

Roundtable Discussion with Presenters
Facilitator: Kevin FitzGerald, S.J., Ph.D., Ph.D.

DR. WILLARD: Thank you to all four of our panelists. We're now going to have a roundtable discussion with all of the presenters and committee members, and I'll turn it over to Kevin Fitzgerald, who will referee.

DR. FITZGERALD: I didn't bring my whistle.

(Laughter.)

DR. FITZGERALD: I'd like to thank again the presenters for wonderful presentations, and perhaps we can get into what Ms. Lewis said, which is certainly going to be an interesting discussion. I don't think that will be a problem. So I'll just look around for people.

I've got Debra, and then Julio.

DR. LEONARD: So, Francis, I hate to keep proscribing what you have to do with your \$300 billion.

(Laughter.)

DR. LEONARD: It's an interesting thought that Ms. Lewis raised, and Mr. Citrin, of this concept of not having them do research on us to benefit them. This is a large population cohort database that's going to be created, and researchers are going to be accessing this database through projects, not randomly but I assume funded projects that will be supported from grant funding through NHGRI or other sources. Is it possible to proscribe that the research will be funded to reflect the ethnicity of the project to be comparable to the ethnicity of the database? So that if you have 30 percent Hispanics or 40 percent Hispanics, then 30 percent of the projects that are funded to access this database have to be directed at the Hispanic population, diseases that affect that population group. I mean, is there a way to assure that it's not them doing research on us to benefit them? Because I don't know that that's been really addressed in how the database will be accessed and how the research will be done on that database.

DR. COLLINS: If I can just give a perspective from the group that thought about this. I think the idea was that anybody who had IRB approval would have access to the data. We felt there needed to be a barrier of that sort so you don't have high school students busying themselves about genotypes and phenotypes in ways that might ultimately compromise the study in terms of privacy. But the sense that the planning group had was that you want to empower anybody with a good idea to deal with what is going to be a massive amount of data.

DR. LEONARD: But sometimes money empowers people.

DR. COLLINS: Well, certainly. Lots of these people would be funded, but it would not be a requirement. But I'd like to hear the panel's reaction.

MR. CITRIN: It's an excellent question. In our work on genomics with our community partners, we've often talked about applying to all genomics research and practice the test of is this activity more likely to reduce or exacerbate health disparities down the road. One could almost consider the need for some kind of an impact statement to justify this.

I know this is very difficult when you're doing basic research to look that far down the road, but I think it's a very useful test to apply on how a database that is gathered from all these communities is to be used, that that connection with the reduction and elimination of health disparities has got to be there if it's going to be justifiable, and this in turn can bring community engagement in the first place, and it can also bring public support.

DR. LEONARD: Because, unfortunately, it is clear that there is not an equal distribution in the research community among different ethnic populations. So you're going to get the disparities created unless there's some motivation to do the research on the non-represented groups and issues and diseases that affect all different kinds of ethnic populations.

MS. LEWIS: I think this also speaks to the importance of how the proposals or the requests are designed and that there is specific language that requires engagement of those community representatives, because as we look around, it's clear that we don't have enough African American researchers, we don't have enough in this field Native American researchers. So for us to think that we're going to put a project out there and somebody is always going to gravitate to that who is from that population is not very likely. So the language we spoke about even with addressing the issue of race and racism, that language needs to be very explicit, and there need to be some measures that ensure that that happens, which again gets to that continuous evaluation, because if it's not there, it will show up that it's not there.

DR. FITZGERALD: Julio?

DR. LICINIO: Hi. I have a few different questions. I guess I'll just throw them all out and see how the panel handles them.

I did some of the first community engagement work in genetics a few years back with the Mexican American community in L.A., and some issues that came up I think were very relevant, and I'd like to see in this much larger-scale project how these would be addressed.

One of them is this. Who speaks for a diffuse community? Let's say you have Indian tribes, which is like a defined group, and they have a self-governing body, you can go to that self-governing body which, in principle, is speaking for the community. But when you have, let's say, Hispanics in Los Angeles and you talk about community groups, who is speaking for that, with what voice, and with what level of representation?

