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TRANSCRIPT

Genomics Roundtable

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DR. WAGNER: And if you were present for the prior roundtable, you're prepared for the genre of question we open up with. And as the -- as our Commission thinks about how we want to talk about privacy and access to genomic data, or for that matter how it is processes of collection and management, if you will, have -- we'd like you to give some thought to one thing you would certainly expect to read there. A particular aspect of this that you would hope we would address.

Greg, you made the mistake of nodding. So may I ask you perhaps to go first?

MR. BIGGERS: Never look a coach in the eye.

(Laughter.)

MR. BIGGERS: Certainly. Consistent with my ten-minute remarks there are two I think underlying themes on our minds at Genetic Alliance and the entrepreneurial things that I'm doing. The first one is this point about expression of rights and desires, expression that so much of the ethics world has needed to focus on protection of rights for the last -- go back as far as you want in history.

And I think we're in an exciting time when it's worth our attention now to examine how we can protect the right of expression of those things and not just protection

of harm to them. So move some attention to how we protect the ability to express rights and desires.

And then the second item, which kind of goes along with that conversation is this observation, is that the -- it's about how quickly the world is moving. The general gestalt of our culture right now and the technological tools for sharing and for analysis are accelerating so quickly and changing so quickly. I think there is a risk that they will outrun our capacity, our collective capacity to influence and legislate the ways we want to express and protect those rights.

And so I think, depending on whether you look at the world in a libertarian view or some other kind of influence way, I think there is a message of urgency here in terms of expressing -- now I'm speaking of collectively expressing how we want this to work.

DR. WAGNER: Very good. Did I see you flinch, Leonard?

DR. D'AVOLIO: Yeah. May I build on that?

DR. WAGNER: Please.

DR. D'AVOLIO: It's great to be able to speak alongside of Greg. Because I think what the panel needs to recognize is that the reason why so much of this is happening outside of the healthcare system is because the

healthcare system is not delivering quickly enough.

And so when you consider how best to keep up with this, or how far -- I guess when you're trying to place these things into boxes and think about how best to proceed. I think you have to realize that genomic science will not happen without enormous numbers and that clinical effectiveness research will not happen without drastically different models of both science.

And I think most important, all of our -- too many of our policies are just absolutely inadequate to get us to where we need to be. And so you -- it's great that you're seeing it outside of healthcare, but it's a shame that healthcare is not doing enough to keep up with what might be going on outside.

DR. WAGNER: So you two are talking about the need to ensure that we have the right kind of -- and rapidly evolving mechanisms for access. How does that square, Madison, with your principles for privacy?

DR. POWERS: These are great questions. Two for me are really important. I'm loving to hear about this stuff, about the line between the clinic and research. I have a couple colleagues involved in that sort of research right now, and just sort of like hearing the sort of fumes of these discussions always lead to consternation for me.

Because I think that is the way the world's going.

And so I think our standard view -- I mean, we could either up our level of protection on the clinical side of things or we could diminish our level of protection on the research side of things. Or we could begin to sort of rethink how the two fit. But it's no longer the case and will not be the case going forward that there's a deep line there to be drawn. I love that line between like doing research and mere learning, God forbid.

(Laughter.)

DR. POWERS: You know, continuous quality improvement must be one of those governmental phrases because that -- there's something more going on there, obviously.

The other point I would make is that it's no longer contained within the nation state and the kinds of things that states can do to protect its own citizens. Research is global and so is delivery of care. So are databanks. And so it's going to require some kind of international form of consensus about how to proceed on some of these rounds as well. And that really changes our view about the standard historical ways of thinking about rights and forms of protection and the like, because we move, the data moves and the research is aggregated on a

global scale.

DR. WAGNER: Sort of a global dimension.

DR. McGUIRE: Yeah. I would definitely second sort of this line of thinking about the sort of the blurring between research and clinical care because it's unavoidable and I don't think it has been addressed quite enough in our policies.

I would say in terms of dealing with genomic privacy more generally, and this is consistent with my talk, but I would encourage us to think more broadly about the relevant ethical principles, ethical values that should go into policy development in this area, and move away from the exclusive focus on sort of protectionism to thinking about how can we better respect, how can we better build trust.

