

**Genetic Discrimination Session
Q&A and Committee Discussion**

MS. BERRY: Thank you very much.

Let's throw it over to questions from members of the committee. Julio, and then Sylvia.

DR. LICINIO: I had a question about the legislation that's in Congress right now. Is it the kind of protection that let's say when you go to the, just as an example, I went to the clinic last week for my own medical need. You have to sign so many forms waiving every kind of, you know, as far as giving access to your records for the insurance company. Like four or five forms, you can hardly understand them.

A lot of people look at very fine print, and you know, do I really want to do this or not? Is this the kind of law, let's say if it's passed, could it just be in the fine print somewhere that you waive your right to genetic privacy for insurance purposes for that purpose? So even though there is an overall like, you know, an overarching principle, it is something that could be waived for third party reimbursement.

MR. SWAIN: I think the same people that design the home residence sale closing forms package are now working in the insurance and health insurance industry. It is not quite that thick yet, but it is getting there.

The quick answer to your question is that individuals have broad authority to waive protections. Health insurance companies have many reasons to, if you seek a health insurance company's reimbursement, they, under their insurance contract, may demand to know details of why that reimbursement is being sought. So that's part of what health insurance is all about, to decide whether treatment is appropriate, unnecessary, or excessive, whatever the case may be.

So typically that's the basic waiver. The doctor is not supposed to share the information that they have about your health condition with anyone else unless you allow them to. So you waive it and say you can send it to my insurance company that's going to pay for this.

I don't see anything in this legislation that will stop or alter that. The health insurance company will still be allowed to have that information. Actually, that's an important question that I'm glad you asked. Everybody that is in the normal flow of genetic information would still be allowed to have that information. It's not the having of the information that's the problem, it's the misuse of it.

If the health insurance company turns around and increases your premium because something in the genetic information suggests that in five years, you may acquire a particular health condition that you don't have now, that would be a misuse under the bill. But for them to have the information would not be misuse under the bill.

MS. BERRY: Sylvia?

MS. AU: My question is for Christy, and a comment. Could you tell me a little bit more about how you got the broad range of demographics for the study that was Internet-based? And then my plea to you is in the presentation, you kept saying Americans, Americans, and it's only 1,010 people. I think it is survey participants attitudes more than Americans.

MS. WHITE: Well, the data is projectable. The data is projectable to the U.S. population with a sampling error of plus or minus three. So when we say that, we're saying Americans, but to your point, yes, within the sampling error that allows. That's the worst case scenario for sampling error, because there's a lot of agreement to a lot of these questions. In most cases we're looking at a sampling error projectable to the U.S. population. I shouldn't even say Americans, actually, but to the U.S. population of at worst case, it is plus or minus three.

In terms of how we collected the data, there are a variety of Internet panels that exist, web-based panels that exist. For this study, we used Greenfield Online. Probably a lot of you have heard of them. They are one of the largest panel houses.

Their panel is somewhere in excess of 7 million Americans at this point. They generate their sample through a variety of means, intercepting people off the web. They do a lot of in-home calling into the homes. We know that the U.S. at this point, in excess of 80 percent of the U.S. population has access to the web, and we are very cognizant of the fact that there are specific populations that are not on the web at this point. I shouldn't say on the web, but underrepresented on the web.

Particularly they are people over the age of 75, Hispanics, and people with less than a high school education. So what we do is we oversample for those populations when we go out, and similar to what we would do with a phone survey, mail survey, or any methodology, we look at the distribution of responses to the U.S. population on key variables, the census data, and we weigh the data accordingly.

Typically with every web survey that's done, you have to wait for those populations, because they're very difficult to get on the web. Certainly there is a chunk of people that are not on the web in the U.S., and they are not represented in the study.

We find that there are as many if not more challenges in conducting phone-based research these days. What happens with phone-based research is you are underrepresenting the high income, high education population that are savvy enough or quick enough to hang up on your predictive dialers, or just tell you that they're on the do not call list. We don't get into an argument with them to tell them that that doesn't really include us. We have to say thank you very much, we are sorry we bothered you, and hang up.

So there are challenges with every methodology today. About one-third of all the research we do is web-based. We've been doing it for ten years. We were one of the first companies doing it, and we are very rigorous probably to the upset of all of the web panels in terms of how they pull the sample, and what we get back in terms of results.

But your point is well taken.

MS. BERRY: Kevin?

DR. FITZGERALD: I have a couple of questions, if I can do one for each. Thank you.

First of all, Ms. White, I was very appreciative, at the end you were talking about in a sense how you ask the question can certainly lead your group one way or the other.

So sort of to make it even more generic, what do you think would happen to your numbers if you substituted the word "nanotechnology" instead of genetics?