Then how do you handle differences of opinion in the community once the community is engaged? How do you handle people who have different opinions? Maybe even if, let's say, you're including minorities because a simple majority rule might not be fair. Then within a minority group, how do you handle that 70 percent of the community thinks one way, but 30 percent thinks a different way?

One thing that came up in our discussions with the community is that there is no simple answer to this issue of inclusion versus exclusion. The threat of genetic discrimination is very real, so much so that there is this effort that Francis has made contributions to legislation barring genetic discrimination. If there was no threat, there would be no need for this legislation. So if the legislation is being thought about, discussed, and even approved by the Senate, it's because there is a problem, or a potential problem.

So if you include a minority group, they can be when the findings come out, some health findings come out that is related to a problem with that community, that they're more susceptible to this or

that, they could be genetically discriminated. But on the other hand, if there was some health advantage, they would be included. If they are not studied, they would not be discriminated because the data would not be available. But then if some advance is made, it would not be applicable to them. So it's sort of a Catch-22 for the community.

My final comment or question is this. The United Nations and the World Bank have ranked quality of health care in different countries. In the United States it's consistently ranked way down, like 38 or 39, next to Cuba, and I forget which one is what. One is 38, the other one is 39. The first two are Italy and France, respectively.

So I am astonished that 34 percent of the public thinks that our health care is the best in the world. How is that possible? Is it misinformation, a delusion? How can people think that when it's so down the list?

DR. FITZGERALD: Anybody jump in, please.

MS. WOOLLEY: Can I just address that last point first, how people can think otherwise? There's evidence in so many ways that the public doesn't know what the facts of the matter are, and this is just one more case of that. But in addition, I would say that there are at least 34 percent of the American public who would like to believe that and long for the day when this country does have the best health care system in the world. I think it's important to hold on to that belief, and I would say people in every country have that. They want the best for themselves and their families, and they will support getting there if they're included on the way.

MR. CITRIN: Your earlier questions, which always pose great dilemmas, who speaks for what groups, I guess part of my answer would be that if we don't follow the model of community approval or of some kind of voting or balloting, while it's a significant question, it's not as significant if you were following that kind of approval model. Neither Ms. Lewis nor I are talking about an approval model. We're talking about a model that would engage sufficient stakeholders representative of the community so that there would be a sense that this is a project of all of us, and particularly those of us who are most at risk. Yes, if there is some kind of stakeholder group at the national level that is formed to represent this partnership, there will be people in it and people out of it, but the people out of it hopefully will have other ways to provide input on a continuing basis, and in different parts of the country, if there's a regional approach as well as a national approach, sort of following the way the study itself would be carried out presumably, there will be regions where some groups will have more of an input and others will have less.

Here again, I think the maxim that was mentioned earlier, the perfect being the enemy of the good, applies. Not everyone will be happy, but it is sufficiency of that kind of stakeholder representativeness that will give a sense that this is a project of all of us.

MS. LEWIS: I'd like to add to that that our reality is that our communities are not homogeneous. In no way are they all the same. So each time I have this opportunity, I like to make sure before the end of it that I give respect to the community which I represent, because they give me privilege to represent them and they share with me their concepts. So I share a perspective of the community, because I cannot speak fully in total for everybody.

It is a Catch-22, and I speak particularly of the African American community. We share the challenge of so many issues because we have not been directly involved in much of the clinical research. So when things come forward, they're utilized, and they don't always work the best, and

we don't always know why, and then you can't follow it back and say this is what the outcomes were from that clinical trial.

So a project like this provides an opportunity for multi-level intervention and inclusion. These kinds of discussions early on help to raise these issues so that there can be some thought as to how to address them. It would be wonderful to understand, have the opportunity to go into each community, identify it to be a part of this and understand who the people are who help make decisions for the community, because they're not your traditional people. They're not necessarily your legislators. They're like the grandmother sitting on the porch rocking in the chair. They are the church mothers who sit in the church and make the decisions even after the multiple leaders have gone. They are those individuals who run the corner stores. They are the individuals who have influence and help to make decisions on a regular basis who may never be viewed as a community leader, but they are the persons who can help us effectively engage.

