



Presidential Commission
for the Study of Bioethical Issues

TRANSCRIPT
Roundtable

Meeting 4, Session 6
February 28, 2011
Washington, D.C.

DR. GUTMANN:

Hank, thank you. I'm going to ask all of our presenters to help us on a specific question that we ourselves, are going to be asking and answering, over the next week or so, and that is, what we, as a Commission, on the broad subject area of genetic and neuroimaging and its ethical implications and the social responsibility attached to that, what can we most productively take on, as a Commission?

So, what I'm going to do is really go around, not ask the Commission members, but the presenters, a very pointed question.

If there is one specific, and I emphasize specific issue, that you would like us to take up, because you think we can be particularly helpful, practically useful in the advice we give, what would that one issue be, or if there is one fact, or set of facts, that you think it is very important that we explore the ethical implications of, what would that be?

One, and only one. There is no, I dare say, there is no uniquely correct answer to this. There could be more than one thing that we could do very productively, and therefore, we fully expect to get different answers, but we really value what your individual and collective answers will be on this, and who are we to begin with?

So, Hank will start. Go first, take a microphone, make sure it's on. Just re-introduce yourself, by name, and give us your advice.

MR. GREELY:

I'm Hank Greely. I'm the real Hank Greely. You're not the President of my university, so I'm tempted to disobey, but that, I guess, would be wrong. I'm really torn. Research use of collected data.

Research use of collected data?

MR. GREELY:

Yes, everything from —

DR. GUTMANN:

Good, thank you.

MR. GREELY:

Everything from consent to incidentals to children, to a whole bunch of stuff.

DR. GUTMANN:

Yes, and we have somebody here on staff, who is going to take — write these down, so, I can see them immediately afterwards, right? Erik, you're next.

DR. PARENS:

If pressed to identify —

DR. GUTMANN:

You are pressed.

DR. PARENS:

— a manageable problem that I think you might be able to speak productively to, and in a short amount of time, it has to do with how to handle an avalanche of probabilistic information, in ways that are going to help, rather than harm people.

DR. GUTMANN:

Go ahead.

DR. PARENS:

My caveat is, I wish you could take on, in parallel, some longer range —

DR. GUTMANN:

Okay.

DR. PARENS:

— more complex undertaking.

DR. GUTMANN:

Okay.

DR. PARENS:

Bare limits.

DR. GUTMANN:

Okay.

DR. EVANS:

Okay, can I tell you why, I've picked what I picked?

DR. GUTMANN:

Sure.

DR. EVANS:

Okay.

DR. GUTMANN:

Briefly, really briefly, because look how many people we have, here.

DR. EVANS:

So, yes, I think that the forensic issues are the most timely, and the reason I think that is that while everything we've heard today is important, things, for example, in the realm of whole genome sequencing in a clinical sense, we are accruing a great deal of data, right now, about that. I think it's premature.

Whereas, I think that the questions regarding forensics, including for example, the searching, the new users, the searching of data bases for cold hits, as opposed to comparing one sample with another, are exceptionally timely, and I think that your input would be very influential because the mechanisms don't really exist to harmonize many of the practices.

DR. GUTMANN:

Okay.

DR. EVANS:

So, that's what I would vote for.

DR. GUTMANN:

Thank you. Martha?

DR. FARAH:

I would say, some attention to the pipeline, through which new neuroimaging measures, predictive measures, are developed, specifically, like who actually is taking on the cost of doing it? Who is doing the research to decide when it's ready to market, and how that pipeline and those owners of the technology shape, and you might even say, distort what actually gets produced and how it gets used.

DR. GUTMANN:

Okay, thank you. Adina?

DR. ROSKIES:

Yes, I think I'm in line with Martha and Erik. I think one thing that definitely needs to be done is better means of interpreting the data, and part of the problem with the probabilistic data is, we don't actually know what kinds of base rates there are, out there.

What is the relevant contrast or what class of, you know, people and behaviors, etcetera, we should be comparing the data to, so that we can really understand to what extent the data is predictive of anything we're interested in, and that has forensic uses, as well.

DR. GUTMANN:

Okay, Stephen?

DR. MORSE:

Well, first, I agree with everything that's been said, so far, but I'm entitled to only one, so, mine is vaguer, but it's more foundational, and it was brought up by both Adina and by me, and this is how the new neuroscience and the new genetics will undermine the image of the human being, because if we treat ourselves as just mechanisms, as just more of the flotsam and jetsam of the universe, the way you come out on some of these ethical issues that improperly raise, looks very different, from if you treat each other as human beings, as full agents.

