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TRANSCRIPT

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Roundtable Discussion

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DR. GUTMANN: Good morning, everyone. I'm Amy Gutmann, I'm president of the University of Pennsylvania, and have the privilege of chairing the Presidential Commission for the Study of Bioethical Issues. On behalf of myself and my vice chair, our vice chair, Jim Wagner, the president of Emory University, I would like to welcome you back to the second day of our 20th meeting.

Let me begin by noting the presence of our designated federal official, Bioethics Commission Executive Director Lisa M. Lee. Lisa, welcome.

Today we are going to continue our discussion about U.S. engagement in the global response to the current Ebola epidemic, as well as finalize recommendations on neuroscience and related ethical issues.

As I explained yesterday, at the registration table and in the hands of each one of our Commission staff members we have comment cards. And staff, you want to just hold up the comment cards? There you go. Anyone who wants a comment card, please take one, write down your comment, question, and, time permitting, we will read and respond to them. If time doesn't permit -- we have a lot to get through -- we will get back to you.

So, thank you in advance for participating in our discussions.

Jim, would you like to get us started?

DR. WAGNER: Just to thank everybody for all the hard work and excitement yesterday. I hope we can bring that energy to today's conversations on neuroscience and global health ethics.

DR. GUTMANN: Good.

DR. WAGNER: And ready to go to work.

DR. GUTMANN: Okay. So, this morning we are going to wrap up our

work on neuroscience and related ethical issues.

At our last meeting, in November, we covered a lot of ground, and we settled on some very important and timely recommendations. I want to take the next 30 to 45 minutes or so to summarize where we ended up, and discuss a few recommendations that we didn't have a chance to -- we deliberated on, but we didn't have a chance to formulate. I want to discuss those more fully with our limited time.

And, keeping in mind that we've discussed these in depth already, I ask that we focus on substance, not wordsmithing. We can wordsmith these in the time we have, the short time we have, before -- between now and getting the report out. But we will do that.

So, as you recall, we decided to focus our analysis and recommendation in three areas. These areas are both important, and they raise controversies that have yet to be fully deliberated and decided upon from a perspective of how they would affect people, and they affect a lot of people.

These three areas are cognitive enhancement and other neural modifications -- we are using the term, as I will suggest later, "cognitive modification," because "enhancements" has become a loaded term. But I use it so people understand that it refers to the use of drugs and other things to boost normal -- people who are thought to have normal cognitive capacity-- to boost it even more. That's the thought. And the thought is that that's problematic, but we have -- that's what has made this very controversial, in part. We are dealing with this in a broader way.

Capacity and the consent process is the second, and neuroscience and the legal system is the third. As I say, each of these is important, and each of these is a controversial way in which neuroscience has moved into the public realm.

These three cauldrons of controversy illustrate the ethical tensions and the societal implications that can arise as neuroscience and technology advance. Our Commission is well situated to clear a path for productive discourse on these topics, and productive policy-making on these topics, clarifying the current landscape of science, identifying ways in which we can come to some agreements on how to move forward, and recommending those ethical paths forward. And ethical, I should say, and "scientifically productive paths forward.

So, let's start with cognitive enhancement, or, as we are going to call it more commonly, cognitive modification.

To begin, we agreed that it's important to broaden the conversation beyond cognitive enhancement to include a wider array of interventions, technologies, behaviors, and environmental conditions that can impact the functioning of the human brain and nervous system. That is, to broaden it to include this wider array that are pursued in order to modify the functioning of the human brain and nervous system.

Within this framing, our discussion coalesced around five modifications -- five recommendations, not modifications, recommendations.

First, we recognize that current knowledge suggests -- the best available scientific knowledge suggests that many non-novel interventions could be safer and more effective at maintaining and improving neuro-health than some novel neural modifiers.

Let me give you some examples. They include getting adequate sleep, getting adequate exercise, getting adequate nutrition, and public health interventions like lead paint abatement. We shouldn't lose sight of these, and it should be -- it's important to get those out there in -- so people know, and rely on the known ways of

modifying. Known evidence-based strategies such as these should be implemented and prioritized.