But they will only do that if they have a basic understanding of what they're being asked to do and they can trust that process. That's why, as we mentioned earlier, the process is so important and cannot be dismissed as an integral part of what will happen. So I think it lends itself thinking about, as we develop this model for engaging community, those various levels that are necessary to identify who it is and how it is they will be brought in and fully engaged, and I think we mentioned earlier that engagement sometimes is a word that has different meanings to different people, like so many words.

But we're talking about people really being respected for what they have to contribute to a process of understanding. If we can think about it in those terms, I think we'll address some of the issues that are raised, maybe not fully but more intently.

DR. FITZGERALD: Joan, did you have something?

MS. SCOTT: I was just going to re-echo the fact that the public, and even communities, are not always easily identifiable as what is a community. Therefore, being open to a wide variety of approaches I think is going to be really critical.

DR. FITZGERALD: Muin?

DR. KHOURY: Well, I want to thank all of you for a very stimulating discussion this afternoon. I certainly learned a lot.

The first thing I learned and something I will incorporate immediately in my next talk is that incremental change leads to a snooze.

(Laughter.)

DR. KHOURY: Or some words along those lines.

I want to pose a question to all of you, but I'd like to preface it with a couple of statements here.

If we were able to sell the Human Genome Project 25 years ago as an initiative that's going to be far reaching, as far as biology, medicine and public health, which was only the first step -- i.e., creating the alphabet and the book of letters -- we could sell that, I think. Our leaders here in this room and others really sold that resource to the world.

I think we're now at the fork in the road in the sense that this next initiative is going to lead to the translation of that first phase of the gene sequencing and the discovery to the characterization of what genes mean for the health of populations -- i.e., the public's health.

I think as we embark on this, all the issues that were presented today, this morning and this afternoon, are going to be so important in shaping that translational research agenda, and I call this translational because it's taking it from the bench to the trench, as somebody said earlier.

Now, the question to the group here is that the appeasement of the anxiety 25 years ago around ELSI led to the funding of the ELSI program and the creation of a large scientific body of information that led to an improvement in the way we think about genetic research, genetic identity, race, ethnicity, all kinds of things, and the answer to this question may come from what you have already presented, but I'd like you to think a little bit about this a bit more proactively.

If we were to think about the next project or the next resource or the next initiative not only as a research recruitment effort to get half a million people and follow them over time but more of a translational population-based effort to take the genes from the bench to the trench, and if you were to carve out 5 percent, 10 percent, 20 percent, whatever that number is, to do those contextual things that will allow such an initiative to move forward, how would you spend that money?

DR. FITZGERALD: Anybody want to comment? Toby?

MR. CITRIN: Well, I'll take a stab at it. In terms of spending some of the money, I think the whole process of engagement and education related to engagement is a costly project. For engaging 200 people, and this is much more intense than one would contemplate here I would think, we spent a million dollars of NHGRI's money engaging 200 people in these dialogues. This is a national project. You can't do it quite that way. But it seems to me a good share of this money ought to be spent in this process of engagement coupled with education, and a number of networks can play a role here.

Muin, you've talked about the role of the public health community and the public health agencies in the project, and presumably they would have a role in the study itself. But public health ideally is a convener of groups, and the ability of public health connected with some of these national networks of organizations that we've been talking about convening sessions that combine education and discussion could be a valuable network in order to achieve this kind of continuing engagement, and that costs money. The specifics of how it's carried out would have to be worked out.

But I think the education engagement combine the role that these community organizations play. If they're going to be partners, partners ought to be compensated the same way as researchers are compensated, and that's part of what it would take.

So these are just a few off the top of my head initial responses to your question.

DR. FITZGERALD: Joan, go ahead.

MS. SCOTT: There are some, I think, economies of scale to some pieces of it. Being creative about materials that can be used broadly is one way of getting more bang for your buck. Utilizing existing networks, as Toby said, is another way.