And it's very easy to lose sight of that, but that is going to end up being, in many ways, the most foundational issue in neuroethics and genetic ethics.

DR. GUTMANN:

Judy?

DR. ILLES:

Mine is very specific. I have the new — the new challenges of protecting human subjects and research that specifically combines genetics and brain imaging technologies, and particularly, as it applies to biomarkers of disease and behavior.

DR. GUTMANN:

Okay, Susan?

MS. WOLF:

I am sitting here thinking, what can you uniquely contribute that's not IOM, it's not National Academy? What you do is public bioethics, and I think one of the biggest issues in bioethics, and it's deeply de-stabilizing, is this question of management of information, because as I tried to argue, it's really going to be a total re-negotiation of the line between research and clinical care and what we think of as researcher duties.

The last thing is, it has the great plus that it cuts across genetics and neuro and it cuts across research and clinical. It's really a deep organizing question.

People apparently want their data, but we have to worry about, in what form, what are they going to do with it, huge questions.

DR. GUTMANN:

Okay, thank you. There are clusters here. Ellen?

DR. CLAYTON:

Well, we came up with the same time. I'm going to follow on with Susan, and say that I also am concerned about management of data, but in a very different way.

I've made the point that I believe in the clinical context, that we will not be able to control access to data, and that — and there will be many forms of interpretation that are not inside the medical system, and I think that we are really going to have to talk about how far we're going to attend to what patients want, and how far we're going to say that we can't respond to that, in the absence of a data base or on the basis of cost.

I think that's also a terribly de-stabilizing question —

DR. GUTMANN:

Okay.

DR. CLAYTON:

— but I think that's one I'd love you to take on.

DR. GUTMANN:

Okay, Bruce?

DR. ROSEN:

I'll just follow up on the point that I think Erik made, Hank, as well.

This notion of how we deal with probabilistic data, in the setting of disease for sure, and coming down the pike is behavior.

I think based on, you know, our discussion, it's clear that, you know, today, the probabilities that we're getting is risk factors, genetically or from the neuroimaging data, are modest, but that will execrably increase, as we begin to troll the kind of data that, you know, Hank was concerned about us trolling.

We will do so, and now may be a good time to take on an issue, before those probabilities, you know, tip to be greater than 50 percent and it begins to be thought of as impacting on these, you know, issues of agency.

DR. GUTMANN:

This is terrific. Now, we are open to questions from Commission members on these — or any other specific topics that you want to raise and ask us.

We have you, you've generously given, not only your time and expertise, but also, your judgment to us. So, Jim is going to begin.

DR. WAGNER:

Yes, Jim, you were sort of unique, in pointing to the forensic issues as a subset of how we would interpret all of the data that people are concerned about.

Help me with what you understand the definition of forensics to be.

DR. EVANS:

Right, so, again, the reason I was specific, because I think that you need to have some degree of specificity in what you tackle, and the dimensions of the forensic issues that I think are important include the expanded use of genetic analysis, to not only determine whether a sample matches, the kind of CSI type of things that one sees, but also, this matter of, for example, determining that the perpetrator would be a first degree or second degree relative, etcetera. There are huge, kind of civil liberty questions, there.

There are also tremendous issues with regard to the increasing use of forensics and sometimes, in fact, there is an article in the Washington Post, about a year ago, about the mis-application of statistical considerations, as we changed the use to with which such analyses are put.

So, and the reason that the forensic issues come up is because there isn't a lot of standardization. Some states do this. Some states do that. Again, it touches on really profound bio-ethical, or ethical issues, with regard to balancing what we need for our basic protection with individual rights.

I think that these are the types of questions, I wouldn't necessarily — you know, Francis left off behavioral issues. I would probably leave those off, too, because I don't think they're quite real yet.

I think that these are matters that are being done right now, and again, you guys could have real influence on that, in a very specific way.

DR. GUTMANN:

Raju?

DR. KUCHERLAPATI:

So, many of you have mentioned that one of the big issues is how to deal with this probabilistic information, and wanted to probe that a little bit.

So, how is that different than how medical practice is today? An example was mentioned this morning, that you know, when we go to the doctor, you get a measure with the cholesterol levels, and then if you have a

certain level of cholesterol, there is certain probability that you would be able to develop heart disease later.