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MS. WHITE: Well, we always try to do qualitative research before our quantitative so we understand which terminology we can use and not use. For example, "gene expression" was something we wanted to talk about initially, and from our qualitative research, it was clear that consumers could not understand that terminology.

So we through qualitative try to understand what are the terms we can use and not use. I mean, we would never use a term like nanotechnology. In fact, we try to keep all of our surveys at a 6th grade reading level, to the extent possible, because that way we can ensure that all the survey respondents are in fact understanding the question.

We also not only talk to them beforehand to understand what we can say, but we pretest the survey instruments. So once the actual questions are written, we have a small number of Americans of the U.S. population go through the survey as if they are a respondent, and then when they're done, we walk through and say every question, what did you think we were asking you here, what did it mean, was anything confusing, hard to understand? We added the survey accordingly from that.

DR. FITZGERALD: Okay. Thank you. Then Mr. Swain, one thing you mentioned, I think it's going to be very interesting to see how this shakes out, this idea of family history versus genetic information.

In a sense, one could use either to sort of get a percentage risk one could say in predicting the future health of an particular individual, family, group, or something like that. I'd like to hear more about how this difference is going to attempt to be clarified in the law.

MR. SWAIN: I guess I'm tempted to say I'd be happy to further comment if I can have your assistance as we mediate this issue. It is obviously semantics, it is conceptual. I just have to go back to our starting point, which has been drummed into me by Sharon Terry, which is that this legislation is intended to remove the popular apprehension about receiving or undergoing genetic testing.

It is not intended to change anything else that's good or bad about our health care system. It is not intended to prohibit or curtail the ability of physicians to take family histories. If some lawyer got in there and read the bill and said this would prevent taking or using family history, then it's our obligation to try to work around that.

We aren't at the end of that process yet, but conceptually, that's where we're starting.

DR. FITZGERALD: Thank you.

MS. BERRY: Agnes?

MS. MASNY: I'd like to thank you, Mr. Swain, for your presentation. We really appreciated the work of the coalition to help move this legislation along. We would hope that you continue in your efforts in back of Ms. Terry.

Ms. White, I just wanted to also say that we're very happy to see that you're reporting on numbers regarding the public's concern about both the privacy issues and the misuse of genetic information. I think this is one thing that the committee has long been asking for to get further and further numbers regarding this issue. So I just have a question based on that then for the committee, our committee itself, is whether we could make use of the numbers, the summary of

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the presentation today, to add as an addendum to what we've already sent to the Secretary, if that would be okay to do.

I think it continues to add to the momentum of the need for this type of legislation.

MS. WHITE: We'd be honored if you did that.

MS. BERRY: Suzanne and Julio.

DR. FEETHAM: A question for Ms. White. You were very deliberative obviously and scientific in your sampling.

My question to you is are you designing this as you go into the third year that you can be looking at trend data?

MS. WHITE: We did actually trend the data to last year. There were not a lot of changes. Actually I was a little disheartened to see that awareness had not increased over the past year.

We did go back and do a literature search to see if there had been an increase, because it seems that way to me. You know, when you buy a red car, it seems like everyone drives red cars. So I thought gee, every time I turn around I'm hearing a story about this. I was surprised that awareness did not increase. But in fact the literature search showed that there was not actually an increase in the number of stories.

But everything pretty much stayed flat from last year, and we will definitely trend that data again. Where there are differences, we'll start to report on them, and hopefully we'll see some of those differences soon.

MS. BERRY: Julio?

DR. LICINIO: I had a question for Mr. Swain, just a clarification. This bill passed overwhelming in the Senate last season, right? And the issue has been the House. Am I understanding that the biggest issue is really the business community's fear that if you try to terminate someone's employment, it is going to be they can kind of turn back and say they are discriminating against me because of my genetic background?

MR. SWAIN: That's correct.

DR. LICINIO: I hear the words, but I don't understand how that would actually happen in practice. I mean, what genetic background could someone discriminate against? I mean, you say I have this particular, you know, gene, and you are firing me because of that? It's so illogical that I can't follow.

MR. SWAIN: Well, many are in your situation. The business community is a bit illogical, because on the one hand they say of course we don't discriminate, we don't, and we would never discriminate on the basis of genetic information. But on the other hand, we're fearful of this law that would say that we could not discriminate.

Putting aside that logical inconsistency, the discrimination to the extent that it is there or it is perceived to be there is less likely to be someone is going to be fired because, or lose their job,

but someone may not be hired because breast cancer, a genetic marker is in their medical file for breast cancer.

So they might not be hired. Why would they not be hired? Probably because the employer would be concerned that it will cost that insurance plan a lot of money when that person gets ill. I hate to be so direct about it, but generally speaking because employers don't like people who have a certain kind of gene, they are really probably looking at it from a dollars and cents standpoint. They don't want to hire somebody that they think is going to cost the health insurance plan a lot of money in some future years.