I think the one thing that we can do a lot better is transparency. I think there's been a huge lack of transparency in terms of how data's being used, how it's being shared. Transparent -- and also a little bit more clarity about what we're asking people for. So I think talking about open or broad consent is not informed consent, that's authorization. And if we want people's authorization, we should be clear we want their authorization and not their informed consent. But I think

we need to be clear about how we're thinking about that.

DR. GUTMANN: So what do you think about that, because what -- if we just listen to you, it would be jarring, what you all and we know, that HIPAA has very stringent privacy norms. And so what do you think about authorization versus informed consent to everything that genomic data can be used for? It's virtually impossible.

DR. McGUIRE: So HIPAA has stringent privacy protections and requires authorization, right?

DR. GUTMANN: Right. In the clinical sense. So if you move from the research setting to the clinical setting, you move from an environment -- I think you move to an environment where HIPAA governs.

DR. McGUIRE: And I think by and large what we're doing right now in the research setting -- although I think we try to fool ourselves -- I think we're getting authorization for most of what we're doing and not informed consent. Because I think that getting informed -- it just goes back to specific consent for each research use versus general consent for sort of this ambiguous, we're going to use this for whatever we want. We can't really tell you the risks, we can't really tell you what it's going to be used for.

I mean, that's authorization. That's assuming

some -- you know, assuming some sort of uncertainty that you're willing to put up with. But it's not really the traditional notions of informed consent as they're written either into our laws or in -- or as they're being exceptionalized in bioethics.

DR. GUTMANN: So what I can't tell from you saying that is, are you -- should we be comfortable with that? Because if it's genomic data, it's not --

DR. McGUIRE: I think we should be comfortable with that because --

DR. GUTMANN: Okay.

DR. McGUIRE: -- I think that is an adequate way to show respect for people. As long as we're transparent about what we're doing.

DR. WAGNER: You seem to disagree.

MR. BIGGERS: Well, I think we have to be careful about generalizing. And I think there is a population for whom authorization is -- would feel like the respectful action to allow them to take. I think there are -- there is a growing population of people who want something more granular than that.

DR. McGUIRE: But do you think we can get more granular than that?

MR. BIGGERS: Oh, absolutely. I mean, yeah. In

fact, the studies that are being run on the Genomera platform are exactly that. People store their data in this system in the cloud. But each individual controls where their data can flow, and they're asked every time.

DR. GUTMANN: But if you're doing research on -- where you need large numbers to come to conclusions, why would you want to do research with individuals who want to give consent to every use as opposed to getting blanket authorization? I'm just --

DR. BIGGERS: Yeah -- no, I think that's a fair question.

DR. GUTMANN: If there's nothing morally wrong with getting blanket authorization. So you're absolutely right, you don't need -- there will be some people who don't want to give it, but what -- why -- I'm being very, you know, up front with what it takes to do research. Why would you want -- why would a researcher want to bother?

MR. BIGGERS: Right. And you know, I don't think I necessarily have a moral objection to the authorization item. But I am observing that this is one of the ways the world is changing. And as people are finally beginning to become comfortable with granular settings on facebook, so that not every photo is shared with everyone, similar things are beginning to happen in health. And we may just

be heading to a world where informed people expect a little more granularity.

DR. WAGNER: Nelson?

DR. MICHAEL: So is there maybe a way for -- and I'm not -- I don't really want to single out you two individuals, but since you're having this little tit for tat, then is there a way to bridge the gap between, I think, relooking at how we define the bright lines between optimization of clinical service delivery versus research? How we look at the difference between informed consent and authorization? Because I think there are meritorious questions that would benefit, you know, the global community if we take these steps. I think those were elegantly outlined.

There are philosophical frameworks that also need to be addressed, and there are, for lack of a better term, there are community issues that Greg raises. I'm comfortable in a research setting when the community is effectively engaged from the very beginning to the very end. And I think that if that dialog occurs, that transparency that Amy talks about -- this Amy -- then I think -- you know, I think in my view you've done that in due diligence.