But starting it as early in the process as possible I think is going to be critical for overall success. So having that money right up there at the beginning has got to be part of it.

DR. FITZGERALD: Yvonne, please. Could you turn on your mike? Thank you.

MS. LEWIS: I'm struck by the way you approached this in terms of thinking about it in translation and developing the alphabet. I think if I would take it a step further, and I was trying to figure out exactly how to put this in terms of dollars and cents, and I don't have that yet except to say from the alphabet we build a glossary, and from a glossary we build a dictionary, because one of the things you said is it took talking about ELSI to get some sense of comfort with this, and if we're going to translate we need a common language. So whatever mechanisms we have to put in place and how we have to allocate those dollars to ensure that people go from understanding their alphabet and how to make words out of that alphabet, people go from understanding that there's a DNA sequence to understanding what that means to them.

I think someone said earlier that really understanding what these concepts mean and then how that will in the future translate to us in having a dictionary that helps us go to a place and understand what all of these things mean. So from that perspective, then we think about what's it going to take to build that.

DR. FITZGERALD: Joseph? Oh, I'm sorry.

MR. CITRIN: Just a footnote. Ms. Lewis spoke in her part of the presentation to media. Media, of course, is very costly. Some of it you get on talk shows may not be. We have some masters in doing that here.

(Laughter.)

MR. CITRIN: But media not looked at as P.R., following Mary Woolley's caution, but media looked at as a way to engage the public, media as a way to actually simulate dialogue or to have a proxy dialogue in which scientists share the potential of this project with stakeholders, these are ways in which one can start stimulating national attention and hopefully national buy-in to the project, and they'll cost money.

MS. WOOLLEY: If I could just make a comment. I think one of the least costly ways to assure more public engagement faster, which I take to be a goal, whether it's for the research we're talking about here or research generally, is for the science community to start actively valuing public engagement instead of dismissing it as something that is either unworthy or too time consuming. It needn't be time consuming, and everyone can benefit from a lot more everyday engagement with the public, starting with one's own family, I might add, who are much more likely to be critical, if I can speak for my own family, than many others in our society. We can find out right there at the Thanksgiving table that maybe we're not communicating as well with non-science audiences as we might be by just trying it out on daughter Susan or son George.

DR. FITZGERALD: Thank you.

Joseph?

DR. TELFAIR: I actually want to thank the panel for clarifying a number of things, because one of the things, whenever a group gets together and has this sort of dialogue as it relates to a perspective, which is engagement, engagement at a deeper level, in partnerships and those things,

a lot of terms get thrown out, and also a lot of terminology like "community" gets used without being defined. I'm glad that you clarified that community is not a physical place, it is not a group of people. It's a way of thinking about it.

I think that's important because one of the challenges is to engage people who do not readily understand or take this perspective. That's the real challenge. That really, to me, is the challenge. My colleague keeps bringing it up, and I appreciate it a lot -- that's Leonard -- the point about who are you talking to, who do we have to also get involved in the process, which is those who are in positions of making decisions on this, and it's not necessarily a lot of people, but those who already have a way of thinking about how this is supposed to work.

So I would actually both suggest that we also think of a broader way of defining the question of who should actually be involved and not limit it to just discussion of particular groups of people in terms of race or ethnicity but looking at those who are actually at risk or vulnerable populations, like Loretta Day talks about a lot. Those are the kinds of folks, and that cuts across, to me, ethnic bounds, cuts across racial bounds, and it gets into other issues that we rarely talk about, which is issues of poverty, issues of those sorts of things, which by and large are common things that are shared across all the groups that we're talking about.

So I would say look for things that are more common, the commonalities, and be able to have a dialogue with those who make decisions such that they understand those commonalities.

The other thing is that I would suggest that, given everything that we've heard today, there needs to be some effort towards making a level of comfort for those who are in the decisionmaking process to feel comfortable with this whole idea of community engagement. I think it's one thing that I appreciate tremendously to say that scientists should begin to appreciate community engagement or public engagement or whatever, but it's another thing to bring those who are scientists and other people to that place where that is a comfort discussion. I think that's the other challenge. So I would recommend that, that we as a committee think about, and I would also be open to wondering what the panel thinks, but that's something that we who engage in community-based research and evaluation all the time are constantly struggling with.