In addition to developing new drugs and devices, funders should support additional neuroscience research on these strategies, and other social, environmental, and behavioral factors that are associated with maintaining and improving neural function.

We should not be biased towards the novel, and good research should test what actually works best in improving brain function.

Second, treatments for brain disorders and injuries, and mental and behavioral health conditions are valuable, and they can be improved. Neuroscience research on interventions to treat neurological disorders should also be prioritized. And we will give examples of what we mean by this, very specific examples.

Third, funders should support research to better characterize the benefits and the risks of novel neural modifiers, including drugs and devices. Such research should consider, for instance, the prevalence in educational and professional settings of using certain drugs: the potential risks, the long-term effects, and the real-world effectiveness. Precious little is known about the prevalence of the use, the risks, and the benefits.

Fourth, when access to effective, beneficial interventions -- when that -- when we know about effective beneficial interventions, access to these should be equitable, and not compound or exacerbate existing social and economic inequalities.

Fifth, professional organizations and others should create ethical and clinical guidance about neural modifiers for stakeholders, including physicians, employers, parents, educators, and patients. For example -- important

example -- medical professional organizations can and should develop guidelines for handling requests for prescriptions to augment normal nervous system capabilities. Such guidelines should generally discourage the prescription to children of enhancement interventions that have uncertain benefits and risks.

Okay? That's -- now we're going to turn to consent capacity, a topic that raises complex ethical questions, because the capacity to consent is necessary. It's not sufficient, but it's necessary for interventions that have -- that bear risks.

So, these questions implicate, for example, issues of justice and equitable participant selection in research, and the potential for stigmatization and discrimination. We lay out three -- I consolidated this to three recommendations in this area.

First, neuroscientists often conduct research with participants whose consent capacity may be either absent, impaired, fluctuating, or otherwise in question. This occurs, in part, because many of the conditions that neuroscience research addresses can affect consent capacity. Think of Alzheimer's, dementia.

To advance research that seeks to understand and ameliorate these conditions, researchers should responsibly include affected individuals in studies with ethical safeguards in place, and they also should engage stakeholders, members of the affected community, to minimize the stigmatization and discrimination that is real and/or perceived. So that's the first.

Second, funders should support research to address gaps in our knowledge about impaired consent capacity. There are significant gaps in our knowledge. And this should include clarifying what consent capacity means, and it also should include research to better understand the background conditions that affect decision-making capacity. Evaluate current policies and practices, and develop and improve capacity

assessment tools. Researchers should publish and widely disseminate the results of such study to inform best practices.

Third, state legislatures and federal bodies should establish clear requirements for identifying legally authorized representatives for research participation. As we discussed before, federal regulations require informed consent from research participants, or legally authorized representatives, before research can proceed. An important step in conducting ethical research with individuals with impaired consent capacity is determining who can serve as such a representative. Ambiguity here is not good. It really is not workable.

So, those are the three recommendations for capacity to consent.

We also formulated four recommendations concerning neuroscience in the legal system.

First, we have recognized that members of the public, especially ones who serve on juries, would benefit immensely from educational resources that help bring high-level neuroscientific concepts into lay terDR. Individuals expected to use and interpret neuroscience, including judges and attorneys, would also benefit from greater availability of basic training that helps bridge the gap between neuroscience and the law.

Professional organizations and government bodies should continue to develop training resources and educational tools that explain the application of neuroscience to the legal system. That's recommendation number one.

Two, relevant bodies should undertake and fund comprehensive studies on the use of neuroscience and policy development and legal decision-making. In addition to educational materials, these studies could serve as a resource for judges,

policy-makers, and the public.

Third, to maximize the value that neuroscience has to offer, scientists, the media, members of the media, legal decision-makers, among others, must avoid hype. They should avoid overstating or relying too heavily on equivocal neuroscientific evidence to draw conclusions which cannot be drawn from the evidence about behavior, motivations, intentions, and legal inferences. The literature is ripe with such hype.

Fourth, neuroscientists should engage with policy development and legal decision-making processes. Academic institutions, professional organizations, and others should encourage researchers to consider the legal and policy applications of their work, and train them to engage with legal and policy processes.

