



Presidential Commission
for the Study of Bioethical Issues

TRANSCRIPT

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DR. GUTMANN: So, we're off to a great start, and now, we're turning our attention to discussing directly, questions of individual privacy and the public good, and I emphasize both, individual privacy and the public good, as they relate to whole genome sequencing, and we've already had hints of this issue in our earlier session.

But we begin this topic with George Annas, the William Fairfield Warren Distinguished Professor at Boston University, who is also Chair of the Department of Health Law Bioethics and Human Rights at BU's School of Public Health, and a Professor in BU's School of Medicine and Law.

He is author or editor of 18 books on health law and bioethics, and since 1991, he has written a regular feature for the New England Journal of Medicine, and I dare say, everyone around this table has read more than one of Dr. Annas's work.

In addition to his academic work, Professor Annas is the co-founder of Global Lawyers and Physicians, a trans-national professional association of lawyers and physicians, working together to promote human rights and health.

He has also held more government regulatory posts than I can imagine, but let me mention a few, including Vice

Chair of the Massachusetts Board of Registration and Medicine, Chair of the Massachusetts Health Facilities Appeals Board and Chair of the Massachusetts Organ Transplant Task Force.

In other words, he has delved both into the theory and the practice of healthcare policy and human rights.

Professor Annas, we look forward to hearing your perspective on how the idea of genetic privacy has evolved in our society, and how it may cohere or conflict with other rights and interests that our society values. Welcome.

DR. ANNAS: Thank you, Dr. Gutmann, Dr. Wagner, Members of the Commission.

I appreciate being invited here a lot, because I'm in the middle of a project with my colleague geneticist obstetrician Sherman Elias, which is a book that we're writing for the public, to try to explain all of these wonderful things, and whether and how they should be excited about that.

So, in preparing for today's talk, I went back 25 years, as I was asked to do, and saw that 25 years ago, Dr. Elias and I wrote a book on the first -- we chaired the first

ELSI Working Group, in trying to set an agenda for that group, found that the most -- we thought the most important problem then facing genetics, was how, once you found something, would you introduce it into clinical medicine, and I think that, as we heard from the last panel, remains the most important, most difficult question that there is in genetics.

I also didn't realize this morning was Groundhog Day, but realizing that, I thought that there are two movies that you could really explain everything that is going on.

One is Bill Murray's "Groundhog Day", and took an insight, a values insight, for him to get out of that day, and the other is his movie "Lost in Translation", which I think it's fair to say, without getting carried away, a lot of genetics is.

So, let's -- I know, to put it another way, we have \$1,000 genome with a billion dollar interpretation, and I think that is right.

So, what I'm going to talk mostly about why we haven't moved very much in the bioethical analysis in the last 25 years, and I think mostly, it's going to be a problem of language and metaphor, and some of it is my fault, which

Mark will say.

The first question, the privacy question is, is it true, as Dr. Watson said in 1991, when he said, "Speaking as a citizen, I think genetic information should be absolutely private. The idea that there will be a huge data bank of genetic information on millions of people is repulsive."

He might take that back today, I don't know. But that is where we start.

But that is definitely where we started, with this idea, that genetic information is exceptionally private, and I've used this Venn diagram to show why it's uniquely private, because it's not only very private information, which is one kind of privacy in our country, it's relational, it's information about not just you, but your parents, your siblings and your children, and it's very critical decision-making information, especially around the area of whether to have a child, whether to continue a pregnancy, and even now, we learn how to diagnosis a child.

So, this, I think makes it uniquely private. Whether that matters or not, Mark and I have just been talking about. The question is, what do you do about it?

How do you keep genetic information private? How do you use genetic information? What does it mean to be private in the real world?

We've gotten a long ways on insurance and employment, but from my mind, the most important part of genetic information that makes it private is it's individual to you.

It's the way you look at your life, and this is a metaphor I've used. I suggested back in -- actually, 1990, at Coal Spring Harbor, that you can look at your genome as your future diary.

It's probabilistic. It's not deterministic. But I use that to say how private it was. It's private as your own diary, and nobody should open that diary, without your consent.

My friend Todd Murray has written, he says, "The metaphor is ingenious, powerful and provocative," and he goes onto say, "It's totally misleading, because it's way too deterministic." Again, I didn't mean it to be deterministic, but not ready to withdraw it, and Alzheimer's is a classic example.

When Dr. Watson did get his genome posted on the

web, he said one thing he didn't want posted and didn't want anybody to know about was whether he was at high risk for contracting Alzheimer's disease, and he has reiterated that, just a few months ago, and they said, "Well, you're 85, what the hell does it matter now," and he said, "No, some people get it in their 90's," he said, "All right." Fair enough.

Privacy is a broad issue. A lot of people have argued with the advent of Facebook, that privacy is gone and the death of privacy.

My friend and colleague Lori Andrews just published this book, "I Know Who You Are and I Saw What You Did", literally, on the privacy of social networks, and many of you know, Lori was deeply involved and head of one of the ELSI committees in genetics, and is still the main lawyer doing the gene patenting cases.

But this book really moves beyond that, but does show that many of -- there are many parallels between privacy in general and genetic privacy, and you know, you can think of posting your genome -- I mean, you can get your genome from 23andMe, but now, think of posting on your Facebook and sharing it with your Facebook friends, and having special groups with people that share the same genome.

A lot of us were heartened last week, when the Supreme Court decided that U.S. v. Jones, that privacy is not totally dead in the 4th Amendment. A lot of us thought it was.

But again, you can think about the GPS tracking devices, that is one thing, yes, they're very useful for law enforcement people, but it's also pretty intrusive to think that somebody is following you all the time.

You may have seen the last debate. You may be sick of seeing these debates, or you may find them entertaining, but -- fair enough, that is too wishful thinking, okay.

But when they were all asked, "Will you release your medical records," and everyone said, "Yes, yes, yes," there was a few things, nobody discussed about.

Well, they were not asked, "Will you release your genome," all right, and I think there would have been a different answer.

My colleague, Bob Green and I have written, we think it should be unacceptable for anyone to try to do a genome screen of any Presidential candidate.

We're not crazy about new laws, although I may

have thought, Mark, maybe we should have a law that outlaws the sequencing of political candidates DNA, because it can only lead to something we call genetic McCarthyism.