Or if you look at blood pressure, you would be able to measure blood pressure. The blood pressure is bell curve, and you fall somewhere within that bell curve and your doctor would say that, you know, you are normal tensive or you are potentially going to become hypertensive, and you deal with that.

So, it seems that there are — you know, that's the way medicine is practiced today. Nothing is completely deterministic. So, how are you thinking about, what is new about the genomic data, large amounts of data that causes problems?

DR. PARENS:

I would be the last — may I?

DR. GUTMANN:

Yes, please.

DR. PARENS:

I would be last to suggest that there is anything unique about genetic data. Like you, I'm very impressed with how similar the problems are, across realms, whether it's genetics or neuroscience or endocrinology.

It is, I think, important to bear in mind, our particular social context, where the human genome project was funded with really, exceptional fanfare.

As Jim Evans and colleagues wrote in Science last week, it is very, very important for us to get a grip on the respect in which the promises made were grander than was appropriate.

He's not saying, I'm not saying, no one is saying that the science is unimportant. It's enormously important, but there has to be a way of battling the hyperbole that has built up around genetics, and one of the concerns is, that when people hear there is information on a gene test, they may give it, I think they often do give it, unwarranted attention or emphasis.

DR. GUTMANN:

Hank?

MR. GREELY:

Yes, I would just add one other to it. It's different from medical use of probabilistic information because a lot of this information is not going

through the medical system. It's being purchased directly from 23andMe or Navigenics or a host of other direct to consumer companies.

I agree with Ellen, that that cat is out of the bag and it can't be put back in, but that doesn't mean that there may not be some useful things to say about making sure that in addition to non-medical analysis and information, everyone gets medical analysis and information, as well.

So, part of the difference is, it's not all going through the medical system.

DR. GUTMANN:

Adina?

DR. ROSKIES:

One of the differences with neuroimaging is that first of all, most of the studies are done on undergraduates, maybe 10 or 12 of them, and that's your baseline population.

We don't go scanning, and I think this is actually an issue, we don't scan the population at large. We don't have a good sense of what the baselines really are.

If we see, for instance, if we scan, let's say criminals, if we scan prison populations and we see a certain pattern, it's very hard to know what that means, without knowing how often that pattern appears in the normal population, whether it appears in the normal population, but we have no means right now, for finding that out. So, it's hard to know what to make of that kind of data.

DR. WAGNER:

But isn't that one of the — excuse me, if I could just follow up.

DR. GUTMANN:

Please.

DR. WAGNER:

Isn't that one of the things that is potentially special about genomic data, the large volume of it and the possibility that enormous populations could be providing those data for us?

DR. ROSKIES:

Of genomic data.

DR. WAGNER:

Yes, did I say — I meant —

DR. GUTMANN:
You said genomic —

DR. ROSKIES:
I was talking about neuroimaging.

DR. WAGNER:
Genomic, yes.

DR. ROSKIES:
And I think there is a real difference in the —

DR. WAGNER:
Well, no, no, I'm saying, isn't that one of the differences, if we — if the neuroimaging is looking at a prison population, or if it's looking at undergraduate population, all by the consent, presumably, of those individuals, isn't that one of the significant distinctions that might actually make — you know, going back to Erik, your point, I'm not sure I would agree to say there is nothing special about genomic data, if for no other reason, then there is just so bloody much of it, it could be dumping down on us here in the next decade.

DR. GUTMANN:
Dan has a question.

DR. SULMASY:
Yes, everybody was, I think, very polite, in looking for cross-cutting issues, when you put them out on the table, and Amy may kill me for giving you a second chance to sort of think about something.

But one way to —

DR. GUTMANN:
I wouldn't kill you, because that's wrong, Dan.

DR. SULMASY:
One way to think about the — doing the work would be that it would be more profitable to concentrate on a specific issue in neuroimaging, or a specific issue in genetics, and then, see what issues emerge from that.

So, I was wondering if people had ideas that would lead us more in that direction. We could do, you know, maybe one or two in sequence, that way.

DR. GUTMANN:
So, what Dan is — here, yes, let's — no, I'm going to let you respond, but I just — I just want to say, just to follow up on both Dan and Jim, we

could look at what are the ethical implications and implications for social responsibility, of the vast amount of genetic data that is inevitably — we don't know how much, but is inevitably not only going to be out there, but it's already out there, and how should we, in a socially responsible way, use it?

That's just one example, as the paradigm of taking a phenomena that's out there and that's worrying a lot of people, and then drilling down to all of the issues, the major issues, not all of them, the major issues that it raises and picking the ones that haven't yet been resolved.