Fifth, and finally, drawing from conversations that informed our report on ethics integration and neuroscience research -- that was in our *Gray Matters*, Volume I -- we have one overarching recommendation. Several of the recommendations we've discussed call for additional research on a number of critically important topics.

Such research requires adequate support. Funders associated with the brain initiative should provide financial, administrative, and infrastructure support for at least one multi-disciplinary center for neuroscience ethics in society to address the societal implications of neuroscience research findings and their applications. Such a center would bring together expertise from a diverse set of fields, which are needed, including neuroscience, ethics, and policy. And it would be well-positioned to answer open questions, consider neuroscience broader implications, and implement -- or help, I should say, help to implement policy change.

So, I suggest we open our discussion with this final recommendation for supporting at least one center that brings together expertise from the several fields that

are necessary to understand the interplay between neuroscience law, ethics, society, and public policy.

And so I open it up. And we can just say we --we are going to develop background, we discussed virtually all of these. And so I'm not requiring anybody to have extensive discussion here, but I think we ought to get -- make sure we're all on board with these before we move on. Okay?

Okay, John. Yes.

DR. ARRAS: Yeah, thank you, Amy. So one global comment here, and that is that I think that a lot of the really meaty and substantive and interesting things that are in these various sections don't really appear in these -- you know, these directives for policy.

For example, in the first cluster of issues surrounding cognitive modification, in the report itself, you know, there is some commentary on the ethics of neural or cognitive modification. There is a huge debate about that out there in the literature. A lot of people believe that this is really wrong, immoral, overstretching the bounds of human -- you know, human possibility. Others think it is natural for us to tinker with our capacities in that way.

And there is also -- I recall, you know, Anita and I went back and forth, trying to figure out the best framework for cognitive enhancement. And we struggled with this issue of, you know, exactly what goes into the framework, you know. And we debated, you know, whether we should have a division, you know, of interventions -- for example, those that would bring people up to a normal level, or keep them at the normal level, versus those interventions that would give people a slight boost in terms of what humans are able to do now, versus those that are, you know,

going to empower people to go way beyond what humans can do now.

I think we really need to spend more time on that framework, because I think that, if we leave that open, it's going to be extremely confusing to the reader. And it's very interesting and important, philosophically. So -- but I do think that someplace in here we might want to find room for a bottom-line conclusion about, you know, the substantive ethics of neural or cognitive modification, rather than simply leaving it to various professional societies to come up with guidelines on their own.

DR. GUTMANN: Do you want to comment on that?

DR. WAGNER: Yes. Just -- John, what if we step back even one step higher? Do we have a recommendation that is appropriate for us to say, based on all that we've heard, and our own backgrounds we bring to this, to have a finding that says that we assert that in these areas -- that pursuit in these areas of modification and understanding consent and legal -- that we conclude, from what we've heard, that there are ethical ways to advance, in each of these, just as an opening?

It has to be phrased well, but just as an opening recommendation that we've actually studied this, and our foundational piece is it is ethical to pursue these things, under the circumstances that are given in the guidance by our subsequent recommendations. What would you think of that?

DR. GUTMANN: Before you -- you should answer. But let me just weigh in on this, because we have deliberated about this--

DR. WAGNER: Sure.

DR. GUTMANN: -- this. And sometimes I think we ought to be, you know, a bit clearer in -- just in the spirit of what we're recommending in neuroscience and the law. We ought to be a bit clearer in expressing our conclusions.

But our conclusion and our deliberations was that there are -- just to put a -- just to pursue what Jim has said, our conclusion is there are ethical ways of pursuing the scientific knowledge of improving brain functioning.

DR. WAGNER: Improving and understanding, because --

DR. GUTMANN: Yes.

DR. WAGNER: -- that's the consent and legal -- improving --

DR. GUTMANN: Understanding for the sake of improving brain functioning. And there is -- the sub-discussion of that is that there is not a bright line between improving brain functioning that is under, you know, normal, to improving brain functioning that is normal. And we analogize this to -- and we don't -- we're not saying that every -- so, again, corollary, not every way of pursuing brain improvement is ethical. We have suggested --

DR. WAGNER: Exactly.