But how can -- how can researchers access the

advocacy organizations, I mean 1,200 organizations. I mean, that's unbelievable. That's like the U.N. of advocacy. How can you actually put that into implementation so that --

DR. GUTMANN: That's even more cumbersome.

DR. MICHAEL: It is. It is, yeah. I mean, how can this actually be distilled to practice so that you can inform a way forward?

MR. BIGGERS: How many questions was that?

(Laughter.)

DR. MICHAEL: I'm Jewish, I'm like that.

DR. WAGNER: Pick one.

MR. BIGGERS: Oh, boy. Okay. So -- okay, so I'll do two parts. There was a thread there about the granularity of consent or not. And I love the way that you distilled it to engagement. And I think from what we see so far, that actually is the essential element, to sustainable communities of trust and research.

And some communities are going to want more granularity, some less. But engagement and the communication, and I think we saw the same thing from Amy's presentation about that.

Regarding how you make sense of this panoply of disease groups who are exercising their locus of control, I

think that there is -- this underscores the role for organizations like Genetic Alliance. And we're not the only group that brings together patients, right?

But one of the frontiers for Genetic Alliance, and groups like us, is now that we're in the -- you know, I was having a conversation with Sharon Terry, the CEO and president of Genetic Alliance about this. And she said -- she was looking back historically. And she said that in the '90s, we had to build whole institutions, whole organizations just to get some of this stuff done, like PXE International.

And then in the 2000s, we added to that a bunch of social kind of technology sharing tools so that we could share concerns and stories. And now in the 2010s, there's this ability to much more fluidly move people around and their data, and get their consent and do things much more quickly than we needed. And it doesn't require having an organization.

So I think that's where we're headed, is this concept of a network of networks that choose to cooperate. That federate together to get research done. And it's beginning to happen.

DR. WAGNER: Greg, I've got a question. It appears to be -- you might start the answer to this from

the audience. Wondering about that now that we have these examples of private organizations gathering and managing data, what -- and what role and by what mechanisms can and should the federal government work to ensure privacy?

MR. BIGGERS: So we already noted I didn't speak a lot about privacy today, probably because many people speak about privacy and we agree with much of what's said about privacy.

There is certainly more room for legislation about privacy and secrecy. You know, GINA, the Genetic Information Non-discrimination Act, we have to see is only a start. There are many more protections that the patient community would like that are not present in GINA.

DR. GUTMANN: Can you give an example?

MR. BIGGERS: Certainly. Life insurance. So GINA protects against discrimination for health insurance, for some employment situations, the use of genetic information. Life insurance is not covered. And you know, I'm not an actuary, and I know that's a hairy challenge, but that is a challenge.

So certainly, I don't want to sound like we are just eschewing privacy as a non-issue. Certainly not. The place where we see that we can bring a contribution to this table is helping people express control. But yes, let's

get the government working for the right kind of legislation that protects us.

DR. WAGNER: Christine?

DR. GRADY: So I want to actually follow up on this question of what can the government do? Because, you know, some of our job here is to recommend things to the government.

So one of the questions I have is about -- and forgive the word, but I'm going to use it anyway -- messaging. We heard this morning -- I don't know how many of you were here, but we heard this morning that one of the biggest problems is the messaging about countermeasures, you know, what the public believes. And I'm resonating with what Amy said earlier about, you know, the perception of risks and benefits as important or more important than the actual.

So does the federal government have a role in teaching people about the limits of privacy in the context of genomics?

DR. D'AVOLIO: I just want to note, it's interesting that your question was should the government teach the limits of privacy versus the potential benefits of participation. Was that intentional?

DR. GRADY: Actually, both. I would say both.

DR. D'AVOLIO: Okay.

DR. McGUIRE: I think there's been -- there's been far less work on the benefits of participation, I think. I mean, you know, in terms of what we're talking about with genomic data sharing, I think there has been a lot less done in that area.

I think there is always room -- I think there is a lot of room for public education about the limits of privacy. I'm not sure I have a good grasp on sort of how well people get that in a generalizable sense. I know that, you know, in all the research that I'm aware of, people are pretty careful not to promise privacy or confidentiality in this area, and they always kind of point to the risks associated with it. But do people really get that? Do they understand it? How do they understand it? I'm not 100 percent certain.

