
Public Comments

DR. WILLARD: We'll now move on to a public comments period for this meeting. One of our critical functions is to serve as a public forum for deliberations on a broad range of human health and societal issues raised by the development and the use of genetic technologies. So we greatly value the input that we receive from the public at large.

We set aside time each day to hear from members of the public, and we both welcome and appreciate the views they share with us. In the interest of our full schedule, I'd ask the two scheduled commenters to keep their remarks to five minutes, if possible.

So today we're going to first hear from Kathleen Rand Reed, representing the Rand Reed Group.

Welcome. Maybe you can find a chair at that end.

MS. REED: Good morning. I am an applied biocultural anthropologist and ethnomarketer. Today's presentations, roundtable discussions and program segments cover broad topics, as large population studies and their subfocus on the scientific community, public engagements and bioethics. Tomorrow will cover genetic discrimination and pharmacogenomics. I won't be here, so I tried to bring to this forum policy perspectives, information and mechanisms that relate to the efficacy of all aspects of this meeting, and they are specifically, one, the need for inclusion of an outreach marketing to the 18- to 34-year-old hip-hop, rap and urban, or Hispanic urban generation for clinical research and genetic educational information; two, the need to create a firewall between health and disease-oriented genetic and clinical research and the use of DNA analysis within the law enforcement realm, specifically CODIS, the FBI Combined DNA Index System; and three, the need for outreach to the pre-migration communities, families, and relatives, incorporating transnationality within the genetic educational models.

I bring this up, and I just wanted to be very quick about this, because I'm very much involved in that community, and especially I serve on an IRB with Heart, Lung, Blood. One of the things I notice is that when people are doing outreach to many of the minority communities, they tend to go to faith-based organizations and churches, et cetera. But given that the rap and hip-hop culture emerged out of the 1970s, we're talking about a popular culture and a cohort that has actually, in many cases, grown up over these last 30 to 35 years. Yet when you look at clinical research and you look at the marketing, and especially when you're talking about the new group in terms of starting families and genetic education, they're almost missing in action.

By the way, there's a lot of fear on the part of people to do outreach in this because historically this has been stigmatized, and it's been linked with crime, violence, and crude thug life. But today, the culture has segmented to the point now where you even have Evangelical aspects called Christian hip-hop. So it's a popular culture international segment of a cohort population that, quite frankly, given the other things that are going on, are just not being served.

The Latino aged 14 to 24 group that comprises more than 20 percent of the Hispanic markets in their new identity, they're now considered pan-Latin in their identity, and they often speak with a fusion of Spanish and English, and many have never visited their parents' country of origin, and yet they're an intricate part of this culture. We don't have to talk about the growth of the Latino and Hispanic population. It was 35.6 million in 2005 that are now 41.3 million, and that's the legal side of the house. So I would recommend that a representative advisor to this committee for this market and this cultural lifestyle for input and reality checks on the effects of these discussions and decisions in this segment.

The second part, real quick, facts on the ground. Let me give you six points.

Number one, in 2003, North Carolina technicians compared DNA left from a crime scene with genetic profiles in the state's database of convicted felons. The crime scene DNA did not match any of the 40,000 felons on file, but since it was remarkably similar to an inmate, the technicians concluded that the unknown man was from the same parents as the inmate.

Florida's DNA database operators have been permitted to give investigators the names of convicted offenders who match a crime scene sample at 21 of 26 alleles. It has been estimated that men who have 21 alleles in common are almost always brothers.

African American males are more than 12 times more likely to be arrested and not convicted than whites, and yet a growing number of jurisdictions are collecting genetic information from arrestees not convicted, and the materials are not destroyed upon establishing the innocence of the arrested person.

Many African American and Latino communities and zip codes are hyper-segregated, to the point of 99 percent, and a growing number of children born in these hyper-segregated communities share known and unknown male parentage, and in some cases are half-siblings.

The reason I'm very much involved in looking at the establishment of a DNA database is for the reunification of Katrina families and children. One of the barriers I'm running into is that because there's no firewall between the CODIS and the law enforcement side of the house and the communities where this word has spread and there's great fear, many people have not come forward to even discuss it because many people in many of these hyper-segregated communities are terrified of the genetic side of the house. So this is an issue that has real effects in the reunification of many of these families that have been separated tragically with Katrina.

So the recommendation would be to investigate the use and abuse of the genetic familial searches, which is really what it's about, and we're dealing with that in terms of anonymizing samples, et cetera, and this being an ethical issue, and the development of a policy position which creates this firewall between the health and disease-oriented genetic and clinical research and the use of DNA analysis within the law enforcement realm; and lastly, develop policy that establishes the destruction of physical samples used in DNA testing.

The very last, which will take less than 30 seconds, is the need to incorporate transnationality within the genetic educational models; in other words, pluralist bioethics. Many discussions about outreach for genetic education to minorities especially, genetic sampling and family histories, still center on native African Americans and, to some extent, the Hispanic population. However, one of the biases incorporated within those discussions and policies is the lack of understanding of the dynamics of transnationalism, transnationalism being the ease with which immigrants live in the United States but support relatives, run businesses and participate in a two-way exchange of gifts, commodities and cultural practices in both the United States and the country of origin.

In the development of policies and mechanisms for genetics, health and the U.S. society, certain aspects of transnationality must be taken into account. One which is critical is the outreach to not only the U.S. communities but the pre-migration communities, families and other persons who act as family or fictive kin, to the residents in the United States, and to provide the U.S. residents with information developed for their pre-migration communities and family members. It increases not only the efficacy and effectiveness of the outreach but often augments from a

cultural perspective the underlying tenets of informed consent. There are people who will, before they give you family information, call grandma or compadres and ask them should they, and if they say no, then they will come back to the researcher and say thank you very much and be very loving and very nice, but they will say no.