DR. GUTMANN: -- various, you know, caveats. But there is nothing in itself -- to put, again -- this is the converse -- there is nothing in itself wrong about pursuing knowledge to improve the functioning of the brain.

Now, there are overly-invasive ways of doing this, there are ways of -- and so on.

DR. WAGNER: Yes.

DR. GUTMANN: But that -- there was broad consensus on that. And it's helpful to look at the non-neuroscientific ways that human beings have pursued improving brain functioning: education, exercise, sleep, games, you know, things like that.

And that is not to cast any kind of, you know, aspersion on previous

debates on this, but it's really to say that we do not want, as a Commission, to draw a bright line between improving brain functioning of people who are clearly unable to function in the world in a way that's been the norm, such as people who are suffering from dementia, and improving brain functioning, as in people who function well, but want to have -- you know, want to do even better.

DR. ARRAS: Right, right. Well, thanks. Yeah, yeah.

DR. GUTMANN: And there are all kinds of distributive justice issues about that, but that does not and should not prevent science from exploring these other ways. And there are all kinds of issues of how we want to prioritize funding of this. But that, again -- that's a different issue. Yes.

DR. SULMASY: I'm not sure we had full consensus on that. Again, I have stated at a previous meeting, would state again, that, you know, the sort of argument that the fact of twilight does not mean there is no difference between night and day, and that our failure to draw the line does not imply that there aren't some judgments that can't be made about things that are actually wrong.

And I wouldn't want us -- because the implication of the sort of way it's phrased is such that it would allow almost anything to be done. And I think we've got to be very clear, if we're going to say we have a consensus, that there are ways of pursuing this that are, in fact -- can be judged to be morally wrong, and that if we have an overarching statement, it ought to also say that, while saying that, you know, we might not be able to draw that line with any perfect clarity. I would be happy with that.

DR. GUTMANN: That's fair. That's -- I think that's the intent, and we should make sure it's stated that way.

Nita Farahany is on the line. We congratulated Nita yesterday for

bringing Ella into the world. But now, Nita, would you like to say something on a recommendation or two?

DR. FARAHANY: Yes, thank you. I'm sorry I can't be there with all of you, but I've been enjoying participating by watching.

I wanted to weigh in, first on this conversation, the cognitive enhancement one, to say -- or cognitive modification -- one, to say that I wholeheartedly agree with the approach that we're taking, which is recognizing that the position that we're in in providing recommendations, I think, shouldn't be to resolve the debates about what the substantive ethics of cognitive modification are.

Rather, I think recognizing that this is a rapidly evolving issue, that there are many different stakeholders and different ways in which cognitive modification may evolve, and recognizing the role that various stakeholders can play in developing ethical guidelines and going forward, I think, is the right guidance and approach.

I also agree that there are ethical ways to do this, and that it's important for us to recognize that in the report, as well. So, to the extent that we are weighing in on the substantive ethics of cognitive modification, it's to say that we don't think that there is any reason to have an outright ban on it, and to also understand that this is part of a continuum, that everything we do is, in some form, and in some way, a cognitive modification.

And then I just wanted to underscore how valuable I think it is to frame this as cognitive modification, instead of cognitive enhancement. And I wouldn't even necessarily use the word "improving," because, you know, things like memory alterations that are coming online now, the ability to extinguish certain memories for conditions like post-traumatic stress disorder, it's unclear whether one would call that an

improvement, if you're eliminating or extinguishing certain memories. It certainly improves the life of an individual, while it changes and might, in some ways, diminish the brain.

So, I think embracing the term "cognitive modification" advances the conversation and the debate in a meaningful way in this area.

DR. GUTMANN: Yeah. And we need to acknowledge that the term "cognitive enhancement" is out there, and say why we believe it is a better -- more accurate to capture neuroscience, the intent and direction of neuroscience research, the better term is "cognitive modification."

DR. FARAHANY: I agree. And just including, I think, within that the idea that brain changes can happen in both directions. And you know, that this term broadens that debate and conversation.

DR. GUTMANN: Yeah, yeah. Good. Raju?