Europe is ahead of us on this, I think, well, at least with the European Human Rights Court, where they've decided that the genome is, even in criminal DNA banks, is very private and needs some very strict rules, if you're going to keep it -- if you're going to keep that DNA.

So, privacy obviously became an issue when we could get information from the genome.

Before that, it was just property, and when we wrote, my colleagues and I, Leonard Glance, when he wrote the Genetic Privacy Act for the ELSI Project, back '95, everybody said, "We had to have a Genetic Privacy Act." So, we wrote one. That was our assignment. We were happy to do it.

As soon as it was published, people said, "No, you can't have that. It's too much."

The core of the Genetic Privacy Act was a property vision that individuals should own their DNA, own their DNA samples and they should be able to control them.

This is the model for the bio-bank model, our model, which was, instead of research, you're not really

doing research on bio-banks, you're not doing anything risky to you, what you should be looking at is the way the law has always looked at this, is you're giving a gift, almost like the Uniform Anatomical Gift Act, and the gift can be conditional.

But once you give the gift to the bio-bank, it's their's to do with what they want, within the strictures of privacy and other reasonable things.

Bio-banks actually do four things, and this was the core of the Genetic Privacy Act. They collect DNA. They analyze DNA. They store DNA and they disclose information about it.

It's only the last one that privacy focuses on. The other issues are just as important, though. Who should be able to collect your DNA, for the purpose of analyzing it? Who should be able to analyze it and where should it be stored, and what kind of information do you need?

In this regard, I think the other -- the metaphor that we've used is wrong, and we can talk about it. We used bio-banks. Bio-banks look like, number one, they're commercial institutions, number two, money is fungible, so maybe DNA is fungible, and that, you know, you can connect

all these things.

Warehouses, I think is a better analogy, but I'm willing to talk about that, because that is more of what we do, we put our DNA there. It's warehoused and then used by other subcontractors.

Maybe the best analogy, though, is we're going to get deluged with information is with Borges' infinite library, and it looks like a library. Borges said, you know, a library contains all the information in the world, but nobody can figure out what any of it means, and that is, you know, I don't want to be cute, but that is -- a lot of that is close to what we're getting with DNA.

We've had cases of exploitation, people have had their DNA used without their informed consent.

The most famous one now is the Henrietta Lacks case, and the book has gotten a lot of attention, not just because terrifically well written, it's a good story, but because I think the exploitation of the Henrietta Lacks, of her whole family, I mean, her daughter Deborah says right at the beginning, "You know, I always thought how strange it was, if our mother's cells have done so much for medicine, how come her family can't afford to see no doctors," which

was like a great question the movie asks, where some people have an obligation to be in research.

I don't think so, and ultimately, I've decided, I don't think it's DNA that is exceptional, it's people that are exceptional, and at the beginning of the Lacks book, the epigram used is by Elie Wiesel, who says, "We must not see any person as an abstraction, instead we must see in every person a universe with it's own secrets, its own treasures, it's own sources of anguish, and with some measure of triumph."

So, this, I'll talk about later, if you want.

So, what do we do with personalized medicine? Where are we going here? Is this really still the goal? Is it a realistic goal? Is it an overhyped goal? That's what I'm writing about.

There is some good things and there is some bad things, but at a time, when the cost of healthcare is the number one political issue on the agenda, it is a little bizarre, to be trying to do things that are going to be the most expensive things medicine has ever done.

We do it. We do it because we don't want to die, I'm totally convinced of that, and we believe if we only knew

more, we wouldn't have to.

I put Facebook on there because although Facebook is a problem, it can also be a solution. It can -- in using so-called re-consent or keeping people informed of what is going on in the biobank, you can have a Facebook page for them. They can go on, you can communicate with people.

Re-contact is not the problem that it used to be. So, that's my last metaphor and then I'll quit.

This is Damien Hirst's diamond-studded skull, and I think it's a perfect metaphor for the American healthcare system, which we're trying to fit genetics into. Our healthcare system is death-denying, technology driven, wasteful and totally individualistic.

Unfortunately, all of those are problems, even though I like individualism, they're problems and genetics, I think amplifies those problems, and we'll hear from Mark and he can amplify some of my remarks.

DR. GUTMANN: Thank you, George.

DR. ANNAS: Thank you very much.

DR. GUTMANN: Thank you for that provocative analysis and other than all those problems, it's great, right. Thank you.

I want to turn to Professor Mark Rothstein, who holds the Herbert Boehl Chair of Law and Medicine and is the Director for the Institute of Bioethics Health Policy and Law at the University of Louisville School of Medicine.

From 1999 to 2008, he served as a member of the National Committee on Vital and Health Statistics, where he chaired the Subcommittee on Privacy and Confidentiality.

He is a past President of the American Society of Law, Medicine and Ethics, a member of the American Law Institute and an Elected Fellow of the Hastings Center.

He is the author or editor of 19 books and over 200 book chapters and articles on bioethics, genetics, law and public health. Welcome Mark, and thank you for being with us.

DR. ROTHSTEIN: Thank you, Dr. Gutmann, Dr. Wagner, Members of the Commission.

I'm going to talk about, I hope, issues that George didn't touch on directly, but certainly, that we need to think about related to privacy, and my only caveat is privacy is very important, but it's just one of the numerous issues that we need to be thinking about when we're concentrating on the issue of whole genome sequencing and

what the effects are going to be, both within clinical care and research and other uses.

So, in my opening remarks, I want to just talk about what I see as four major concerns raised by whole genome sequencing.

First, is that genomic information in electronic health records will be accessible by healthcare providers without a need to know.

EHR's and EHR networks are designed to be comprehensive and longitudinal and inter-operable and they hold great promise, in terms of improving healthcare, but the very factors that make it such a promising technology linking all of these longitudinal records, raises privacy concerns, and one of the things that many people think about in the clinical arena is that well, doctors need this information.

But the same EHR that's accessible to a treating physician without access controls is also accessible to every nurse, to every physical therapist, every chiropractor, to every dentist, to every physical therapist, and the list goes on and on and on.

Now, hospitals use what is called role-based access, which means that not everybody gets access to all the

records. So, if you are in the billing office, you only get a subset of the information.

That is helpful, but it's clearly not enough, because there are concerns that even individuals with treating responsibilities might have too much information.

