition of genetic test to basically force the Secretary of Health and Human Services to create a master list. So in a sense, we're only protecting tests and information that fall under this category with master lists created and maintained by the Secretary of Health and Human Services. So I think that is kind of a huge regulatory burden for the Secretary of Health and Human Services and also not very functionally efficient as well. So, obviously, there have been some attempts to narrow the scope of the bill like that, but I would say that those attempts have been more problematic than anything else.

I'd be happy to hear what Michelle has to say on the subject or anything that Kris would have to say about how the current definition functions and whether or not they think that the Secretary of Health and Human Services will be able to provide the necessary guidance through regulation to make sure that some of the things you mentioned are properly addressed.

DR. TUCKSON: Thank you.

Francis?

MS. ADAMS: Just to add on to what Brian said. This is Michelle. The attempts to change the definition were defeated. So we're moving ahead with the definition that's in the bill.

MS. BRADSHER: And as far as regulation goes, we'll work with Congress. We do have a regulatory process. The regulatory process usually works with public comment. So it is something that we're prepared to address, but we'd look forward to seeing what comes out of the House as a final bill after reconciling after recess.

DR. TUCKSON: Thank you.

Francis?

DR. COLLINS: Thanks. I certainly would like to compliment those of you who have taken time to be on the phone with us this morning, Kris, Michelle, and Brian, for the efforts you all have been putting into getting this bill as far along as it is. And after 12 years of trying to see this happen, it's truly gratifying to see this coming together in a bipartisan way that has real momentum. I particularly would like to recognize the important efforts of Representatives Slaughter and Biggert in the House in making that so by their strong sponsorship of the legislation and to many others who have endorsed it as well.

I'd also like to recognize the Coalition for Genetic Fairness, an organization that has come together to support this legislation. It has become a very important voice in that effort, led by Sharon Terry who's here this morning, and has, I think, brought together many different constituencies that all see the need for this particular form of protection, and in a very detailed way, I think, assisted in a process of trying to be sure that the bill is crafted and put forward in a way that's going to provide what the public needs and deserves. So a lot of people putting a lot of effort into what now appears to be a very encouraging series of events.

But we're not quite there yet, of course. There are still some obstacles that could get in the way. As you heard, the Rules Committee will have to figure out what to do with these three different versions, then will have to figure out, in terms of the House and the Senate version.

In terms of the question that was just asked, that was actually something I wanted to bring up. There was this proposal that, in fact, the definition of a genetic test might be something that would require sort of an ongoing list to be generated, curated by the Secretary. I just want to comment from a purely scientific perspective what a really bad idea that would be because the ability to define at any given moment of the day on a Thursday what has actually arrived at the point where it could be potentially useful as a genetic test in a research project is such a moving target. I don't know how anybody on the planet would have the ability to do that, especially as we are now seeing in the course of this year and a couple of years to come, we're going to have all of these discoveries about genetic risk factors in common disease, in diabetes, in cancer, in heart disease, and asthma. Each one of those discoveries, if validated -- and many of them will be -- will potentially be a useful topic for research to try to figure out how to use that information to help people in their own personalized medicine agenda, but we'd want to do that in research before you'd do it in clinical practice.

But, obviously, one of the great risks right now, in the absence of federal legislation to protect against genetic discrimination, is that research is being impeded. We have very good evidence of that at NIH, that lots of people who would like to be part of such projects opt out because of their fear of this kind of discrimination. One of the things we hope to be able to say to them very soon is that there is now that kind of protection and they need not fear participating in an NIH research study because of that risk that their genetic information might get used against them. If we had to somehow also fold this sort of ongoing curation minute by minute of what is new and exciting into a research study somewhere, it would be, I think, totally impracticable.

So as difficult and challenging as those definitions of genetic tests and genetic information are -- and they've been developed, of course, over many years -- I think probably one should not try to impose upon that the responsibility of any person to try to say what's on the list and what is not. It just simply won't work.

DR. TUCKSON: By the way, that's very important.