So if this pre-migration information can be provided to the families and, in the case of many Latino families, the godparents, you may see the efficacy and the effectiveness of the sampling go up.

Thank you very much for your time. Are there any questions?

(No response.)

MS. BERRY: Thank you very much.

Next is Joann Boughman, American Society of Human Genetics.

DR. BOUGHMAN: Good morning. On behalf of the American Society of Human Genetics, and as its executive vice president, we thought it appropriate that we make some comments on the proposed large cohort study. I'd like to thank Dick Marchase as representative of FASEB, an organization in which we are members, that I think he has addressed some of the broad issues extremely well, but we would like to make just a few comments.

The need for large-scale population studies to understand genetic and environmental factors that are involved in the relationship to disease is certainly evident to those of us in the fields of human genetics, medical genetics and genomics. The design, implementation and analysis of such comprehensive studies are obviously, as we've heard many times over, of enormous complexity.

As with any group of scientists, the human genetics community does not speak with a unified voice on the promise of such studies or on the priorities that should be assigned to them. The leadership of ASHG has discussed many aspects of this proposed population cohort study. While there is widespread and general support for the concept, as expected, there are some diverse views -- the devil is always in the details -- on the manner in which the study would be implemented, the nature of the data collected, and the extent to which the data will translate into the promise of treatment or prevention.

ASHG applauds the NHGRI convening working groups and gathering comments from many in the scientific community, both inside the NIH and in the extramural community, and we also commend SACGHS and others for continuing this dialogue. The gaining of interest and communication among the scientists will be enhanced by every one of these dialogues that we have.

The design of the study, including ascertainment of systematic data, structured collection of variables, and quality-controlled data analysis, should be of enormous benefit. Nevertheless, it is clear that the design of this study is an immense challenge because the specific aims will necessarily evolve with time. In contrast to the Human Genome Project, as we've heard, which had a specific and defined endpoint, in the case of this cohort study, the good news and the bad news, if you will, is that the goals must be broad, and many specifics cannot yet be defined, and the data gathered would need to be broad enough so that yet undefined or currently unrecognized questions could eventually be asked and answered.

The strong interest and general support for the large population cohort study derived from the widely held conviction in our community that such a rich data set should have important clinical implications that we hope can be translated into general benefit, and the hope is underlined there as you all have discussed earlier this morning. That is one of the challenges, is the translation of the results of such a study into action in clinical practice.

We see the challenges proposed to the study coming in at least four forms, and in some respects this becomes a summary of this morning's comments. Would or do existing data sets have sufficient breadth and depth to provide at least some of the information as proposed in this study, and if not, are there ways that the existing data can be further mined to limit the costs of the cohort study? In the written remarks I've listed a few, but a few others have been named this morning, including the Framingham Study, the Children's Study, NHANES, and the Veterans Study. Are there ways that we could further mine some of those data sets to ask new or better questions?

The second point is a major one. Given the current fractious state of health care in the U.S., can a truly coherent cohort study be designed, data collected and analyzed, and benefit returned to the participants and others in the U.S., at a reasonable cost? For example, it is proposed that information will be collected from medical records, a daunting challenge, as we might expect. Or would the health care system itself have to be revolutionized to benefit from such a study?

Many in the genetics community wonder if such a systematic study can be carried out in a way that can be fully utilized in the United States. In our patchwork system, absent systematic electronic medical records and any realistic vision of a uniform or universal delivery of health care, the direct applicability of the results to the broader community must be appropriately questioned. In other health care systems around the world, the implications of study results could be more quickly, efficiently and effectively utilized, integrating the results of a well designed study into the point of practice much more directly. That doesn't mean this shouldn't be done. It just might be done quicker and more effectively elsewhere.

In contrast to the Human Genome Project, which required a development -- and I'm amazed that these were the terms that my colleagues used -- which required development of relatively inexpensive high-throughput data sequencing and computational tools to assemble, compare and analyze digital data, the cohort study demands the identification of a population that has sufficient breadth and depth to allow analysis of a myriad of relevant questions, the identification of numerous biological variables to be measured, and their tabulation, and the creation of robust assessment and computational tools to define, measure, and assess the effects of environmental changes over time. Compared to the Human Genome Project, these perceived requirements are far more complex.

Fourthly, as spoken about by Dr. Marchase, the costs of the project will have to come from funds outside the usual funding mechanisms as they are likely to be so large that the effect on usual biomedical research funding could be highly deleterious or even devastating. It is therefore anticipated that this study could not and would not directly deter or redirect the current limited biomedical basic research funding.

Finally, as recognized by others, the choice of individuals and populations to be included, and their relative representation, is far more complex in our highly heterogeneous society here in the States, and the need for the diversity, and the manner in which that diversity is handled, need to be carefully considered prior to the identification of those to be actually included in the study. The many issues related to recruitment, ascertainment, fully informed consent and privacy will be

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more directly addressed by others but remain in the forefront and concerns of the human genetics research community.

Our researchers and clinicians have been consistently in the lead on addressing and discussing openly ethical, legal and social implications of our own research, and we maintain that this endeavor, along with the educational issues, are of the utmost importance.

As an organization, ASHG generally supports this concept and recognizes the importance that results of the proposed study would provide to all of us. We encourage individual members of our organization to remain active in the process of the design and the development of this proposal, and today we'd like to again commend the SACGHS on the development of timely and important questions to consider in the analysis of this proposal and bringing them to the public, and support your effort to analyze this proposal in detail.

Thank you.

MS. BERRY: Thank you, Dr. Boughman, and Dr. Rand Reed both for your comments and your input. We'll certainly take all of those comments into account as we proceed.