DR. GUTMANN: Just to follow up, and this goes to something that Nita has asked earlier. There's no -- sometimes medical information, that's -- we're talking about genomic information, our panel, has -- sometimes there is a quantitative or qualitative difference from other information, other times not. So let me just ask the question on life insurance.

If a life insurance company can ask me what age my

mother and father died at, why can't -- why should they be able to ask that and not be able to ask something about genetic information? And in fact -- or when I want to get life insurance, should I be able to control access to some information, not others? There's a flip side. So if -- why should I have to give them, you know, the age at which my father and mother died and not the other?

I don't -- I'm asking because I don't see a qualitative difference between those two kinds of information. So I don't understand how one could ask the government to legislate against one and not the other. Both are pieces of information beyond my control. They both -- in fact, my father and mother's age of death is predictive, but not entirely so. And this is a practical as well as -- this is where, you know, facts and ethics sort of come together.

I'm also thinking of Raju's question, you know, what -- so in this particular -- I understand why people might want to protect that information. But the same way I might want to protect an insurance company from knowing when my mother and father died. And I'm using this example because my mother and father both died very young.

Let me say I hope that, given my lifestyle, compared to my mother and father who I -- who are

wonderful, dearly loved, very wonderful people. But they lived without consideration of cholesterol, smoking and may other -- exercise and many other things. But that's beyond the point of my question.

But since you asked.

MR. BIGGERS: Dr. Gutmann, would you like to direct your question to one of us?

DR. GUTMANN: Greg, anyone --

MR. BIGGERS: I've spoken a lot already today.

DR. GUTMANN: No, anyone. Madison? I mean, this is a serious question for us.

DR. POWERS: No, let me put this in a broader justice-based framework once again.

Within many European countries, life insurance, disability insurance are two things that are thought to be on a moral par as social entitlements in a community. And with health insurance. And given that sort of background framework of a certain ideal of distribution, the fair distribution of benefits and burdens in a society, there would be no plausible rationale for treating life insurance and disability insurance and health insurance differently.

To the extent that there is -- if you look at, you know, a lot of popular opinion polls and you ask people, you know, do you think there's a right to healthcare, like

90 percent of the people say yes. And then you ask them would you spend $100 a year to make sure everybody gets it, and they go, well, maybe not.

But at least facially we have, at least within a high information voter, a fairly large commitment to an idea of some measure of healthcare as entitlement. And so you would not think it appropriate to put a number of road blocks of that sort in the way that might be otherwise appropriate if you conceptualize life insurance and disability as more of an optional market-based commodity where a willingness and ability to pay are the operative central norms rather than a baseline of commitment for everyone.

I'm myself puzzled as to what I think about that particular European versus American conception. But your view about whether you treat life insurance and health insurance and disabilities all on a par depends on that background view of the proper distribution of benefits and burdens on society.

DR. GUTMANN: But then, what you're saying, you're basically saying that the distinction isn't between the privacy of genetic data and the other thing, which isn't even privacy. It's whether -- it's an anti-discrimination concern.

DR. POWERS: Yeah, it's predicated upon how you treat the category of benefits, whether it's a social entitlement or a market commodity, principally.

DR. FARAHANY: I'm going to ask a maybe slightly provocative question about the privacy conversation that we've been having.

It seems like we're assuming that there is some privacy interest in your genetic information by the nature of the conversation that we're having. And you put up on one of your slides, Amy, that the Supreme Court has recognized a right to privacy. Of course, they've recognized a very limited interest potentially just in procreation, right, and not necessarily a broad interest in privacy.

So I want to ask all of you, if you think there should be a privacy interest, forget who should assign it and whether the federal government should assign it or anything like that. But should there be a privacy interest in your genetic information? And if so, why, on what basis?

Because if you could obtain it without intruding upon your body to get it, which is what, you know, some people think the Roe v. Wade line may be based on. If I could get it from the glass that you leave behind so no

physical intrusion into your space to get it, what would be the basis? Is it a property right, is it me? What would be the basis for a privacy interest, if you think one should be recognized? Or you may think one shouldn't be recognized.