DR. KUCHERLAPATI: Just a -- to maybe respond to John's comment.

John, I think you're coming from one end of the spectrum of healthy people and how you might be able to alter, you know, their cognitive abilities. But we could also come from the other end of the spectrum, of people who are ill, such as, you know, dementia, or Alzheimer's, or something. And certainly, you know, in those instances, for those people suffering from those types of disorders, one would really, truly consider that anything that we could do to help them would be desirable.

So, if you come from both instances, whether -- the first examples are the kinds that you talked about, whether you want to make individual superhuman by enhancing their abilities, whether -- that could be debated. But the other end, I don't think that there would be much debate about that.

So we need to make that clear distinction, and say that we are not painting one broad brush across all of them, and that there are clearly areas where this is highly desirable to do.

DR. ARRAS: I agree with that completely, yes.

DR. GUTMANN: That said, there is -- I think it's worth adding there is greater urgency to help people who are not able to function well in society through this research, and it's not a coincidence that that's what President Obama emphasized in kicking off the brain initiative.

It's also worth emphasizing, as we do in the recommendations on consent capacity, that not everything you can do to a person who is under -- in a diseased state is ethical. So, we -- you know, we -- there are ethical guidelines, both for cognitive modifications for people who are suffering diseases, and cognitive modifications for people who want to improve their brain functioning.

The -- it -- there are, you know, issues in both -- ethical issues in both cases. So Dan was emphasizing -- I agree, I've used the same gray area-- just because there is dusk and dawn, doesn't mean there is night and day. There are things that --

DR. SULMASY: Actually, Samuel Johnson, if you want to attribute it.

(Laughter.)

DR. GUTMANN: There we go. Right. It's Samuel Johnson was a wise -- had wise little phrases.

The -- we -- but we did agree. I think it's important that we did agree that it is not, per se, unethical to pursue research that would improve -- has the potential for improving brain functioning.

DR. ARRAS: Yeah, right. And I guess -- although I think the most

interesting parts of all these different chapters are in the guts of the chapters, rather than the recommendations.

I do agree with Jim's suggestion there, just to say that we -- you know, up front, that we have agreed, we have a consensus that this kind of research is ethical to pursue because, you know, I mean, we don't want to get involved in a big dispute with the prior commission. I appreciate that. But people will read this with that commission's very negative judgment about enhancement technologies in mind. So I think that we owe it to our readership, we owe it to ourselves, to be clear on those points of disagreement with that prior commission.

DR. GUTMANN: While I attempted to focus us on one recommendation, I failed in that, and I am happy to have failed, because this was a very good discussion.

(Laughter.)

DR. GUTMANN: So I should just say that all the recommendations are open. And if I don't hear any -- we've done -- we've deliberated about all of them, so I will assume what -- that our previous deliberations stand, and we -- but if there is any that you want to enhance, because -- cognitively enhance --

(Laughter.)

DR. ARRAS: Nicely done.

DR. GUTMANN: -- or modify --

DR. ARRAS: Tweak, yeah.

DR. GUTMANN: And I see Steve, and then Jim.

DR. ARRAS: Sure.

DR. HAUSER: Thank you. Well, I think, especially given John's comments, but our deliberations earlier, when we -- if we say in the report that using

science to modify brain and nervous system function is, on its own, not ethically problematic, that is a big deal. And that could be a --

DR. WAGNER: Under -- yeah, subject to the comments --

DR. HAUSER: Yes. And, because of that, I agree with John and I agree with Dan, that we need to be -- maybe we need to be more active and explicit in the way that we say this, and we need -- although, in our prior discussions, Raju challenged us to, I think, find the line beyond which one couldn't go, and maybe there isn't a line. But I do think we need to have the caveat that you raised.

DR. GUTMANN: Yeah, absolutely. I mean I feel as strongly -- and I think it's as intellectually and ethically necessary to say both things. One is that what we've focused on, the other -- that Dan said, that does not mean that every form of cognitive modification is ethical. There are, you know --

DR. WAGNER: Or every circumstance. It's not just form.

DR. GUTMANN: Or every circumstance. And we put out guidelines that have some relevance here.