DR. EVANS:

I think I am responding to your query. I actually completely agree that you should pick very specific things. I actually think it is probably too grandiose, to try to come up with things that are necessarily cross-cutting and synthesize the two fields.

I think it's more probably a matter of really convenience to have neuroimaging and genetics on the same day. There is no incredible synergy there, yet. There may be, some day.

The other thing, in follow up, to the last point, I just would make is, while yes, we are going to have lots more genetic information, I do not think you should necessarily succumb to the idea that everybody is going to be out there getting their genetic analysis.

The data that exists so far, would suggest the contrary. People seem to be smarter than we sometimes give them credit for, and we are not seeing — I mean, one of the three big companies went bankrupt. We're not seeing an embrace by the public, of this, and I think it's because the public, in general, sees that this is information of little benefit.

Likewise, in medicine, doctors embrace things typically, usually late, but typically, when something shows that they can help their patient with it, right?

There is a big push to push a lot of genetics into medicine. I don't think it's going to be the avalanche many people think.

DR. GUTMANN:

What issues are here, now? So, we spent a lot of time predicting. There is a theme about predicting, not only of behavior, but of what the sciences will be in the future, and we already dealt with a science and technology in its infancy, synthetic biology, and a lot of the talk there is, what will become?

So, let's step back from that a moment, because we don't live now, in the ideal world, otherwise, we wouldn't be — have been charged by President Obama.

What are the — of the issues you put out, and other issues, again, what issues are here today, that really need to be dealt with, and one of them, Stephen, how the new neurogenetics will undermine, could be changed to is undermine — is it undermining, the image of the human being?

But what other issues right now, are before us, that have not been clearly answered? Yes, Adina?

DR. ROSKIES:

Well, one thing that nobody really spoke about today, that I think is a major issue are the interventional techniques, like deep brain stimulation, or just psycho-pharmacology, ways that we can intervene to change people — people's brains, maybe for treatment, maybe for enhancement, under what conditions can they be used and what are the risks, because some of the risks are things like altering personalities and to — you know, how do we value those kinds of tradeoffs, and I think we don't have a good framework for thinking about those things.

DR. GUTMANN:

Judy?

DR. ILLES:

Thank you. I think the science of science communication is something that perhaps, Adina touched on in her remarks, but we're probably among the most neuro-modest group that you could have convened, and we make a concerted effort to communicate with the public, individually, through the media and so forth.

But there is a lot of work to be done there, and I think science communication and how we increase public literacy about the science, neuroscience in genetics is something that would benefit everyone, all stakeholders.

DR. GUTMANN:

Ellen?

DR. CLAYTON:

I think one issue that is already here is the issue of multiplex technologies and genetics.

It has driven newborn screening. It is already going on at Vanderbilt, where we do pharmacogenomic testing in practice, and it is certainly a

major issue in the work that Susan has led, in regard to incidental findings in genetics research.

So, I think the idea of multiplex technologies is — that's not a future issue. That's a now issue.

DR. GUTMANN:

So, can you say something more about the ethical issues that that raises for you?

DR. CLAYTON:

The ethical issue that that raised in the context of newborn screening was, is it possible to use tandem mass spectrometry and to identify just the particular disorders that you know need treatment, or do you have to identify everything that's potentially detectable?

The fact of the matter is, we ended up with the latter, or very close to the latter.

Where we are, with regard to multiplex testing for pharmacogenomics, is that we currently use the same platform to test people to see whether they need a different dose of clopidogrel, whether they need a different dose of warfarin, what do we do about — do we just access that information when we need it, or do we tell them at the front end that, "Oh, by the way, not only do you need to use prasugrel rather than clopidogrel, but just by the way, if you ever need to be warfarin, you better take a boat load of it, because you don't respond to it very well."

I mean, these are issues that —

DR. GUTMANN:

And I assume, you talk to your patients more slowly, so they can absorb this.

DR. CLAYTON:

Well, it —

DR. GUTMANN:

But I appreciate it, that you're doing that.

DR. CLAYTON:

So, I'm just —

DR. GUTMANN:

It does give you a sense of the challenge.

DR. CLAYTON:

No, I mean, but the point is, this is now. This is now, in the work that Susan is talking about, and it's now, in the emerged consortium, where I'd share the ethics working group of that, where we, in fact, do detect sex chromosome anomalies and the GWAS studies and are trying to figure out what to do with it, and decide whether Ullrich-turner and Klinefelter's need to be returned. These are today's problems.