DR. McGUIRE: I was waiting for one of the lawyers in the room to kind of call me on my Supreme Court thing.

So okay, so this is sort of just coming out as I'm thinking about it. But I mean, I do think that there is a privacy interest that people have in their genomic information. And I do think it goes back to this idea of it can -- it gives information about me and about the future me.

I think property is the wrong legal concept to be thinking about this, and I think we've seen that in the court cases that have tried to deal with biospecimens and property. And for sort of all the nuanced legal reasons that you succeed or don't succeed on a property claim, I don't think that's the right legal framework for this.

But I do think sort of stepping away from the law, I think that people think they have an interest in their information from a -- they think it's private information, they treat it as private information in some respects. So I do think it's something that we want to protect and to

respect. But again, it's not absolute. And so just because you have an interest in something doesn't mean that it has to be protected or safeguarded absolutely.

DR. FARAHANY: Just to make sure, so not because you own it but for some other interest that we need to identify, which presumably is going to be applicable to any kind of information. Because my email traffic and my banking records are all quite predictive of my future behavior, and of the future me and probably better so than my genetic information.

DR. McGUIRE: And I think I would agree that you'd have a privacy interest in those pieces of information about yourself as well. But again, as I said before, we sacrifice that privacy interest all the time because of the benefits that accrue to us because it's convenient to do online banking and shop on Amazon and things like that.

DR. WAGNER: But you generate all those forms of information as opposed to genomic information, which is attached to you, essentially.

DR. POWERS: I think there are privacy interests without reflecting on the constitutionality questions that are real substantial and diverse from a moral point of view. And they do -- they are cross-cutting across domains of information gathering. It's not just genetics and it's

not just the rest of medicine. It's also moved over into economic and a variety of other things.

But all these sort of privacy interests are not on a moral par. And whether it's predictive genetic information or maybe even predictive credit card behavior, I don't know. It's -- some things are highly sensitive, and so very old-fashioned idea about medical confidentiality, one that still, to me, holds a great purchase is that there are tiers of information requiring different levels of sensitivity. This is a point additional to Greg's point, which is that sensitivities might vary by person.

But by general classifications, we know psychiatric information is different. We know a whole host of behavioral information is different. You know, it's different as to know whether I've got the -- perhaps the chromosome for human -- the hemochromatosis or some other fairly increasingly commonly discovered thing like celiac. That's very different from something associated with, say, psychological phenomena or those sorts.

So at least socially, we've got good prima facie generalizable reasons to protect some bits of data, whether it's genetic or medical, more generally in a more protective fashion. So there are reasons to go for

socially-tiered levels of protection.

DR. GUTMANN: Let me just give you an example -- just to be -- because I think there's a general question, whether we have heightened privacy interest in everything about our genomic data versus do we have any privacy interest in some of our genetic data. Just an example that comes to my mind, I just -- it's a random example. Most kids as well as adults have -- I'm talking about private people, have enemies. Somebody, I think almost everybody would feel they have a privacy interest whether the question of whether you want to protect and someone getting ahold, mapping your genome and finding out you have the gene for early onset Alzheimer's. Just your -- and publishing it. And just having an enemy of yours, you know, making it public because the person hates you and just wants everybody to think you're really -- you know, you're doomed.

It doesn't mean -- it doesn't tell you what you should do about it, but that is a privacy interest of not wanting some information about you that could only be found in your -- by mapping, you know, your genome. But only through genetic testing, to be out there in the world.

That's why I thought it was important that Madison, you know, just list of all the values that

private -- that a privacy interest covers. It doesn't tell you what to do about it, but it does heighten the notion of what can be exposed about you publicly by somebody who just doesn't like you.

DR. WAGNER: I think Leonard wanted to comment on this question also.

DR. FARAHANY: Let me follow up on this for one second to make sure.