DR. SULMASY: Perhaps to help me, I could have some idea of -- from other members of the Commission, what you mean, even by -- you know, point to examples of what you think might be within the bounds of good and what might not be, because that would help me to know whether or not I can actually, you know, sign on to this. Because there is -- to some extent, this is different than what's been said, and I'm not totally comfortable with it. Perhaps --

DR. GUTMANN: Okay, I --

DR. SULMASY: -- pursuing some of the research -- I mean, obviously, in my view, again, there is a difference between drinking a cup of coffee and putting a

brain chip in somebody -- you know, a computer chip in somebody's brain in order to make them, you know, function better than other people.

And if we don't think there is a difference between those two -- and I certainly think, you know, specifying how we would do that is going to be complicated, and, you know, I think we probably would suggest that others have failed in it, and we're not going to, as a commission, draw that line --

DR. GUTMANN: Yeah, I'll give you --

DR. SULMASY: But tell me what you think would be, you know, within the bounds of good, and maybe --

DR. GUTMANN: I will give you an example or two which are not in the realm of science fiction.

Since we are talking about research on the brain, not just invasive technologies, but research on the brain, it is within the realm of possibility that scientists who do research on the functioning of the brain from very young age will find out that diets that contain heavy amounts of fish oil and other -- increase brain functioning above what's now normal. And, if we introduced more of those elements into the diet from an early age, we would, as a species, on average, function more. It would raise issues about the distribution of that diet, but I see nothing that would be -- I see a lot that would be good with that research, and nothing that would -- no, you know, moral boundary that that would -- similarly, neuroscientists may find out that exercising the brain in various ways increases the connections between neurons early on, and that increases over time.

This is directly analogous to seeing how generations have gotten taller over time because of diet, and things like that, and the norm has changed. I think those

are excellent examples of things that are often not thought about. People think about putting a chip in the brain, rather than the other -- so I think you would agree--

DR. SULMASY: So it may be helpful, then, if we're going to do this, to sort of suggest that these are the examples of the kinds of things that we think would be within the bounds, and that there are others that may be beyond it.

And so, what I don't want to see us, you know, suggesting is that, you know, if people want to be able to take, you know, a drug to sort of enhance their capacity, that we think that that's perfectly okay for all humans who engage in (sic), and I think that we've got to be clearer about that if we're going to make this kind of a statement, from my view, and if you want to have full consensus. So --

DR. WAGNER: Dan, I had, actually, something a little different in mind, going back to the scope of our purpose, which is to advise the brain -- B-R-A-I-N... -- and, really, the thing I had in mind was more focusing on how we advise that mission, okay? And let me -- well, let me just blurt out, and then we can beat it up.

It seems to me that there has been consensus, that there really is nothing inherently, as Amy said, unethical about pursuing research that helps us understand brain modification, understand what it means to have competency for consent, understand the potential roles in the legal system. I would suggest, as a Commission, we should stay away from specific practices, but rather, advising about the ethics of understanding these, and giving guidelines that might help folks interpret practices.

But it would be impossible, it seems -- you know, we keep saying a chip or a drug. For all I know, as we develop the precision with which we can do transcranial magnetic stimulation, there are things I could do against your will. But I

don't think we've said anywhere -- and I think we should, and, in some ways, this is in counter to our colleagues around the globe that are more precautionary in their principles -- but I think we should say that -- if we believe it, and can say it with consensus -- that we don't find anything ethically inherently wrong with understanding all of that at the deepest levels possible.

DR. GUTMANN: I think we are repeating -- I think we have agreed on that, and I think we have agreed on examples of what would be ethical. And I think we have also agreed that we are open to the idea that not -- I mean we agree that not everything would be ethical in this realm. I don't want to give science fiction-y examples, myself, and I think you -- so I think we have consensus on that.

There may be examples that come down the road that we wouldn't -- that would be very controversial, and we wouldn't agree on. But they're not here for us to decide on at this point. And I think what we've just said, and what we've deliberated in the past, would be very helpful to say. Partly it would be -- and let me just put a -- I think it would be helpful to say, in no small part because we would be practicing what we're preaching against: hype.