So, if I fall down and they take me to the emergency room to treat my injured ankle, the doctor who is treating me in the ER, probably does not need to see my genomic information to treat a sprain or a break, and as well, other sensitive information, which might be my reproductive health history, et cetera.

Now, you may be thinking, "Well, obviously, ER docs and healthcare providers in general don't have the time to troll through detailed records."

The privacy point is, they could, and many individuals with stigmatizing and sensitive information in their health records, are going to be very concerned about creating this longitudinal comprehensive record, when there are no access controls on who gets access to that information.

The second area of concern is the research uses of the information.

Now, in the last panel, you heard all about the promise of genomic information for research, and it seems to me that there are three main options for protecting genomic information in research.

First, you can de-identify the information. So, under the common rule and the privacy rule, de-identified information is not subject to regulation. So, you could de-identify everything and use it however you wanted, as the custodian of the records.

If you ask the public, they do not agree with this concept. That is, there are numerous studies that if you ask the public, "Do you think it's okay for healthcare researchers to get access to your information in a de-identified form, without your knowledge or consent," overwhelmingly, the public says no.

If you ask them, they're likely to consent. If you don't ask them and they find out what you're doing with it, they're very unhappy.

The second possibility is that you have an opt out provision, as was discussed in the Vanderbilt model, and I think allowing individuals to opt out is better than nothing, from a privacy standpoint, but many people are

reluctant to exercise their opt out privileges, even if they understand them and understand what the implications might be.

The third option is to have an opt in provision.

Now, requiring informed consent is obviously, the most protective of privacy, although many researchers increasingly are making the argument that it's one, burdensome, two, that it results in lower accrual of individuals, and third, they're raising this argument that has been called consent bias, that if you require informed consent, that the sample is somehow biased.

In my view, I think these concerns are overblown, and I'd be happy to discuss them at the tail, later.

The third of my four issues is the non-medical uses of the information without consent or authorization.

Under the privacy rule, there are many kinds of information, that -- or many uses of identifiable information -- that do not require any consent or authorization from the individual, and I'll just very quickly run through the 12 categories of information that do not require any consent: uses and disclosures required by law for public health activities; about victims of abuse, neglect or domestic

violence; for health oversight activities; for judicial and administrative proceedings; for law enforcement purposes; about the decedents, for cadaveric organ, eye or tissue donation purposes; for research purposes pursuant to a waiver of authorization; for reviews for research and for research on decedents information; to avert a serious threat to health or safety; for specialized government functions, including national security and intelligence activities; and for worker's compensation.

Now, this is a very broad and diverse list, and it's one of the reasons that many people working in privacy think that the HIPAA privacy rule is problematic.

So, with more valuable information I think there is a very great risk of sort of function creep, and more pressure put on regulators to allow the even more wide spread disclosures.

My fourth area is compelled authorizations by third parties, and this is often overlooked in the privacy literature.

Each year in the United States, at least 25 million times a year, individuals are required to sign authorizations for release of their health records as a

condition of employment, applying for various types of insurance products and submitting claims for benefits, such as Social Security Disability Insurance or Worker's Compensation.

Just those four that I mentioned, employment entrance exams are about 10.2 million per year. Individual life insurance applications are 6.8 million per year. SSDI is 1.7 million and worker's comp is 1.6 million.

Most of these authorizations are of unlimited scope, even if the authorization is more limited, that just says, "Send us information about such and such issue," because the people who have the health records, don't have any easy way to limit the information, and it's costly and burdensome to do so, they just send everything, and that doesn't matter whether it's paper or electronic health records.

So, clearly, we need to be thinking about ways for what is called contextual access criteria.

So, some final thoughts. Here is my general rule that I am going to suggest that you consider.

If you test it, or you sequence it, the results will be used. The only questions are, how broadly and for

what purposes, and with what consequences.

So, that raises some very important questions, such as will genomic information eventually replace Social Security numbers as a universal identifier? Will ubiquitous genomic information lead to a wave of genetic reductionism and determinism?

Will we become a society of the worried well, because we've got predictive information that we are 'x' percentage more than the average at risk for something, and will genomic information increase health inequality?

At the least, genomic information and various findings attached to them, whether validated or not, are likely to be used in ways that we can't predict now, but certainly, including family relationships, for virtually all insurance products, from criminal law beyond forensics, for civil law such as personal injury litigation, for various aspects of employment, for educational and school-based purposes, for commercial settings and for military and civilian governmental uses.

So, I wish you lots of luck, in your considerations of these issues, and I thank you for inviting me to be here this morning.

DR. GUTMANN: Thank you very much, to both of you. I'll lead off with a question and then ask Commission Members to join in.

So, and you correct me if I'm wrong, but my impression with the two presentations is, we've gone from a panel which has shown us all of -- a lot of the upside of having genome sequencing and sharing data for the good of not just science, but of being able to help people with rare diseases, which you can't do if you just have a few -- if this information is private, to the brave new world of genomic sequencing.

And George, you're attributing the desire for it to -- the desire for immortality and Mark, pointing out all of the, you know, somewhat scary ways in which the information can be used.

So, I want to just see if I can pull us back a little, or at least get a little bit more what I would think of as nuance in it.

So, let me give you an example, that has nothing to do with genome sequencing, and tell me why genome sequencing is, you know, so much scarier, as you seem to be painting it.

So, if I -- I get a life insurance policy now, and I'm very -- I'm a healthy -- I'm healthy. I've never smoked. I don't drink, very much, honest there, but and you know, everything you could know about me now, a life insurance company, and this is not a hypothetical, it's actually a true story.

Everything a life insurance company can know about me now, would put me in the lowest risk category.

All they have to ask is one question, which they ask, which is, "When did your mother and father -- how old were your mother and father when they died," and the answer for me is, my father was 56 and my mother was 71, and my risk category changes immediately.

Nothing as a -- you know, you don't need any genome mapping. So, why are we -- I mean, there is an issue of what you can allow insurance companies and other places to know, and how you protect it, but you know, we're not really in a -- the new world is the difference in the technology and the amount of information, and how it may be misused, but there is a lot of information already out there, that can be misused, if you will.

So, I just want you to -- and we have to balance

this against what we heard earlier, which there is a lot of good that can be -- that can come, about people sharing their genetic information with responsible users.

Now, mind you, I asked you -- I asked the other panel the opposite question.