I've asked Sharon Terry to come up. She was going to be quiet there in the audience. But, Sharon, I think it's so important to hear from you, especially with our legislative colleagues on the phone, sort of your response to how you see things and any issues from your point of view in terms of barriers to getting this done. By the way, let me, in doing this, explicitly second Francis' comments about not only your personal leadership, but the organization's leadership in moving this forward.

MS. TERRY: Thanks very much. And as you know, I've had many visits to this committee where I wasn't able to be smiling all the time to say we actually are moving the ball forward.

I, again, would second or third the thanks for the huge effort made, especially by Michelle Adams from Louise Slaughter's office and Brian Petersen from Judy Biggert's office. They've really worked day and night and literally day and night, sometimes through the night, on this bill especially over the last few weeks. So a huge, huge thanks to them.

I am really thrilled to be where we are. It's almost quite remarkable to me to think that this early in a session we have this number of cosponsors -- 215, 219. I don't remember exactly what today. And to be able to have gotten the bill through all three committees this quickly -- and there were many hearings, many markups over the last few weeks -- has been enormous.

It has not been easy. When those on the outside say, isn't this fabulous how this is flying through, I think Michelle and Brian will agree with me that it didn't fly. It was a big rock that we rolled up a very steep hill. It wasn't without bumps and there were certainly a lot of the special interest groups' interests along the way, including other interests that I learned. As soon as the bill started to move fast, I joked that only the beef lobby didn't jump on the bill. So we're very pleased to have it in this shape, even in this form, this far.

I think my main concerns going forward would be that we could be really clear in the reconciliation of the three different sets of issues around the bill. I know that Michelle, working with Chairwoman Slaughter will be very careful about making sure that the bill is as strong as it can be and that it does what it needs to do.

Around that, I think the issues around genetic testing definitions, for example, were worrisome throughout the process, and I think it might even be good for Francis to make another comment about the issue around the definition, particularly since the issue that Marc brought up about whether or not metabolites and proteins that indicated genotypes should be included. I think Francis made that quite clear in his testimony and he did testify twice during the time. And I think that would be good for him to comment on.

And the last thing I'd say is one thing I didn't get to say so much in the hearings because they mostly wanted to hear from me about the history of the coalition, which has been fabulous with industry and patient groups working together with professionals. But I think that we should, as a nation, think about so what have we lost. Not only the numbers of people that have been discriminated against all these years, but in the numbers of people who did not enroll in research in clinical trials and where we might be as a nation today had we not had this impediment that other countries don't have and that other countries look at us as an advanced nation and say, we can't even protect our people's genetic information. So I think that that's very significant as we move forward.

I think that both Republicans and Democrats, that insurers and manufacturers and patients can stand together when we finish this bill and say, what a great thing we did for people. It's late in coming, but here it is.

DR. TUCKSON: Before Francis engages your question, I don't know whether you were in the room earlier when we talked about the health information technology discussion. I don't expect that you do, but in case you do, I wanted to give you the opportunity, if you have any thoughts on the privacy and security elements in that discussion and any relationship that you see. I tried to underline that issue and don't know whether you wanted to comment.

MS. TERRY: So I appreciate your underlining that. I heard Secretary Leavitt at the PMC talk at the Press Club on Friday, and he was quite clear, as were the people here today, about the importance of the health privacy issues in health IT. I can't imagine that without this bill passing, any of that can go forward. I wish we came, again, to this game sooner. I wish we had had more forethought several years ago from the Secretary on down that we really had to push hard to get this bill done and quicker. I'm glad to see that there are clearly practical issues on the table before us so that we can get real about how fast we need to make this law and implement it. So I think those things are totally married, and without it, it wouldn't be very effective.

DR. TUCKSON: Thank you so much.

Francis?

DR. COLLINS: Well, this issue of the definition of genetic tests and genetic information has certainly been a challenging one to try to put down in a limited number of words what exactly is intended, again, with the goal being to protect people against discrimination based on that kind of genetic information.