DR. SULMASY: So, if I'm hearing this, then, it's limited to a recommendation that we would support research, which would be directed towards understanding how to improve the capacity of human brain function beyond its current range of normality, recognizing that not everything will be, in fact, morally permissible, that there will be some things that could be, in fact, judged to be wrong.

But some examples of the kinds of things that we would consider to be morally permissible might include early dietary manipulations of young children, or various kinds of cognitive stimulation that might enhance the general capacity of human

beings, if, in fact, equitably applied to all developing young human beings. I mean that's the kind of thing that I think I would be able to say I could agree with.

But I'm not sure how far beyond that. And if you want consensus, that's as far as I probably am willing to go, so --

DR. GUTMANN: That seems -- I don't think we have gone any further than that in our deliberations. And, again, subject to saying it in a very clear, clear way.

Others -- Steve?

DR. HAUSER: Although we agreed that we would title this area "Cognitive Enhancement," we have peppered, I think, our discussion with other areas of enhancement. So I think, when we write the report, if whenever appropriate we can use "neuro-enhancement" --

DR. GUTMANN: Yeah.

DR. HAUSER: -- including "cognitive enhancement," that would be useful. Many of the near-term drug -- and, I think, game and teaching opportunities to modify function have focused on, broadly, frailty. And we probably -- we may well see muscle, you know, or balance -- things quite early.

DR. GUTMANN: Yeah, agreed. Agreed.

Nita, would you like to comment on law and legal recs?

DR. FARAHANY: I would, but I want to add just one comment here on the cognitive enhancement, which is two different issues that I hear.

One is I'm not sure that the method of modification is something that I would want us to cite as potentially problematic, because some of the things that Dan says, like taking a pill or brain implants, to me, it isn't so much about the method as potentially the context in which the enhancement occurs.

DR. GUTMANN: Yeah.

DR. FARAHAANY: So just, like in sports, we might decide that certain types of modification are impermissible, in other --

DR. GUTMANN: We are agreeing with you, Nita.

DR. FARAHAANY: Great, great.

DR. GUTMANN: I mean we did not mean -- in giving those examples, we did not mean to suggest that it's the method.

DR. FARAHAANY: Great.

DR. GUTMANN: Yes. Go ahead.

DR. FARAHAANY: And the second is Dan also said that there will be some things that will be judged to be wrong. I wouldn't be comfortable with us going that strongly. I think it is possible that there are certain contexts in which modification -- we could set the rules to say it would be impermissible. But, as a per se matter, I don't think I would feel comfortable saying that there are things that we will judge to be ethically impermissible for cognitive or neuromodifications.

DR. GUTMANN: Let's just stop there. I think that's correct, as well, because we don't know. And so we will -- that's why I said subject to wording this in a way that captures the intent here. Okay?

DR. FARAHAANY: Great. I wanted to comment on what you had opened with, which is the multi-center approach to setting something up. I agree with that, that there should be something -- the way that we've stated it right now doesn't recognize or identify at kind of what level we think that should be. And one conversation that we've had in the past, and that we've had a number of speakers come in to speak with us about is some of the successes or limitations of the NHGRI approach, the ELSI approach --

DR. GUTMANN: ELSI.

DR. FARAHANY: Yes. And I think it would be useful for us to have some perspective on what it is we're calling for. Are we calling for something that is private institutions? Are we calling for something that is more like the ELSI setup?

And what might some of the concerns or limitations or differences be in how we think that should be set up here, to be more successful in this context, and to address some of the previous concerns that arose from the ELSI setup?

DR. GUTMANN: Yeah. And we heard, not surprisingly, conflicting views. We had people who were extremely enthusiastic about replicating ELSI, and people who were equally critical about it. And the question I have for the Commission members is, do we want -- we have agreement that it's a good thing to fund centers that bring together neuroscientists, experts in ethics, experts in law, experts in other relevant areas. Do we agree that what we want to recommend is multiple -- do we want to recommend -- let me read what the recommendation -- as it's now worded.

So, such a center -- do we want to recommend a center, or more than one center? Is there one center that we want -- I have -- okay.