So, I just want to see what your -- give us the way in which privacy, an undue concern for privacy, too much privacy in this area, might be harmful.

DR. ROTHSTEIN: Well, I want to try to answer your insurance question first, and let me preface that by saying, I am a supporter of genetic research. I do lots of collaborative work with geneticists and have been doing it for the last 30 years. I think it has great prospects. I'm not trying to impede science.

What I am trying to do is help science integrate their findings into a culture that may not be ready for it.

To answer the insurance question, it's not different in kind, that is, the kind of information that we're getting, but it may be an add-on.

And so, your life insurance example would be the -- and the traditional side. Let me give you another example, that would --

DR. GUTMANN: Just to add to that.

DR. ROTHSTEIN: Sure.

DR. GUTMANN: And I'll let you -- actually, adding genetic information might improve your chances of getting a better -- a more accurate and fairer life insurance policy.

DR. ROTHSTEIN: It could do that, but suppose you were applying for a long-term care insurance policy.

The cost for a long-term care insurance company, for people who need skilled nursing care, such as Alzheimer's patients, is much higher than the typical person, and there are many risk factors for Alzheimer's. One is a genetic factor.

So, should we permit long-term care insurers to require individuals, as a condition of being written a policy, which are individually under-written, that they take a test for Alzheimer's disease?

Now, there are many people who wouldn't want to know that, and now, we're forcing people to consider information that they may consider to be very harmful.

But now, from a social standpoint, the question is, how should we under-write the risks of long-term care?

It's not a genetic issue. It's not an insurance issue. It's a much broader issue, and are we going to do it socially, the way some companies do it? Are we going to do it on sort of an individual medical under-writing basis, or are we going to say, "Okay, in this area, maybe there should be more community rating," and just base it on your age or whether you've had head trauma or some other risk factor?

So, these are very complicated questions, and when you move beyond the clinical and the research setting, to the applied settings, each one of these areas, whether talking about criminal law or tort law or family law or insurance, they are very contentious, and you can see where all the different interests are now weighing in.

So, privacy is an aspect of this whole big problem.

DR. ANNAS: Very provocative question, for two reasons.

Number one, most of us, I think, think we're going to have the basic same health that our parents have, and that's why family doctors ask about family history, and it's probably the most important predictor of how you're going to do.

On the other hand, adding genetics to it adds not just this component of, you know, the future diary, predicting the types of diseases that you might get, a little more specifically, but adds a precision, at least in some cases, and it's the old example, but it's a good genetic example of Huntington's disease.

If one of your parents had Huntington's disease, you know you're at least a 50/50 change of getting it.

Does that mean that someone else should be able to tell me I have to have the the Huntington's test, because I want insurance or I want anything?

You know, what is -- so, I'll know 100 percent, one way or the other.

I think the answer to that has got to be no. I think you have -- that kind of privacy, which I mean, authorization, that nobody should be able to do your genome without your authorization, I think has got to remain that.

It is 80 percent of the people who are at risk for Huntington's, because of their parents. We always thought that -- people in genetics always thought, as soon as that test is available, everybody is going to want it, and that is kind of what we're talking about today, as soon as

the whole genome test is available, everybody should have it.

Maybe, but maybe not many people are going to want it. I mean, 23andMe thought a lot more people were going to sign up for their services than did. Yes, they got 125,000, that is great. They can't make money with 125,000.

We all want it, and I want it. I'm a booster of genetics too. You know, we're with this. We're true believers, but someone wants -- I think you said it, you know, 99 percent of the public has no idea what the hell genetics is all about. I think that is true, and most of them aren't interested either.

So, I think for privacy, for consent, for all these things, we need a lot of public education, before we're going to get there and before we don't get it, I think what I heard Mark saying, a lot of unintended consequences, a lot of things we haven't thought out, that we could prevent, if we thought about them beforehand, at very little cost.

DR. GUTMANN: I'm going to open it up to the Commission Members.

DR. FARAHANY: Very interesting and provocative presentations.

I've been thinking for a while, and I think kind

of building on Amy's question, what is so special about genetic information that would make us think that there needs to be different privacy rules, with respect to it?

And you know, I am a bit more concerned right now, having seen at least my SNIP profile from 23andMe, about Google and its new privacy policies, and kind of complete access to information of every search term I've ever had, my email and everything else, than my genetic information.

So, in trying to think what is it that we're afraid of, right, like information gets out, and we're moving toward a society of greater transparency, and interestingly, 23andMe actually has that kind of Facebook component which is, you can share your genetic information with friends, and I have a pretty large circle of friends who have all shared their genetic information with each other, and so, I thought, okay, well, what is special about it?

So, it seems to me like the one thing that people end up collapsing down to is, it's unfair because you can't control your genetic information, whereas, you have greater control over things like my search terms that enter on Google or the emails that I send.

And so, judging people based on something that

they little control over seems unjust and unfair, which to me then would suggest, maybe the right answer is not to try to prevent transparency, but to govern the rules about the types of use and applications, to which genetic information could be applied.

But you know, when I hear, kind of the seclusion aspect of privacy that I think you both spoke of, which is the ability to keep secret and keep secluded genetic information, I wonder, what is the aspect of privacy that you think should govern genetic information?

Is it really the ability to keep it secret, and when you put up U.S. v. Jones, you know, it made me think, well, Jones simply invoked a property based analysis of GPS technology.

It didn't actually say, keeping secret movements that you have is something that you care about, and in all of the genetic cases to date, what Courts have said is, we shed DNA off of our skin. We shed it on the cups we leave behind, and when the police get it, it's just like the trash we have left behind, they're able to sequence it, because we've abandoned it, in a sense.

The truth is, we do leave traces of ourselves

behind all the time, and so, the idea that we could keep it secluded from public view seems improbable.

So what is the kind of privacy that you're talking about? What do you think should govern it, and what is so special about genetic information that you think we should have special privacy rules to govern it?

DR. ANNAS: Well, I would actually be happy with a general privacy rule that covered everything. I just think our current privacy rules are just so weak and there are so many exceptions to it.

I mean, Mark talked about HIPAA and its 11 exceptions. I think most health lawyers think of HIPAA not as a privacy law at all, but as a disclosure law, as a law that authorizes many more people to disclose private information they never could before.

The medical record is usually used as the analogy, but that -- you know, that is a wide open thing, in most systems, and Mark talked about that too.

