

**Public Comments
Day 1**

DR. McCABE: Now, we will move into public comment. I think it's important to recognize that we always invite public comment. This is an extremely important part of the process for us, and we look forward to contributions from the public.

We've had some written comment. These are in Tab 2 of your notebooks and in the table folders. Just to give you who those are from, Kathleen Zeitz, J.D., from the Nebraska Breast Cancer Action Network, Diane Dormond from the National Organization for Rare Disorders, the Oncology Nursing Society, the National Society of Genetic Counselors, which has signed up to make oral remarks, I think, tomorrow, and Mark Bale from the U.K. Human Genetics Commission Secretariat.

We had three individuals but one of them has graciously volunteered to move until tomorrow morning, so we have two. First will be Dr. Thomas Hooyman from the Catholic Health Initiatives, and I would ask all of you to try and stick to three or four minutes, so that we have some time for questions to you.

DR. HOOYMAN: Thank you. I will certainly attempt that, and I very much appreciate the time with the Committee to provide some public comments from the perspective of Catholic Health Initiatives. We're a national Catholic health care system based in Denver, Colorado, with, as you can see, our particular size out of the Catholic tradition. I work as a theologian ethicist within that organization and welcome the opportunity today to be here.

I wanted to give just a very brief comment regarding how we would approach not just the area of genetics and advances within that field but generally the broader question of the relationship out of a faith-based organization, such as Catholic Health Initiatives, in regard to science as a whole.

I think it's interesting, some of the questions that were raised just before. I won't go through these, but the last dot in particular sort of raises the question that from a particular perspective out of a Judeo-Christian background, that by our very nature, we're limited, and it's interesting as we listen to comments and discussion through the course of this meeting, that there's a certain sense that there's an unlimited possibility where human genetics, the Genome Project, and various advances within genetics may lead us, and so I think there's somewhat of a philosophical tension there.

The other thing I want to say is that there is nothing out of the Catholic tradition that is inherently opposed to the work of the Human Genome Project or advances in genetics at large, and I think sometimes there can be sort of a biased perspective right away that a faith-based organization, such as CHI, would be opposed to that, and we are not in principle.

Just very briefly, a few ethical concerns that we would have in general in regards to the area of genetics. What I'm concerned about is the potential advances that may exist within this area of genetics may become mired in the apparent irreconcilable dispute that has already existed within our society around the beginning-of-life issues, and from our perspective, it would be a shame that if we would have potential advances within this area sidetracked by those ongoing beginning-of-life disputes. It's just a recognizing of them in the first place.

Secondly, as you've already heard, in our consumeristic society, whether it's the coming up with new discoveries for your makeup or the skin disorders or what have you, or just the enhancements of that, if

the services are provided, if they're available, as what was mentioned before, consumers will go after it, and as a provider of health care, being in a variety across this country, that imposes a significant burden upon us as a provider not only in the area of capital, of making investments within the capital infrastructure for laboratory services and equipment itself, but also with regards to personnel. So there's a tension there that we have to deal with, I think, and that the work of the Committee should address.

Final just general concern, as has already been mentioned, with the 40-plus million people who do not have access to health care already, how we will look at this question in the area of justice and expanding access to just the basic care, such as what was mentioned before, just aspirin.

As a provider, Dr. Juengst had already spoken of testing and therapy and also pharmacogenomics. Just looking at now what's possible, as you're all very familiar with, just the area of genetic testing, we have patients in our clinics that are approaching a variety of family practice physicians, internists, oncologists, what have you, that are already proceeding with these particular tests and the fundamental policy questions that I've outlined here are really unresolved.

So I would look towards and encourage the looking for priority work around for the Committee for your work in the coming year to possibly address some answers to some of these key policy questions. Appropriate genetic testing for disease processes where there's no proven treatment, the sharing of that information with family members or others, and then if there is such a responsibility, how could that be regulated, as you've already been discussing.

As an employer, we employ approximately 67,000 individuals within our organization, and so there are several concerns that we would have as an employer. In order to remain competitive, our benefits plan will need to continue to evolve into to include genetic services. Otherwise, we'll have key employees who would be going to competitive organizations. So that's going to impose additional financial pressures to us.