DR. GUTMANN:

Is too much knowledge a bad thing, or when is it a bad thing? It's — Hank, yes?

MR. GREELY:

Building on that, Ellen, the classic, the great genomic multiplex technology is whole genome sequencing, because that gives you the entire sequence and although I agree with Jim, that there are reasons to be skeptical about an immediate mass outbreak of it, clinical whole genome sequencing is going on, all over the country, right now. Medical centers are doing it, both in very unusual cases, in the rare public health cases, in cases of rich people who just want to get themselves sequenced. That happened to three people in Saratoga, California.

It's happening. Nobody is paying enough attention, I think, to how we'll deal with these issues.

So, I would build — the multiplexing idea is the right one, I think, and whole genome sequencing is the ultimate genomic multiplexing, not ultimate, but for now.

DR. GUTMANN:

Martha?

DR. FARAH:

Just to put out a specific example, that I think might be kind of instructive in a more general way, but it is specific, that is brain based lie detection.

So, in the laboratory, fMRI can achieve, you know, depending on the task, and whose lab, you know, something like 90 percent correct judgments of, you know, when you're lying and when you're telling the truth.

On the strength of that, at least two companies are offering their services, commercially. We think of it in the legal context, and certainly, it has a role there, you know, but there is lots of people who, you know, settled relationship issues, you know, "Honey, I really was just working late at the office. I'll go get scanned and, you know, show you."

The sites certainly say —

DR. GUTMANN:

That doesn't suggest a marriage in good shape, to me.

DR. FARAH:

That is why it is so profitable, because there's a lot of marriage problems, and you know, relationship problems, screening, security, the intelligence community, certainly has, you know, I understand from researchers supported some of this research.

The whole horrible history of the polygraph is instructed here.

DR. GUTMANN:

Can I just ask you a simple factual question?

DR. FARAH:

Yes.

DR. GUTMANN:

You've pushed out the number 90 percent accuracy. What is the percentage of accuracy of the best lie detector test, which do not — you know, do not use neuroimaging?

DR. FARAH:

Let me be a little vague about this, because I don't — I haven't — I don't have the numbers.

DR. GUTMANN:

Because that is very relevant.

DR. FARAH:

Yes, but it all depends —

DR. GUTMANN:

Very relevant.

DR. FARAH:

In general, there are certainly some experts in the field who say fMRI does a better job than the polygraph.

The polygraph is — involves a lot of expertise on the part of the person conducting it. There is also a lot of disagreement about, you know, what the sort of gold standard trials are.

In general, it's — when looked at by, for example, the National Research Council, they published a report a few years ago on the polygraph and lie detection, National Academy of Sciences. They concluded that the accuracy was poor.

So, in —

DR. GUTMANN:

But 90 percent accuracy would not be good for criminal justice, because one out of 10 innocent people would be convicted or one out of 10 guilty people would be seen as innocent, either way. So, I just wonder if, you know, lie detections hasn't been out there. This is important because —

DR. FARAH:

Absolutely.

DR. GUTMANN:

— trying to get facts. Lie detection tests have been out there for decades, now, so, it's no wonder that people have looked at them really carefully and seen what their limitations are.

DR. FARAH:

Absolutely, well, listen, I am not —

DR. GUTMANN:

This is not — and I'm not making any medical — just, let's be clear, this has nothing to do with meta-physics. It just has to do —

DR. FARAH:

No, no, no, this is not meta-physics.

Well, first of all, you know, yes, 90 percent is not exactly, you know, perfect. On the other hand, it may be better than a lot of the other ways we currently use to decide on the truthfulness of testimony, and that's been argued by like, Fred Shower and others.

DR. GUTMANN:

Okay.

DR. FARAH:

But the point is, that 90 percent comes from laboratory studies where people, you know, enact a little, pretend theft and answer questions.

We know very — we know almost nothing about the validity of this in the real world.

DR. GUTMANN:

Okay, okay.

DR. FARAH:

And yet, it's being introduced into — it's being attempted to be introduced into Court, in India —

DR. GUTMANN:

Okay.

DR. FARAH:

— on EEG based system of lie detection, is actually routinely used in homicide cases.

DR. GUTMANN:

That is very, very helpful. Thank you. That's really helpful. Yes, Susan?

MS. WOLF:

So, you had asked what's already upon us, two things. First of all, the return of results, incidental findings is already upon us. The imaging people are actually ahead of the genetics people, because UBOs and — they've had to be.