If you had, if you could control your Facebook -- Facebook has a 45,000 word privacy policy, which I doubt anyone has read, except someone who is writing a paper about it.

It would be good, all right. I mean, Lori Andrews book that I mentioned is just about that, just about how can we improve the privacy aspects of Facebook?

She doesn't want to shut down Facebook anymore than I want to shut down genetics. We want to make it better. We want to make it more user-friendly, and we don't want people to have to worry about how people are looking at them, or using their private information to make decisions about them, that they may never even know about, all right.

So, again, you know, I'm not a big genetic exceptionalist. I get accused of that all the time. I started out trying to protect medical records 30 years ago, and I'd still like to do that. I think that is still a challenge.

In genetics, the model, one of the models, we heard some models before, is that your medical record will not contain your genome sequence. It will be -- that will be separate on a cloud somewhere, but it will be linked to your medical record.

So, both because of the size of it, but also, because it is seen as something that we're just learning about and we don't know really, what to do with it yet, in

that. It's probably wrong to put it all on your medical record, and not just because of privacy, but because that it can be used in ways that just aren't true, all right, because we don't know enough yet, about what is true.

DR. GUTMANN: Raju?

DR. ANNAS: I don't know if that helped at all.

DR. KUCHERLAPATI: I hear, you know, one of the arguments that both of you are trying to make, is that, you know, doing whole genome sequencing might be not good, and that, you know, having that information may not be good.

I want to try to bring in other things currently in place, and how you will compare them.

For example, there are laws in many states in our country, where a newborn, you know, would be able to take a little bit of blood from their foot and test them for a number of disorders, that are very infrequent in the population, and yet, you know, you do the test, so that is for public good, because if you don't do the test and if the child were to develop a deadly disease, they might die from it, or if they don't die from it, that the society would incur some very significant amount of costs in taking care of those.

So, what is different from doing such a blood test today, in many of them, and if that is replaced, let us say, by genome sequencing, one gene, 10 genes, or 22,000 genes, how do you see the difference?

DR. ROTHSTEIN: Well, I know there are many people who envision that the newborn screening test eventually will be a whole genome sequence.

We recently increased the size of newborn screening panels, right. So, with tandem aspect in many jurisdictions, we went from say, eight or 10, to 40.

That has not been entirely without cost, and one of the costs is a generation of tremendous numbers of false positives, that were very costly to track down, caused a great deal of mental anguish to parents. In many instances, involved very rare disorders that weren't treatable to begin with, before diagnosis, which is the key for newborn screening.

So, it's -- can we imagine what would happen if we did a newborn screen and we found that the average child had 50 abnormalities, or if we found that the -- we just found many more things where we would find, you know, 500 false positives for every true positive, and it's

questionable, whether we could provide any benefit by learning earlier, how this went along.

I was on the panel that -- at HRSA, that was trying to decide to expand the panels, and we had, on this group, many state health directors, and many people from smaller states said, "This is going to cost a fortune for us, and it sounds nice, and we got very persuasive, emotionally compelling testimony from parents, but I'm going to have to cut somewhere in my budget to accommodate this. Should I cut well-baby care? Should I cut immunizations?"

You know, it's not free, and so, yes, you raise a very good point for every, you know, child that we can save and intervene on, wow, that is wonderful.

But I'm afraid that it's much more complicated than that, and all I'm trying to do is raise the complications and so, that when we adopt policy, it's a more comprehensive one.

DR. GUTMANN: Can I just see if what you're saying -- because when I hear what you say, what I translate that into is, we're not ready to have whole genome sequencing for every newborn because the costs now considerably outweigh the benefits in being able to treat the things that we find.

But that suggests that there is no -- that the difference is that we haven't -- the science hasn't progressed far enough to do the good that would need to be done, to make it worth while.

DR. ROTHSTEIN: I think that is exactly right. I mean, it's a moving --

DR. GUTMANN: But it might happen.

DR. ROTHSTEIN: It might. If before 1961, we didn't understand PKU and how to prevent it with diet, identifying it was not going to be very helpful, right. So, absolutely.

DR. GUTMANN: Good, well, that is very helpful to understand your perspective then.

DR. ANNAS: It would tip the balance for me too, except I would still want -- maybe we're different, a parental consent to screen my child.

DR. GUTMANN: Nelson?

COLONEL MICHAEL: Yes, so, maybe that last discussion was a little more clarifying for me, because I wanted to probe two comments, one each that you made, that would almost suggest you have intrinsic concerns, and I think that maybe your last few remarks would make it more

moderating.

Dr. Annas, you mentioned that maybe the public doesn't really understand genetics, doesn't want to know. What would you do with the information? You used a specific example of Huntington's Chorea.

Well, I was a medical student another institution just south of here. That's where I cut my teeth, and it was during the beginning of the HIV/AIDS epidemic, and I've devoted the rest of my life to studying and implementing counter-measures for that disease.

So, the people made the same argument about HIV, why would you want to know, and before the era of combination -- effective combination therapy, I think that was probably more fungible argument than it is today.

So, I just wanted to just reiterate that I think that it sounds like in the last remarks that you both made, that your issues with whole genome testing, is really just a scale of, of what we have -- are already doing in a relatively gene specific or candidate gene level, you don't have intrinsic concerns for.

And Dr. Rothstein, you mentioned something that as a -- and I still see patients several times a year, that

healthcare providers maybe shouldn't have full access to the medical record. I have to say, I take significant exception with that.

If I'm an emergency room doctor, and you come in with a sprained ankle, if you have a genetic test that indicated you might have a bone disease, isn't that something that you want you and I to collaborate on?

So, you know, I'm just wondering of both of you are using examples that are relatively extremes, to make points. I just wanted to confirm if your view really is intrinsic or not.

DR. ROTHSTEIN: Well, I do have problems with over-access to information. The world is changing and I think physicians are going to have to recognize that they no longer control the privacy interests of their patients.

I think the physician/patient relationship is evolving, and there are many kinds of information that have no current clinical utility.

So, a report that is 30 years old, in a women's medical record, that a former companion had beaten her up, right, where there is no head trauma, there is nothing that's going to carry forward, now, should that be in her record for

the rest of her life, where every healthcare provider is going to have access to that?