Secondly, as has already been mentioned, we see this also as an employer and we're one of those organizations that ERISA preempts us, we're self-insured, so the local state regulations don't apply to us, as you were discussing before, but just how we on go maintaining the privacy and confidentiality of our own employee databases and with regards to their private health information, in regards to HIPAA, and also a final point, as internally within our organization, we would not discriminate against our own employees based upon their genetic makeup.

Some suggestions for your work agenda as you are currently doing via the webcast and just as mandated by Congress is to engage the public, not only just to engage them but to provide an increased awareness and understanding of the public and the potentiality of what will result from the work of this group and with the project human genetics going forward.

It's interesting. We have a grave concern around education of health care professionals. I don't think I heard anything through the course of today of the dearth or the lack of qualified, certified genetic counselors. We did an asset map within our organization just to see what services, who do we have available, and we have two certified genetic counselors out of an organization of possibly \$6 billion in revenue.

So I think nationally, there's only 2,000 certified genetic counselors, and I think you'll hear probably public comments from that organization tomorrow, but we really need a comprehensive approach for dealing with education, not just genetic counselors but health professionals in general.

Perhaps, and it's probably the most difficult challenge that you may have, is to develop some kind of ethical framework going forward of how all the variety of genetic advances may be evaluated, and in a pluralistic society, I mean that's the heart of our society in the democratic environment, that's where the debate occurs, but I think, just as Dr. Collins mentioned before, there was a line that he was drawing in reproductive cloning. Well, what is that framework and where else can those lines be drawn? I think some of your discussion's already occurred around that area.

Finally, I was struck a few days ago, perhaps some of you had seen it, there was a photograph on the front page of the New York Times of a woman in South Africa collecting water with a bucket going down to basically a muddy pool in a roadside collecting the water for the day for her family, and I think there's a need that we have to maintain a global perspective over balancing our needs as a society just around genetic testing perhaps or other genetic advances in regards to global needs, for instance South Africa, just in the basic idea of public health and access to water.

In conclusion, we would like to maintain a very optimistic view of where the work of the Committee will proceed and with medical genomics in general. We're also somewhat cautious about the potential hazards, and as I'm sure you've sort of picked up within the comments thus far, we'd like to remain in a collaborative fashion with the work of the Committee as you go forward, and we very much applaud the work of the Secretary at this point and the Committee of the whole.

Thank you.

DR. McCABE: Thank you very much.

Any questions for Dr. Hooyman? Yes?

DR. SHEKAR: Not a question, but a comment.

DR. McCABE: Please identify yourself.

DR. SHEKAR: Sorry. Sam Shekar, representing HRSA, the Health Resources and Services Administration in HHS.

Just a comment, that in terms of the issue of health professions education, we did a study through Judith Cooksey, who was here earlier today, earlier with regards to genetic counselors in the United States and the issue about training is a very serious one. In fact, we only have 1,800 or so genetics counselors in the entire country. So in terms of the translation of research into practice, the issue of workforce training is an important one and one that we would suggest or recommend is also a priority area that needs to be looked into.

DR. McCABE: Thank you.

Other comments? Yes, please.

MR. DANNENFELSER: You raised the issue of cloning. Dr. Collins did as well. He mentioned reproductive cloning, where there seems to be a general consensus that that should not be allowed. The controversy seems to be more in the area of experimental cloning or what is often called therapeutic cloning, and it seems that the term "therapeutic" is supposed to refer to providing therapy for benefit to the person receiving the treatment, and that in fact is not the case with what some call therapeutic cloning.

It is really cloning for the purposes of experimentation, and I just wonder if that's an issue of concern to you.

DR. McCABE: Just for the record, that was Mr. Dannenfels from the Administration for Children and Families.

DR. HOOYMAN: The concern that we would have would be out of that slide on the ethical framework, the very first dot, the protection and the inherent dignity of the human being. There'd be nothing opposed to cloning of therapeutic cloning, for instance, if I needed new kidneys or a heart and you could take cells and somehow come up with a new heart for me or kidney. My human dignity and my totality is being protected.