MR. CITRIN: If I could just make a quick response, I think that was quite an important statement that you made.

When I looked at the PowerPoints for Dr. Willard, it was quite clear at least that this is not labeled, at least it wasn't in his PowerPoints, as a genetics project. "The goal of such studies, large population studies, include determining the mechanisms underlying common complex diseases," or looking at the earlier bullet, "one approach to learning more about the relationship among genes, the environment and common diseases." I think that's a powerful clause. I did not hear, frankly, Dr. Fink's labeling of the project, which sounded more like a genetics project.

It seems to me that if this project, in fact, is described as one to understand better this relationship between genes, environment and common complex diseases, then it really is a project for everyone, particularly a project for people who are experiencing those complex diseases, which again leads us to the issue of health disparities and how to resolve them. This can be a very unifying project.

Again, I kind of part company not in what Dr. Kardia said but in terms of a sequence, that the study itself can start building bridges across the social sciences and the genetic sciences by looking at all of the determinants, all the major determinants of these diseases at the same time,

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and it can build bridges to the community by doing the same, because our community partners -- and Ms. Lewis is one of the most valuable ones -- do understand this ecological view of public health which embraces genetics and biology in the middle bull's eye, and runs all the way out to social, family, and structural determinants in the outer rings. If the project is seen that way, it could be an extraordinarily connective project which can lead to buy-in by the community as well as by policymakers.

DR. FITZGERALD: Joan, please.

MS. SCOTT: I'd like to add one additional comment about the educational piece of it and framing it more in the context that Toby was just talking about. Particularly amongst the scientific community, there's much about the deplorable level of knowledge of science within the public, and specifically around genetics. I don't know how my car works, but I'm a pretty good driver and I can make it work, and I'm an ethical and a good driver. So I'm really less concerned that the public understand down to the nitty-gritty of what a polymorphism is or whatever.

But the public is very capable of understanding very complex both technical issues and social issues and ethical issues and having very nuanced conversations about them, and putting them in the context of what they already know, which is the complex diseases. People can get it.

So I think education, yes, is a very important component of it, but I'm less concerned that people understand that we have 46 chromosomes in every cell than what that really means in the application of it.

DR. FITZGERALD: Yvonne, please.

MS. LEWIS: I'm also hearing that there is another community that needs to be engaged in dialogue from a different perspective. The science community needs to be engaged in understanding the language of those who are not in the science community. Toby mentioned earlier bidirectional, and we talk about bidirectional, but we also talk about cross-fertilization, which is to say that we talk amongst each other enough to begin to understand what we mean. So when you're all in a room with the people you work with all the time, and you all think alike, and you discuss a lot of wonderful things, when you walk out of the room you still all think alike. The idea is how do we get people who think differently in a room to have a conversation about a complex issue and get some understanding about how they think differently and walk out with a common way to address the issue? I think that's what's critical here, and that gets into how you translate.

So if we were to take this room as an example and have a dialogue, it would really be a conversation based upon a scientific perspective and then sharing what does that mean to me from a community perspective, and then how do we come out with language that helps us both know we understand what we're talking about. So I think that element might be a part of the process that not only are we thinking about going out into the community out there, wherever that is in the world in the United States of America, and identifying 500,000 or 1 million people and saying let's also figure out how we bring the geneticists, how we bring researchers, and how we bring community together in a discussion that helps us figure out what steps to take next.

DR. FITZGERALD: We have time for Hunt, and then one more.

Go ahead, Hunt.

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DR. WILLARD: My question is going to be a little bit different in the sense that both the NIH working group and this committee have identified public engagement, and the need for public engagement is a major issue. Our job, other than just enjoying this exchange and these conversations, is to make specific recommendations to the Secretary, to guide him and his thought process for how to consider proceeding with a project such as this.