So there is a difference between whether I want to keep something secret and whether or not I should be entitled to do so, right? And so I think it's true that many people would want to keep that information secret. The question I was asking wasn't presuming an answer or taking a position, it was simply asking whether, in light of, you know, the changing world, about information, should you have some right? Yes, I have an interest, but should you have some right? It isn't going to be based on property because that doesn't work. What would be the foundation for such a right to keep things secret?

DR. GUTMANN: Well, you asked whether people have a privacy interest. And I think --

DR. FARAHANY: I asked if people have a right to privacy, which I think is different.

DR. GUTMANN: A prima facie right to privacy, as

much as to -- for that as much as we have a right to a lot of other things, yeah. That doesn't mean in all things considered, but certainly a prima facie right.

DR. WAGNER: Leonard, did you have a comment?

DR. D'AVOLIO: Just a very quick comment. So I won't speak to whether or not someone has a right to privacy. But I do want to give some information to consider when thinking this through, and I haven't heard it discussed too much today.

There was some conversation earlier about, you know, well, what's the value of the genome? It can tell me that I'm short, or the color of my skin potentially. I've heard it said that the only thing -- I've heard it said that the -- I did remember the short comment.

(Laughter.)

DR. D'AVOLIO: You know, it's been said, and I forget by whom, that the only thing genomics can accurately predict is who's had sex with who over the last 10,000 years.

But remember that it took 200-plus years for the microscope to find its way to clinical utility. And what we've learned in the last ten years has outpaced any era of scientific discovery that man has known.

And so while right now twenty-three and me can

tell you that your ear wax is wet versus dry, and not too long from now if you only judge it by the rate of discovery, we're going to know a lot more, and it's going to matter. And it may not be from the gene, because remember the gene is just a blueprint. It's very likely to come from the proteins, which the genes tell you to create.

And so having the genome may be not incredibly powerful right now, but it opens the door to outrageous rates of discovery which I'm pretty certain are going to happen over the next five to ten years. So just keep it in mind, when debating this right to privacy, I guess.

DR. WAGNER: Did you have comment on it before I go to our next --

DR. McGUIRE: Yeah, I just wanted to go back, because it ties into this question of what can the government do with regard to this interest in privacy. And I think with regard to genomic data sharing, I mean, there's two point of entries where the government can intervene, right? They can try to limit access to the information, which I personally think is a losing battle. I mean, I think people are going to be able to access information, they can link up databases, there's so much information about us out there.

So I think where the real sort of -- the real kind

of gusto is, is in preventing the unauthorized use of that information in harmful ways. And it goes beyond life insurance. I mean, it's any kind of unauthorized harmful or offensive use of the information that's out there. And that's where I think the legislation can probably be most beneficial in this area.

DR. WAGNER: Dan, did you want to ask a question?

DR. SULMASY: I wanted to just return for a second to the question of sort of blanket authorization versus specific consent. I certainly understand why scientists want the blanket authorization. But I wonder, particularly picking up on your last comments about what could cause, you know, harm or offense to someone.

You know, I think, you know, there are very few people who give blanket authorization who anticipate possible uses for that information that might, in fact, be considered offensive or immoral. If that involves, for instance, creation, using something related to chimeras or you've got the Havasupai example of people whose conception of the universe is undermined by the research that's done on their genetic information. And the list could be very long. We don't know what it is that would affect each person.

So I wonder how blanket authorization actually is

respectful as was suggested of individuals?

DR. McGUIRE: It may -- does anybody else want to respond?

MR. BIGGERS: No, I'll go next.

DR. McGUIRE: It may not maximize respect for autonomy, but I still think it can be respectful in the sense that some people think of wanting to feel respected. At least you contacted me, you asked my authorization, you told me the limitations of what I was agreeing to in terms of the openness of it, the uncertainty of it. That sort of thing.

And I think you're right in some ways, and I've been thinking over the last couple of minutes as we've been talking about this, the difference, the sort of research versus medical care setting and sort of the -- and there are some differences. Clearly when you are going in to seek medical treatment, it's for your own personal benefit. Presumably when you're signing up for this type of research, you're doing it for altruistic reasons, it's for the benefit of society.