Another example I use is where a graduate student celebrates the end of exams by having a liaison with a commercial sex worker, and Monday morning, realizes, "That was a terrible thing to do," and goes to his doctor and says, "I want you to run a test for every STI known to medicine," and they run this complete battery of tests and they're all negative.

Now, should that information and the reason why it was run, remain in that individual's health record for the rest of his life, where an employer can get access to it, to a mortgage -- where a mortgage company can get access to it, to anyone who has economic leverage over you can get access to that information? I don't think so.

So, my bigger point is that not all genetic information is sensitive. There is some genetic information that is sensitive, and that subset of genetic information, I would regard as -- on the same level as other, very sensitive medical information, which would include a treatment for substance abuse, mental illness, and you can imagine the list.

Once we have a well thought out list, where physicians understand what is on the list, then I think it's possible to have sound policies.

In terms of the emergency example you gave, when I chaired the NCBHS task force on privacy, we heard from all the medical specialty groups, including the emergency docs, and they said, "Give us 10 points of information that is accurate. We don't care about anything else."

We're -- we would be ahead of 99 percent of the patients with medical records that we see now, that are incomplete, inaccurate, or don't exist at all.

So, if we could get access to nine things, you know, what meds, diagnoses, allergies and so forth, that would be fine, and you can always imagine some rare case, where I have some genetic bone problem, but the main issue is whether people feel confident.

What I also don't want is people with stigmatizing conditions, not going for medical care in a timely manner, because they're afraid it's going to follow them around for the rest of their life and they'll never be able to get a job.

I want people with mental health problems, with

substance abuse disorders, with infectious diseases, et cetera, to be able to control some aspect of that information, even though we may pay some, and I'll concede this, some slight clinical price from removing that information.

COLONEL MICHAEL: I just don't know that we're smart enough as physicians, frankly, to be able to know what that list of exclude-able information would be. Medicine evolves.

DR. ANNAS: I understand, but your HIV example is like a perfect example. That's where this whole exceptionalism came from, this HIV exceptionalism, and it actually wasn't exceptionalism at all.

It was informed consent had become standard and it wasn't before the epidemic, you know, you actually did need to get informed consent to do that, and but it was exceptional in the sense, there was no treatment.

So, it was just stigmatizing, as Mark would say, and you would drive the epidemic underground if you, you know -- I don't have to tell you, if you forcibly just said, "Routinely, we're going to screen everybody and tell everybody what your status is."

But facts change and that is the most important thing about ethics, good ethics, got to be good, you know, based on good facts, and when the facts change, your considerations may change, as well.

COLONEL MICHAEL: Yes, just to counter-point that, you know, the U.S. military decided in 1995, the instant the tests were available, that the entire force would be screened, in perpetuity, and I can tell you that, you know, we soldiers are under different constraints, you know, different legal system than, you know, than our counter-part American citizens.

And from a public health standpoint, that reaps enormous values, not just for the Armed Forces, but just the understanding that HIV was a spectrum of disease, came from frankly, that initial understanding in the military.

And so, you know, again, I think it's an issue where it made sense in the civilian world to take one approach and in the military a different approach, I think made more sense.

DR. GUTMANN: Christine?

DR. GRADY: Thank you, both. I wanted to ask about a solution to the access problem, because I don't think

either one of you would say, no access to information is good, that some information needs to be accessible for people to be able to do things.

But especially you, Mark, mentioned contextual access, and some of the particular examples that you gave, like role based access and hospitals and even the HIPAA exceptions, seem to me, they are examples of contextual access, but maybe they're not good enough.

So, I was wondering, what is the way to, in your views, control access more than it's controlled already, in a way that protects privacy in the way you think it ought to be protected, and who gets to control it?

So, in response to Nelson's question, you said something about maybe patient controlled access, but there are, you know, I think legitimate concerns about some people will expunge more things than ought to be expunged from their records.

So, how do you -- you know, who do you give control to, over the access?

DR. ROTHSTEIN: Well, that is a very perceptive, but difficult question.

Let me just say that the same debate that we are

having in the United States on this issue, is going -- is happening all over the world.

DR. GRADY: Sure.

DR. ROTHSTEIN: Right, so, it's every nation in the developed world is transitioning to electronic health records. They're debating many of these same issues, and on the NCBHS panel, we had basically three approaches.

One is that let's not change anything, that the patient -- patients don't know enough to sequester or segment information.

The other extreme was, patients need to have sort of line item control over their medical records, and the middle ground was that patients should be able to elect from a finite list, of expert determined conditions, some of which are already legally required to be kept separate, to put certain things in sort of a separate file, and physicians would know that there are five classes, let's say, of information, one would be reproductive health. Another would be substance abuse and so forth.

We could still have, and by the way, this was the middle ground that was recommended to the Secretary in 2006, we could still have the clinical decision support scanned

even sequestered information for drug interaction.

We also have the ability of a physician to say, "Look, I can't treat you and prescribe powerful pain killers, unless I know exactly all the meds you're on, because I'm getting error messages. So, you need to share with me, the code that's going to let me see everything."

There is also a 'break the glass' feature for emergencies, where you can get access to that information, and then the healthcare providers who need it on a routine basis, so, that your ob/gyn automatically has access to your reproductive health history.

That was the recommendation. I think there is evidence that HHS is leaning that way, now. There are some pilot programs. I think there are a lot of things that still need to be worked out.

But the two extremes are not options. You can't have patients with line item control over their health records. No doc is going to trust it. They're going to have to retake everything, right, and destroy all the benefits of it, and you can't do nothing, and if you don't have any control, people, in electronic health systems, are going to be much worse off, in terms of health privacy, than they are

today, and that is not going to go down very well.

DR. GUTMANN: Dan?

DR. SULMASY: Thanks. George, you had said earlier that at least at a previous point in your career, you had talked about DNA sequences as property, and almost alluded to the idea that you might have -- that you're thinking, might have evolved on that, because I've been sitting here trying to think about that idea, and thinking, well, is it something we own, like our liver, you know, and you may not even think you own your own liver, but maybe you can think of it that way.

But then we're thinking of chromosomes, but it's not really chromosomes we're thinking about, it's the information contained in the chromosomes that's the sequence and then you sort of think, how does information become property?

Well, usually it's intellectual property, something we, you know, have created ourselves, we consider to be property, and that is not true for, you know, a gene sequence.