Now, I say "they." In fact, I don't think most employers operate that way. There are some that do, unfortunately, and I suspect, I have represented employers for a long time in various contexts, and there are certainly outliers. But there is a concern about that, that even if I'm a good employer, for every 1,000 employment decisions I make, I know that 100 of those are going to sue me. Out of those 100, if 10 of those can add genetic discrimination, it's going to cost me a lot more time and effort to fight that off, even though I'm a good employer and I only make decisions on the merits. So it's that balance that we're trying to strike.

MS. BERRY: Joseph?

DR. TELFAIR: I want to thank both of you for the presentations. I appreciated that. My question is for Ms. White.

In the sort of next to last slide, you had a contrasting example there between, which is this, I see it sort of consistent on what subject you ask. Is that should the government work really hard to protect your rights? The answer is yes.

Should the government be able to tell you what to do or whatever should be no. The question I have, because it's relevant to decisions we have to make in terms of recommendations is public engagement. Yesterday we had a lot of conversation of that, involving the public, advising us to make decisions in this way.

Did you have, or did you think of in your survey, maybe not some of the questions that are here, a willingness of individuals to work with the government in terms of making recommendations related to issues of privacy, issues of confidentiality, those sorts of things? Did you have any of that in your --

MS. WHITE: We didn't cover that issue specifically. I'm not sure. My inclination is to think that they would want to be involved, but you never know.

DR. TELFAIR: Well, I ask because that is a critical concern that this committee has. So thank you.

MS. WHITE: I mean, one of the things that we do on behalf of business all the time is create, we usually call them consumer groups or consultant groups, advisory groups that are made up of consumers. So if we're working with a pharmaceutical company and they are trying to figure out how to communicate something, you might get together a group of general consumers who are in their specific target audience and have them serve as an advisory board to the marketing team or the public communications team.

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DR. TELFAIR: Well, ma'am, as you consider additional questions, could I sort of suggest that you may ask that? That may be something that's important.

MS. WHITE: Sure.

DR. TELFAIR: I would think this committee would be interested to see what the direction is.

MS. WHITE: Absolutely.

DR. TELFAIR: Thank you.

MS. BERRY: I have a question for Mr. Swain. I was wondering if with the IBM announcement regarding its policy towards its employees and not using genetic information against them, have you seen any impact on your negotiations? Or is that rippling through the employer community or having no impact whatsoever? What is your view of that?

MR. SWAIN: Well, I think the IBM announcement, which was just a week or two ago, is really singular. It's obviously the right thing to do. I believe Sharon Terry served as an informal consultant at least to IBM working through some of the questions that came up internally.

It's a leadership move, and it is certainly our hope and Sharon's hope that many other U.S. companies and U.S. employers adopt and articulate similar policies. I don't really have any information to respond to your question because it's too recent.

I can tell you that our sponsors, particularly our republican sponsors in the Congress, are very happy about the IBM announcement, because it confirms what they are telling their business constituents, that it's really in your best interest to go ahead and support this bill.

I think it is going to have an influence, I think it is having an influence. It's a little too early for me to gauge what the level of it is.

MS. BERRY: Sherrie?

DR. HANS: My comment is actually a request for Ms. White. You indicated at the beginning of your talk that you do have data on the preference for delivery method in who is involved in returning genetic data and information.

Would it be possible for you to share that information with the committee and a couple of top line slides that you have on that? I think it's particularly pertinent to the conversations we had yesterday about large population studies, and if and how such information should be returned to the participants if information is found.

MS. WHITE: Yes, we do have information on that. In particular, I think questions about how involved the physician would be in the decision or who influences would be, what level of influence different organizations would have on their adoption. For example, the government, pharmaceutical companies, health associations, we have a lot of data on that as well, which we're certainly happy to share.

We're also, and I don't know if I mentioned this, but we're also getting ready to launch the first physician-based study, which will be a complement to this research, which will look at physicians, both general practitioners and specific specialties, very similar, although you might

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not think it would be on the face of it, but what is their awareness, what are their perceptions, what are the catalysts and barriers to their adoption.

We would get of course more with them into usage, and then also looking at issues of how they would best like to have this delivered so that it's easier for them. We may remove some of the cost issues that are there.

So we'll also be starting, that study is going to be launched early next year as well, so we'll have some data there, too.

MS. BERRY: Thank you both very much for coming today and sharing your perspectives and your comments. I hope you don't mind, I'm sure many of us will want to follow up with you. We'll have additional questions and thoughts, and we'll enjoy working with you in the future.

MS. WHITE: Thank you.