But I think we can draw some parallels in terms of there are things that, when you go to get medical treatment, you sign a general blanket consent to treat, and they don't ask your specific permission for those things,

like diagnostic work-ups and tests. And presumably because -- for some of them, certainly, when you go into a hospital, you sign a general consent to treat. And there are certain things that are done under that consent to treat that you don't have to get specific consent for those things.

DR. SULMASY: No, you don't write a consent. But certainly I think that's one of the things that we, at a very basic clinical ethics level, teach our residents and interns. The fact that the patient has said, you know, I agree to be treated doesn't mean that you can do whatever you want to them without at least asking their permission. You might not have to have it formally written. So don't think it works that way, even in the clinical setting.

DR. GUTMANN: And the -- part of what I think you two would agree both on is that regardless of whether it's authorization or specific consent, there are side constraints to what you cannot do in harming somebody on the basis of -- consent may be --

DR. SULMASY: And how do we build that in?

DR. GUTMANN: Consent or authorization you'd both say is necessary but not sufficient to define the things you can do with information.

DR. McGUIRE: And I think the nuance and the level

of detail in the type of consent authorization you're getting for different types of decision varies significantly. I mean, you might have a very brief conversation about one thing, you might have an extensive, you know, conversation about different alternatives that takes weeks to come to a decision on for other types of decisions.

And so I'm just saying, I think there's variability in the type of general authorization to very informed consent and shared decision making, depending on the type of decision that's being made and the type of thing that you're doing.

So I think we can kind of -- I'm not sure where this line of conversation is kind of derailing to, but I think we can kind of take that in the research setting and recognize that there are certain things in research and types of research that require much more extensive informed consent and conversation than other types of things. And if we think about it that way and try to think about what are the properties that define what's required there, then we might be able to see where this sort of fits in.

MR. BIGGERS: Yeah, so I think there -- the communities that we work with mostly are excited about the promise of additional research with genomics. But the

two -- there's a two-sided cloud, when you look at the clouds over the genomics world, okay? And simplistically speaking, it's the deterministic side and the uncertainty side, right? And we all know stories on both sides.

And so when we get -- but I think that analysis can inform how we think about broad consents and authorization. And especially on the uncertainty side. And so because there still is so much uncertainty about how our genomes may be applied. It is incredibly difficult to predict unintended consequences. And so a possible way to reduce the risk of undesired unintended consequences for research subjects is at least informing. And I don't think informing necessarily implies shared decision making, although sometimes it does.

But because we can't know the unintended consequences, shouldn't we at least communicate about what's going on so that people could at least have the opportunity to withdraw if they're concerned about a particular topic?

DR. WAGNER: And I think we will, for the roundtable, let that be the last word as we thank the four of you for participating in this.

DR. GUTMANN: Thank you.

(Applause.)

DR. GUTMANN: We had a very full day, and I want to thank everybody in the audience who participated and stayed so attentive through this very long day. And of course, I want to thank members of the Commission who -- we have our work cut out for us, but we've certainly got a lot of good advice today. And thank you all as well.

And Jim, do you want to -- why don't you have the last word.

DR. WAGNER: Just to echo you, these were two very disparate subjects today. Raju, thank you for the cut to the chase question, but I must say that, while that really got a lot of information out of our experts at that time, we need to remember that that cut to the chase question was a little deeper than our question. We are not to be opining on the likelihood of the incident but rather that, if there is a risk, under what ethical conditions would it be appropriate to do testing.

And this afternoon, I thought the conversations about the value of privacy and right to it, how to preserve them for genomic data, which may or may not merit exceptional consideration, and also starting to help us think about some of these novel approaches to securing and managing and even curating genomic data is a new twist for me. So I just echo your thanks, and thank you again for

your leadership.

And with that, I'm ready to go home.

DR. GUTMANN: I do have to tell everybody one thing. You can go to our web site, bioethics.gov to submit any comments to us or any follow-up. And I just came to mind the Ogden Nash saying, which doesn't -- which you, all four of you were definitely on the other side, which is progress may have been all right once, but it went on too long.

(Laughter.)

DR. GUTMANN: So thank you all very much.

(Whereupon, the session was adjourned at approximately 5:20 p.m.)

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