And so, in CT colonography and neuroscience, there are actually scales that are already out there, that people use to grade incidental findings.

There are, even in the world of genetics and genomic research, the researchers are already doing this. They are already — some of them, including intramurally, at NIH, are trying out return of results.

So, it's already with us. Researchers already are sitting on these things. That's one of them.

I just wanted to cross the fence for a second, to talk about neuro, because I, like several people around this table, have been involved in the MacArthur project on law and neuroscience, and one thing that I did with some colleagues is, search for reported neuroscience cases, reported, meaning in Westlaw, that make cases — criminal law decisions, that make reference to neuroscience.

It could be evidence. It could be testimony. It could be argument, looking over a 15 year span, and finding over 580 of them.

I think Nita has been doing this study, as well, looking, trying to harvest cases that already are in some way, playing with neuroscience. I think neuroscience truth detection is a whole different kettle of fish. There were two very highly reported cases this summer, where Judges rejected

the admissibility of MRI for truth detection, or lie detection. That hasn't really gone into the American courts, yet.

But in terms of other kinds of neuroscience, including just arguments in mitigation, in the sentencing phase, don't kill me in a capital case, or don't lock me away forever and throw away the key, because of all of these neuro-related problems I've got. That's with us.

DR. GUTMANN:

Bruce?

DR. ROSEN:

I'm not sure whether this is a new problem. I suspect, in fact, I know it isn't, but I think on its scale, it's going to be new, and that is, you know, the high predictability of diseases with either no treatments or even worse, very expensive and not very effective treatments.

Obviously, the one that is right upon us now is AD, but I think we're going to see that increasingly for a whole range of other behavioral diseases, where we'll be able to diagnose them with increasing accuracy, but where our treatments really are falling behind and what we do with that information and how we deal with it —

DR. GUTMANN:

Yes.

DR. ROSEN:

I mean, we've had to deal with it, with HD, right? We can make the diagnosis. We can't treat it, but not on the scale that we've had to, say, with AD.

DR. GUTMANN:

Yes, and Judy, and then Anita has a question.

DR. ILLES:

I think there is a real opportunity, in the here and now, to effect a change on technology that is developed in the laboratory and that is being hijacked and leapfrogging the clinical — the bedside application into the open market place, and whether it's in genetic testing, whether it's in a neuroimaging for non-clinical applications, it's a wild west, and we know that the direct to consumer market place is vibrant. It preys on vulnerable people, whether they're vulnerable people at risk or the curious, or the elderly, and there is a real opportunity to have an impact on either a regulatory or guideline way, in terms of moving technology safety into the self-help open market place, where those regulations or guidelines do not currently exist.

DR. GUTMANN:

Okay, thank you. Nita?

DR. FARAHANY:

Thank you. I wanted to return to Dan's question, for a minute, about thinking about the cross-cutting versus the individual technology, since we're talking now, kind of an individual technologies.

A number of you mentioned that one possibility that you would suggest that we look at is collection and use of information, whether it's genetic or neurological, and I heard a few different issues, whether it's access by individuals and individual autonomy over information, consent to the use of data, how to manage incidental findings, how to address probabilistic information, the concepts about neuro-essentialism and genetic-essentialisms, and definitions of self, public education, all which are cross-cutting across this dimension, which is data collection issues.

And so, we got one answer to Dan's question about whether or not you think it makes sense to look at kind of broadly, genomic information and thinking about the implications that could arise and many different uses of that technology, or neuro-technologies, which I agree with you, Susan, are you know, prevalent in criminal cases and are prevalent in investigative techniques and Judy, to your point, are now being hijacked, whether it's through open EEG or direct to consumer genetic testing.

So, I was hoping a few more people could weigh in on your what — both, what you proposed and whether or not you think actually, the issues that I've identified here, these cross-cutting issues are the ones you would really align with, or not?

DR. GUTMANN:

I am going to go to the audience, for anybody who wants to ask a question, or make an observation, an answer to anything that's been said.

So, you can raise — just raise your hand. We have roving microphones.

MR. GREELY:

Can I respond to Nita?

DR. GUTMANN:

Yes, you may.

MR. GREELY:

Okay, I think the — all the ones you listed, I think, are useful. I would add, on the collection of data, the idea of dealing with non-medical and some times, surreptitious collection of data, that's particularly significant

right now, with respect to DNA, when I could get the DNA of everybody at this table, off the table, and do with it, in most states, pretty much what I would, other than deny you life — health insurance, on the basis of it.