So I would ask each of you for some specifics in terms of what would be concrete specific steps that you would suggest in order to take the pulse of the public and/or to have them engaged in a project like this, because we've all identified that it's important, and you each have your own experiences in how you've done this in other specific settings. But in the context of this setting in a project of this potential magnitude, what specifically would you have us or have him do in order to bring the public into this partnership?

MS. WOOLLEY: I was just going to say that taking the pulse of public sentiment is probably the easiest thing that could be done, although saying it's easy is not the same as saying it should be quick and dirty and not thoughtful. It does need to be done well and respected once it is conducted. So I'm talking about public opinion surveying. But I think Joan has laid out very effectively the stream of getting involved with public engagement and doing it thoughtfully. There's different levels. There's simply putting your finger on the pulse, and then there's really empowering and working with members of the public.

But I think using Joan's model, if I might suggest this, using Joan's model back to the Secretary, let's say, and saying here's a model stream of how to engage the public, and we want to propose taking steps in each of these areas and move forward that way. It's going to cost money, and the further upstream you go, the more it's going to cost, but I think it's money well spent, and that's also been discussed here as to what percentage it is or how many dollars it is. I don't have the expertise to comment, but it's worth doing, and I think that's the thing to say to the Secretary, and to start now.

DR. FITZGERALD: Joan, please.

MS. SCOTT: I would suggest that the start be with clearly identifying the communities of who you are looking to engage and whose pulse you want to take, and then going to those communities to get some initial idea of the levels of concerns, just a broad brush stroke, what are the optimisms, what are the issues of concern, and then begin to focus more in on a long-term engagement process that's going to carry those communities along with you for the long haul. So as Mary said, there's this initial pulse-taking that needs to be directed clearly, but then starting from the very beginning of what's the long-term strategy to move them all along with you down the track.

DR. FITZGERALD: Toby?

MR. CITRIN: Maybe some of this has been done, but I know we talked earlier about working groups in a number of meetings and sessions involving various stakeholders, but the convening, even if it's informally, of some kind of a group that actually could engage in dialogue at the national level the way that Ms. Lewis has been talking about dialogue; in other words, that would be representative of the scientists who want to proceed on this as a scientific process, public health leadership, and stakeholders with national prominence and some credibility with communities who are very interested in health, in furthering the health of their constituencies in reducing and eliminating health disparities, and having a group like this, even if it doesn't have

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any official status, engaged in dialogue on how they might all come together in their constituencies to further this kind of a project and to maximize community engagement.

I think a lot could be gained from that kind of a group having a repeated series of sessions and discussions to get things started.

DR. FITZGERALD: Yvonne, please.

MS. LEWIS: I support what has been said. I'd like to add to identify representatives for the committee up front. Whatever your recommendation is, if you're recommending a committee, identify representatives from the communities of concern and have them be at the very first meeting, and allocate resources to ensure their participation, and commit for the long haul.

DR. FITZGERALD: Thank you.

We're running a little over, so I just want to ask one last quick question, just a simple yes/no, clarification for the public since we want to empower and engage them. It is my assumption that the true partnership that you're talking about requires that everyone who comes to the table be willing to hear someone else at the table say no, I don't want to do it that way, I prefer to do it this way. Is that correct?

MS. LEWIS: Yes.

MS. WOOLLEY: Yes.

DR. FITZGERALD: Great. Thank you very much. Thank you very much for all your attention.

MS. BERRY: Thank you so much.

We will now take a 10-minute break, not 15. We'll be back here at, say -- let's just say it's going to be a little bit less than 10 minutes; at 3:20 we'll start up again.

(Recess.)

MS. BERRY: Let's get started if we can.

One thing I'll call to the attention of the members of the committee is the fact that you should have two documents pertaining to the coverage and reimbursement report recommendations, and as I mentioned earlier, one will outline some suggested editorial changes recommended by staff. If everyone would read these tonight and be prepared tomorrow to decide whether we want to go ahead with the proposed changes or whether we want to stick to the original version that we worked on at the last meeting.

I will turn it over to Hunt.