I think obviously that other point of saying getting into the beginning-of-life issues or depending upon what's being presented out of the Catholic tradition, there are going to be some very serious concerns around the protection of life. So I don't think it's irreconcilable. I think it depends upon what the technology's presenting and there again to be again to, through a democratic process, be able to work out what's accepted public policy.

DR. McCABE: Thank you very much.

DR. HOOYMAN: Thank you.

DR. McCABE: Our next speaker is Dr. Kathy Hudson from the Genetics and Public Policy Center, Johns Hopkins University.

DR. HUDSON: You all deserve an award in endurance and stamina.

My name's Kathy Hudson. I'm the Director of the Genetics and Public Policy Center at Johns Hopkins University, and I wanted to speak today to just let you know that we exist and that we'd like to be a resource for you. We were created by the Pew Charitable Trust about a year ago in order to create resources for decisionmakers in considering issues that are emerging from advances in human genetics, and so I'd like to just familiarize you with some of the resources that we have available and would welcome input from you as you begin your deliberations in how we might be helpful.

We currently have a major initiative underway in reproductive genetics. As you know, there are now over 900 genetic tests that are available, either clinically or in development, and we can do genetic testing at virtually any point in the reproductive cycle. We can test parents. We can select gametes. We can test embryos. We can test fetuses, and we can test newborns.

The goals of the initiative are here. The one that I would like to highlight with you is some of the work that we have done to assess the public's knowledge and attitudes and values not only about reproductive genetics but about human genetics in general. A folder was passed around, I think, that includes this report, which is part of the center's effort to understand what the public is thinking, what the public values, what the public priorities are. This was an initial pulse-taking of where Americans are, and we are now following up on that with detailed qualitative research.

In April of this year, we did 21 focus groups in five cities around the country, and after recovering from our exhaustion, we're now evaluating the large amount of data coming out of those focus groups. This summer, we're going to be doing 200 interviews with individuals with specialized expertise or experience or perspective with relationship to reproductive genetics, and then this fall, we're going to try to validate

some of the hypotheses that come out of that, test the hypotheses that come out of that qualitative work with a larger more robust survey.

The other thing that I'd like to make you aware of is the extensive information resources that are available on our website, which is www.dnapolicy.org. We have an extensive bibliography on science, ethics, policy, and law related to reproductive genetics and genetics more broadly, much of that having been annotated in-house by our staff.

Our major goal at the center is to develop a set of policy options. So we're not going to be developing a single recommendation of this is where the country should go in dealing with the development and use of reproductive genetics; rather, we're going to try to develop a broad base of analysis and then take that analysis and put it together with what we learned from the public about their values, what they hope for, what they're concerned about, and develop a diverse set of policy options that you as a Committee and others in government and in the private sector can consider as you make decisions to move forward.

Again, I invite your input, particularly as we're developing this survey for this fall, that if there are questions that you have about what the public's thinking about certain issues that come under your deliberations, we'd be happy to think about how we might be able to work together to answer some of those questions.

Thank you.

DR. McCABE: Thank you very much.

Questions or comments for Dr. Hudson?

DR. REEDE: It's more of a general comment, and it relates to many of the presentations that we've heard today, and it's reflected in everything from building the huge data bank and the need to make sure that it's inclusive in terms of race, ethnicity, diversity. It relates to comments about the workforce and the low numbers in the workforce, but we haven't really spoken about who is represented within that workforce and is there diversity represented within that workforce. It relates to Jack Rowe's comments about certain racial or ethnic groups' concerns about genetic testing and being involved in genetic-type issues and the comment that part of what needs to be done is educating our physicians to better deal across communities which is true in general, but also, how do you have better representation there.

I would carry it here in terms of as we seek a better understanding of the public's perception about genetics, making sure that we're inclusive and that our understanding is representative of our entire society and we're getting the perceptions from the various racial/ethnic groups and that this work is not done as an afterthought. So after we've put our data bank in place or after we have put our workforce agenda in place or after we have done our surveys, we then come back and say what about the diversity issue.

DR. McCABE: Thank you.

Other questions or comments for Kathy?

(No response.)

DR. McCABE: If not, thank you very much.