In the long run, maybe brain data. I don't think there is much of that now, but I think that — so, it's kind of the forensics, but a little broader than just criminal, official prosecutorial investigative process, other non-medical uses of this collected data, I think would be a very useful thing for you to look at.

DR. GUTMANN:

Thank you. Yes?

MR. SCHATZ:

Good afternoon. My name is Gerald Schatz. I'm a Vice President of CRCR, the Citizens for Responsible Care and Research, a non-profit organization, and I taught university law and ethics of human subjects research.

I think the Commission will find it very helpful, as it goes about this task, to take a look at the current state of aggregation of medical record systems, and the state and capabilities of the data mining industry, which is something we have with us now.

DR. GUTMANN:

Thank you. Does anyone want to respond to that? I think that's consistent with a number of what — what a number of the presenters have suggested, as well.

Any other — we have time, so, I really want to make sure that anybody who wants to ask a question or make a brief comment, hasn't done so, is able to do so, now. Yes?

PARTICIPANT:

There are probably at least, thousands of — Rose, Madison, Wisconsin. There are probably at least thousands of military reports, scientific articles, patents, that support what a couple of people have brought up here today. We will be talking about that tomorrow.

Secondly, the topic of the throat chip, people had said it was mostly just a translation device, but if it was paired with imaging technologies and used in maybe a large sample, a large number and — of the population, then for example, you can see what the image looks like, when people are talking — I mean, thinking, something in their mind.

You can — over time, develop better and better idea, which I think can lead to possible — well, I know it can, but anyway, possible manipulation behavior, biomimicry, possible predictive value.

And then the third thing I wanted to say is that the term coined neuro-arrogance is a little bit offensive to me. It's a little bit slightly Orwellian and I think it tries to discredit people who are sincerely trying to talk about the fact that there are lot of physical things that can influence our biology.

So, that term, it set up a flag, right away, and I think your talk a little bit earlier about mind control was a possible red herring you threw out there, because yes, mind control, we don't know if it's 100 percent, but there are things that can make people tired or on the other hand, make them awake, and U.S. News and World Report, for example, I think it was 2006, said there was a Department of Defense study, looking at that, and that's just one of many. So, thank you.

DR. GUTMANN:

Sure, thank you. Yes, go ahead.

MR. JAY:

Hi, I'm John Jay. I do work in bio-ethics, as a contractor at NIH.

So, I think one of the themes that's come up over the course of the day is identifying areas where genetics and neuroimaging don't raise novel, ethical or legal issues, and so, the reaction to that is, sort of, "Oh, those aren't interesting." So, maybe that's not something the Commission should deal with, and we're all concerned about genetic exceptionalism and neuro-silliness, right?

But I wonder if any of the speakers think there might be areas where it would be valuable — areas in their field, where it might be valuable for the President's Commission, for there to be a President's Commission report, pointing out that these areas aren't as unique as maybe some members of the public or policy makers might tend to think.

DR. GUTMANN:

Okay, yes, so, let's turn it on its head, the question on its head, which you've done, that is, I'm just going to repeat your question.

Are there areas where there are lots of — there is a sensibility out there, and lots of claims out there, that genomics and genetic engineering, genetic testing or neuroimaging and neuro-testing are very different and we need to look and say something about why that isn't the case.

Isn't that —

PARTICIPANT:

Don't pose unique, don't pose new ethical or legal issues.

DR. GUTMANN:

And presumably say what the ethical, legal and other policy issues, that they raise are, and how — what the current understandings of those are.

DR. CLAYTON:

I would endorse that. I actually wanted to respond to Nita's question, if it would be okay.

DR. GUTMANN:

Sure.

DR. CLAYTON:

I think, actually, listening to a variety of the comments, I see two things going on here.

One is a question about the extent to which the individual can control how information about him or her is used.

So, the primary locus of decision making there is in the individual.

I think that there is another question that can be raised, which is that even if the individual may not entirely be able to control how — may not be able to exercise independent control, that there may nonetheless be externally imposed controls about how particular information is used by others.

And so, I'm actually, just sort of, trying to think about — through this on my feet, but say, for example, anybody can look at me and know that I am female, and I can't control whether anybody knows that or not.

But society has made a decision that is different from the one when I was a child, that says that I should have very much greater opportunities in the workplace than I used to, and when I was born in 1952.

And so, I think that there are — so, the question that I am thinking about, in response to Nita's question is, is it all about what people do with their own information, what information they get, what information they give out? This also goes to Hank, with this question that he raised, about re-thinking what the research enterprise looks like, or is — or is there another question that says, yes, there is some element of control.