So, if it's information, then it's information like the rest of health information about us, and then the

question is, well, do we own our medical records, and I don't think we do, but maybe you're advocating we should own our genomes and all of our -- the rest of the health information about us, and treat it as personal property, rather than, you know, an instrument for the physician.

So, I am wondering, what you think -- has your thinking about property evolved and do you still think that genomes are actually, our personal property, or that is the best way to think about it?

DR. ANNAS: Yes, no, if I left that impression, that was wrong.

What I was trying to say, and I'll try to say it again, is your tissue, your blood, you know, is your personal property, and this was -- this goes to the first point of collection.

You know, in order for somebody to do a DNA test on you, obviously, they need part of you, and that part of you can be looked at as your property, and historically, it was. That was all that was looked at, was property.

It didn't become an information or a privacy issue until someone could take that blood and do something, and learn something with it, which is what you're talking

about, get a DNA sequence, right. That is information, all right, I totally agree with that. That's not property.

You could, I mean, we now have people patenting it, right, and it's their property, at least temporarily, right, that says they can control it. They can control access to it. I think that is very problematic, as well.

But it's the information that someone takes from your property, your bodily property, that is the privacy issue, and I believe that is why I don't think anyone should be able to take that information from your property without your consent. We can call it consent or authorization, and the slide I put up with the two characters from end-game in the tin cans, was from the -- I call it Norwegian bioethicists who say that we've gotten -- all the bioethicist's have gotten crazy lately, by just redefining consent, and call it broad consent, bio-consent, this kind of gets at that.

It's not consent at all. We're just playing word games and it gets us nowhere, which is what -- kind of what I suggested, we just go back to the beginning and say, what is it we're trying to accomplish?

How can we -- and how can we both accomplish what

we want? How can we support science and research and also protect the individual privacy, and I think it can be done. I don't actually think that's that hard.

DR. GUTMANN: Let me give you a model, you know, an ethical model, and you can tell me what is right or wrong with it, and it would be called conditional -- the conditional use model of genetic data, and it goes something like this, and it's going to be rough. It will need to be refined, but just assume we can refine it.

So, I want the expertise and the help of a doctor, and let's add nurses in there, too, because I didn't like the suggestion that somehow, doctors could -- you had earlier said, "Why don't -- oh, so, doctors use it and then nurses."

So, I want the use of the -- you know, the medical expertise of doctors and nurses and the whole, you know, institutional infrastructure that has enabled them to provide me with help, medical help, and as a condition of that, they say, if you -- in order to give you this service, we're going to, you know, take a blood sample or it may be a genetic sample, and we're going to use it, and use it not only to help you, but we're also going to put it in a

database to help others, because the only way we can actually get this help for you, is by looking at aggregative data, okay.

You don't have to take our services, but if you do, so, you can opt out, but if you do, we're going to use this, plus, and there is a very important plus, we're going to put a set of protections, or there are a set of protections in place, and here is where I can't go through all of them, but there will be protections, so you won't be discriminated against.

It won't be, we're going to set up, you know, side constraints, so you won't be discriminated against, in various ways.

What is that -- is that a reasonable model for the use of data about yourself?

DR. ANNAS: Well, I think that presents a problem that Mark talked about, as well, which is the conflation of treatment and research, and if we're going to look at this bank that I'm contributing to, after you help me as a research bank, we probably wouldn't let you --

DR. GUTMANN: You wouldn't be able to be treated, had there not been research to begin with.

DR. ANNAS: Of course not, of course not, but you

--

DR. GUTMANN: So, why should you be able -- why -
- isn't that the classic free rider -

DR. ANNAS: Free rider?

DR. GUTMANN: I want the benefits of the research
that came from aggregative data, but I don't want my data to
contribute to anybody else. That is a classic free rider
problem --

DR. ANNAS: It is, but more likely --

DR. GUTMANN: -- which everybody in a classically
individualist --

DR. ANNAS: Yes.

DR. GUTMANN: -- you know, ego-maniacal society
would love, and I don't suggest that that is our society, but
to the extent that individualism and consent are ethically
defensible, it has to deal with the problem of the -- you
know, the common good, as well.

DR. ANNAS: It certainly does, but in our
society, mostly it's the poor and the people unlikely to get
access to these expensive treatments, who are more likely to
be scooped up in any kind of privacy drag-net, if you will,

or looked at their medical records.

It's not going to be you and me, you know. I think that many people who are fully insured and are going to have access to the fruits, of course, they should participate, I got no problem with that.

But I look at Henrietta Lacks and her family, her family couldn't eat. They didn't have any food, and Johns Hopkins was very happy to take her material and make money out of it, you know.

That is the reality. We're not talking here in a equality society.

DR. GUTMANN: George, you're scooping a lot out.

DR. ANNAS: I am, I know that, but so are you. You are assuming that we're going to have research done with my tissue, that was going to have -- that was going to have some fruit, and maybe it will. Most research doesn't pan out, is all the researchers will tell you.

Okay, so, you can't have a quid pro quo. I really don't think that works. I just think there is factual matter, again, we have to start with good facts. That doesn't matter.

DR. GUTMANN: With protections?

DR. ANNAS: Well, the biobank model in Europe now, is going in your direction, actually.

What they're doing is collecting DNA and they're not going to talk to you again about it, but they have set up an ethics governing council, and that council, hopefully will have some representatives from the public on it, as well, will make those decisions, to try to protect you. You're right, and there is a lot to be said for that.

But it depends on the details, I think we both agree with that, it depends on the details, right.

DR. ROTHSTEIN: Well, my question is, would you have to consent to have your biological materials and records used for research that you deem unethical?

So, in other words, not everyone agrees with everything that is being done, like embryonic stem cell research. Should you be presented with a choice of, "Well, if you want to be treated at this institution, you have to give a blanket consent, and we're going to decide all the things what we want to do, irrespective of your, you know, moral obligation -- or moral objections to some of the research that we might do?" So, it gets kind of tricky, I think.

DR. GUTMANN: That is another question that needs an answer. It's not a question about privacy. That is a question about your complicity in research you deem unethical. So, that is another set of issues.

DR. KUCHERLAPATI: Thank you. Amy, I just want to follow up on the question that you had.

One of the questions is that who should make the decisions about keeping this genetic -- or genomic information to be private?