One recognizes that the ways that you detect genotypes are not always limited just to DNA and RNA, but certainly there are indications at times where one can do that using the measurement of a protein or of a metabolite. And it would be unfortunate, therefore, if you intended to protect somebody but it just happened that the test that was being used at that point was not a DNA or an RNA test but was a protein test.

For instance, if you wish to protect people with sickle cell trait from discrimination. And I think we would want to, and in fact, some of the state bills that have been in place the longest were for that very purpose. Sickle cell trait is generally not detected by DNA or RNA. It's detected by hemoglobin electrophoresis. So it's a measurement of proteins. You would want to have that under the umbrella of protection.

Similarly, a Tay-Sachs carrier. Tay-Sachs carrier testing is generally done with an enzymatic analysis to see if the enzyme is present at 50 percent of the normal level, and if it is, that essentially infers rather directly what the genotype of that individual must be without actually going to the DNA level. That kind of circumstance is covered, therefore, under the way the definition is written about what is protected.

But in terms of other kinds of metabolic measurements, where perhaps genes are playing a role but a very complicated one, such as cholesterol, the example that you mentioned, or not to use a totally silly one, your serum sodium, your serum calcium, all of those are, of course, levels that vary over time that are affected substantially by diet, by other circumstances of what's going on in your environment, the intent of this bill is not to sweep those under the umbrella of protection given that what you are measuring there, while it has some relationship to perhaps a long list of genotypes, is influenced by many other factors.

I think it will be very helpful when the dust settles on this. I think what I've just verbalized is the consensus view of all of the people who have been commenting upon the definition. It would be good to have that incorporated into report language in the bill when it's ultimately brought to its conclusion, and that will then assist the process of figuring out the regulations which, of course, have to be implemented after passage to be sure that this bill is interpretable by those who need to enforce it.

DR. TUCKSON: Terrific.

Marc?

DR. WILLIAMS: Yes, I appreciate that and I certainly am completely with you in terms of where that is.

I think the concern that I have is that as much as the genesis of this bill has been from the perspective of the harm that could accrue from the discrimination that can result from genetic information, I think there's also the realization that there are interested parties that would look to bring as much under this bill as they could possibly bring under to essentially protect all information under this rubric of genetic discrimination, which would be equally harmful in terms of the ability to do things such as quality improvement and disease management and things that

we, I think, would all agree are good things. So, again, it's a tension issue and it's an interpretation of what reasonable people would consider to be the intent versus what unreasonable people on either side of the debate would consider to be how they could use the language to foster an agenda.

DR. COLLINS: So I appreciate your clarification also of some of those concerns.

I think there are two issues here. The one really is which part of information is protected under this legislation in terms of it not being something that can be used by a health insurer or an employer to make a discriminatory decision. Then there's a separate issue about will this get in the way of actual delivery of health care. As has already been touched on several times this morning, particularly by Reed's earlier question, the intent of this bill is in no way to damage that relationship.

I think the bill is written, though, with the understanding that it is health care providers who make those patient care interactions and decisions, not health insurance companies. Health insurance companies are, of course, in a great position to encourage wellness programs, to put out information about what's now available that might be valuable for individuals to take advantage of as far as personalized medicine, but not to request or require that someone actually undergo that kind of a genetic test. That really, we felt, was a conversation that ought to be between the provider and the patient. And I think the bill has been very careful to try to make that distinction.

DR. TUCKSON: Members of the committee, do you have any other questions?

(No response.)

DR. TUCKSON: Well, this is just fantastic. On behalf of all of us, let me thank Kris, Michelle, Brian not only for your willingness to be on the phone with us today, but for the efforts that you've been doing behind the scenes to make this a real opportunity to actually deliver something. Sharon, thank you again for coming up.

Any last comments from our members on the phone?

MS. BRADSHER: Thank you for inviting me.

MS. ADAMS: Yes, thanks for inviting us too.

MR. PETERSEN: Thank you very much.