But another thing that we can control is used by third parties.

DR. GUTMANN:

Yes.

DR. CLAYTON:

And I think that those — I would ask the Commission — I think that's what I heard Nita to say, and I think that would be a really fruitful way — it might be a fruitful way. Maybe I'm wrong. Maybe the whole thing is just individual control, but —

DR. GUTMANN:

No, no, it's definitely not all individual control. There is definitely a question of third party control. The only question there is, that is a huge, you know, that is a huge area —

DR. CLAYTON:

Almost like —

DR. GUTMANN:

Every piece of information, almost every piece of information about ourselves, lends itself to the question of how much do we control it and how much can third parties control it?

So, I mean, it's a very — and it's a very important issue. Anita Allen has written a lot on privacy, as have other members of the Commission. So —

DR. CLAYTON:

So, I want to follow that up. I've done a lot of work about people's interest or willingness to participate in genetics research, and there are some populations, some segments of the population who their first reaction is forensic DNA. There are other segments of the population, for whom that's not the issue.

DR. GUTMANN:

Right, right.

DR. CLAYTON:

And so, you know, so, I think that these — you know, so, I think the question that Jim raised, about what we ought to do about forensic DNA is a really important one, and it makes a huge difference in what people think about this research or not.

DR. GUTMANN:

Right, good. Stephen?

DR. MORSE:

Yes, I want to return to the problem of old and new problems, because I think it's a very important one.

As I've been listening to this discussion, from my point of view, virtually none of the issues that have been raised has really been a new issue, new applications, but not really a new issue, and forgive me for harping on a familiar theme, already, but what our present state of bio-ethics presupposes is the picture of the human being that we all take for granted.

But if we get — we move to a mechanistic picture of the human being, then there really — all bets are off and then, ethics will be turned on its head, and that is a problem for the future.

DR. GUTMANN:

although, let me just understand you now, because I heard you say two different things, one, in your talk, and one, just now.

You said in your talk that even if you hold a mechanistic view of the human being, that doesn't dislodge views of freedom and responsibility.

DR. MORSE:

Yes, yes.

DR. GUTMANN:

And you just now said, having a mechanistic view will —

DR. MORSE:

A purely mechanistic view, that leaves out agency.

DR. GUTMANN:

Okay.

DR. MORSE:

That's all. If we move to the victims of neuronal circumstances, then — and somehow, we could cash that out, that is what the science did all convince us, was true, then, I think ethics is turned on its head, and that would be a very different ethical universe, indeed.

DR. GUTMANN:

Okay.

DR. WAGNER:

Stephen, let me follow up your premise that you really haven't seen any new ethical issues arising, doesn't leave us much of a mandate.

DR. MORSE:

No, that's fine, no, it really does.

DR. WAGNER:

But it's —

DR. MORSE:

It leaves you with huge mandate, because these are new applications.

DR. WAGNER:

Well, that's part of what I was getting at, are there not new aspects of that?

DR. MORSE:

Yes, absolutely.

DR. GUTMANN:

So, let me just full circle, here. It would be hubris, on our part, to think that there are new — and on anyone's part, and I mean ours, as the Commission, the scientists, doctors and so on, to think that here is a new application that's come up, a new technology, and of course, there are going to be totally new ethical issues after millennial, you know, millennia of dealing with ethics and new technologies and science.

I think it is not modesty, it's just, you know, being aware of how many difficult ethical issues there are, how many important ones there are, whether it be, who controls information, you know, what is the ability to access care, after you have information, where the access to care will make a difference?

Those are not new ethical issues, but they are — our answers and our way of dealing with those issues are challenged when new technologies come about, and they're challenged because the understanding of new technologies is much less perfect. They are always imperfect, but it's much less perfect, because there is a lot of fear often, with new technologies, a lot of hype on the part of people who even understand them, because you get something from hype.

You sometimes get funding because of hype. You often get publicity because of hype.

So, I think it is important for us, as a Commission, to recognize that we're not going to come up with new ethical issues or principles — we're not going to invent new principles, but we are in the business of trying to advise on how problems that arise with new technologies can be responsibly and ethically dealt with, and that, I think, you've helped us to do tremendously, and with that, I think I'm going to, on all of our behalves, every member of this Commission, and everybody in the audience, and many people who couldn't be here today, thank you for a most stimulating and informative set of sessions. Thank you so much.