Is it the responsibility of the state? Is it the responsibility of the individual? Is it the responsibility of the society?

I think it will be very useful to get your ideas about that, just some of you may already know, like for example, there is a program out in Boston called 'The Personal Genomes Project', which is recruiting several hundred-thousand individuals, and they're providing samples and their tissues will be banked and their genome sequence one day will be made publically available, and all of them have, you know, volunteered to actually support that.

So, is that okay, or you think that that type of approach, where they are actually making the decision, that

is not a good thing?

DR. ANNAS: You'd probably be horrified to learn that I have worked with George Church and his group, on their consent form.

No, think it's a good -- I think he's misguided on this. I think that he's going to find that people are not desensitized to have their entire gene -- is because James Watson and then his -- all his people now, George Church's group, is willing to put their genomes on the web, doesn't mean that everybody else is going to do it too, I don't think.

But I think it's a good piece of research. I think it's worth doing, and I support it.

DR. KUCHERLAPATI: You haven't answered the question.

DR. ANNAS: I'm sorry, what?

DR. KUCHERLAPATI: Who should make the decision?

DR. ANNAS: The individual should make their own decision, whether they want to do it, all right, and then whoever is holding the information, has certain obligations, not to disclose it to -- in harmful ways.

DR. ROTHSTEIN: But there is a role for public

policy in this.

So, let me give you an example. Somebody could take this cup after this panel is over, and do a DNA testing without my consent.

DR. GUTMANN: How did you know what we were planning on doing?

DR. ROTHSTEIN: Well, okay, but you could go to jail in the UK for doing that, and --

DR. ANNAS: Not here.

DR. ROTHSTEIN: So, that is a public manifestation of view that that's not proper and the United States, we haven't reached that point, yet.

DR. GUTMANN: Jim and Nita, and Lonnie, did you -
- and Lonnie.

DR. WAGNER: Perhaps, this is a naive question.

We have so many medical conditions and disorders that are really understood and even diagnosed, based on a variance from a norm.

We only know that your vision varies from what somebody can see at 20 feet because we know what the norm is for what people can see at 20 feet.

We have certain charts of height and weight that

we expect children to fall within certain parameters.

So, how is it that we are going to be able to have this sort of iron-fisted lock on privacy and still pursue these kinds of important indicators that are necessarily going to require aggregations of large amounts of population data, that are genetic now?

DR. ROTHSTEIN: Well, I think as a practical matter, you're still going to be able to get enough information to be able to do the research you want.

We had witnesses testify from some European countries, where individuals, for example, in Denmark, that individuals have basically, total control over their own health records, and they can put in and take out.

It was a provision that was much loved, but very rarely use, and I don't know that the same would be true in the United States. I think it might be, but protecting the rights of individuals at some level, I don't think necessarily would undermine that sort of stuff.

There may be some level of acceptable imprecision that we're going to have to reach, and that's where pilots and exploratory research comes in.

This is too important to just roll out something

one way or the other. I think we need to be careful and do it in stages.

DR. GUTMANN: Nita?

DR. FARAHANY: I want to build a little bit on Dan's question, about informational property versus regular property, and I just want to run something by you, to see -- just to understand exactly what your position is on genetic information versus other types of information.

So, just a few pieces of information that you could gather about me, fingerprints that I leave on things throughout the world, footprints that I leave on things throughout the world.

The router on my emails that tell you what service provider that I'm using. My record of my banking transactions. The log of my internet activity.

These are all things that are passively created, without, you know, active engagement, even my fingerprints, you know. Yes, I do some action, but it's a byproduct of my activities.

Do you think that information should be something that I get to control in the same way as my genetic information, or is your argument -- so, that really like, all

of the complete transactions about the byproducts of my life and information that you can gather from me, are things that I should have control over, or that there is something different, unique and special about genetic information, that should mean I should control that information uniquely and differently?

DR. ANNAS: I'm going to give you what I'm sure is an unsatisfactory answer.

I think that genetic information is uniquely different because again, it's mostly about your future probabilistic things, although you could say your bank account is too.

But I think all of those things you said, you should have control over, and I think it should be wrong, as Justice Sotomayor implied in her opinion, and concurring opinion, for someone to aggregate all that data about you and then make it available to some other people, without your authorization, although right now, they do.

DR. ROTHSTEIN: Now, George and I have disagreed on this for many years.

I think that sometimes genetic information is sensitive, but genetic information per se is not, and I don't

believe it should be treated differently, from other kinds of health information.

I think what we need is a comprehensive health privacy law, which we don't have in the United States, and that would scoop up, as the term has been used this morning, that would scoop up genetic information, as well.

I think it's a mistake to try to signal -- separate genetic information. I think it's a self-fulfilling prophecy and I think those attempts have actually, in my judgement, made things worse.

But so, I would not treat genetics separately.

DR. GUTMANN: Lonnie?

MS. ALI: Thank you, gentlemen. We are talking about privacy and we're talking about here in the United States, and you're talking about -- Raju was talking about the Boston Project, where they're collecting all this data, and people are voluntarily putting their information in and allowing their DNA to be collected.

I don't know if they know what they're going to be doing with it, but they're allowing them to do it.

Our privacy laws here in the United States, as we structure them, or however we may structure them, is for

here. What are we talking about when we talk about sharing this information globally, and the privacy laws that affect, or may not affect, us in other countries?

I mean, you really get into a larger space there for consideration, and one thing that you said to me, that you said to the Commission, Mr. Rothstein, was about, "We may be a culture that is not ready for this."

Would you expound on those two things?

DR. ROTHSTEIN: Sure, the reason I say that is because we don't have very good privacy laws in place now.

We have the HIPAA Privacy Rule, which was never intended to be a comprehensive national privacy law, and it can't bear the weight that's being placed on it, and it's -- and in some respects, it's had negative consequences, and we don't have a law that prohibits the testing of biological specimens, including genetic information, without the consent of the individual, and that was never ordered by a physician.

So, taking my cup and running a DNA test is legal in the United States, where it's not in other countries.

So, that is the part of the answer, where I said, I don't think legally, in terms of protecting individual rights, we're ready for this huge onslaught of additional

information, because I think there is too much of an opportunity for misuse.

DR. GUTMANN: Thank you very much. The only thing standing between us and lunch is our thanking you very much for a most provocative session. Thank you, Professors Annas and Rothstein.