So, Nelson, go ahead.

COL MICHAEL: Yeah. Well, I think my recommendation would be to probably get away from the brick-and-mortar concept of a center, because so many of us now operate in virtual laboratories, virtual consortia, that, just in terms of funding, are usually centered at one brick-and-mortar, but involve many others.

So, I mean, in my own field there are large consortium funded by NIH to do vaccine development for HIV. And they may involve up to 10 different universities. So --

DR. GUTMANN: Can someone on staff just give me the -- I have so many pages here -- the recommendation, just for the center?

COL MICHAEL: I would just make the recommendation, I think, flexible for that kind of arrangement, which is pretty typical, and I think would probably provide the most responsiveness to the initiative.

DR. GUTMANN: Okay. Okay. Here we go, I have it here. Several of the -- okay. Such a center -- funders associated with the brain initiative should -- I have it, so don't -- should provide financial, administrative, and infrastructure support for at least one multi-disciplinary center for neuroscience, ethics, and society to address the societal implications of neuroscience research findings and their applications. Such a center would bring together expertise from a diverse set of fields. And that we have -- we're agreed on. Yeah? Yeah.

Christine?

DR. GRADY: I think the idea is good. I think the main thrust of that recommendation is that BRAIN Initiative researchers, or the funds that are available for BRAIN Initiative, should be used for multi-disciplinary input, whether it's a center or something else. Some kind of way to bring together multi-disciplinary perspectives, but it needs funding, and so the funding should come from the brain initiative. I think that's the thrust of that.

And whether or not we say "center" may -- I mean it may -- some people may read that, as Nelson said, as suggesting one place, one building, one -- I don't know if that's what we want.

DR. GUTMANN: Well, it doesn't --

DR. GRADY: I don't care about that.

DR. GUTMANN: But it has to be multi-disciplinary enterprises that bring together, in an ongoing way, to do research. And, ideally, to do research and teaching in this area, as well.

So -- okay, so it's not one. We're not asking for one ELSI. We're asking for -- and I will give the rationale after I say it -- we are asking for -- that, in order to be effective in moving neuroscience research and teaching forward, there needs to be funding for multi-disciplinary programs and activities that are directed at the important issues, emerging issues in neuroscience. Okay.

DR. GRADY: I think that's important, because "center" has a particular meaning in the funder world.

DR. GUTMANN: It has many -- yeah. Steve, did you want to add? Dan?

DR. SULMASY: Yeah, I think that what you're trying to do with this is to sort of continue the idea of having the multi-disciplinary research, but recognize the criticisms that we heard from some of the speakers about ELSI and its being sort of subject to politics and the sort of concerns of investigators inside the NIH.

So, I like the idea, actually, of taking it outside toward universities. I don't want to leave it as vague, as sort of saying "funds will be available," because then it, I think, can be more easily ignored. So if we want something like, you know, "centers," then it could be something that would be more like, you know, big data centers that are being funded --

DR. GUTMANN: Yeah.

DR. SULMASY: -- that it would be like, you know, clinical translational research, you know, grants that are given to a -- you know, competitively, to a particular number of centers that would do this, and that funds be made available for something

like that.

I think that might be a wise way to sort of go forward, because it doesn't make it absolutely captive to the people who are doing the research, and could, in fact, be a way to get beyond some of the difficulties that we heard about from the ELSI project, and free up the investigation, from an ethical and policy perspective. And that's the way I would think about it.

DR. GRADY: Can I just say something about that?

DR. GUTMANN: Yeah.

DR. GRADY: Just to be clear, though, ELSI is not at the NIH. It's funding for people at universities to do research. That's what it is. So --

DR. SULMASY: Yes, but it sort of comes out of -- I mean the direction of it is coming --

DR. GRADY: Some of it is investigator-initiated. I mean it's NIH funding, but it goes to --

DR. GUTMANN: It's NIH funding, yeah.

DR. SULMASY: Yeah, some of it, yeah.

DR. GUTMANN: And that's what we do want to -- I -- there is a concern that was expressed over and over again, that we -- it's really our job to make sure we say very clearly -- and the concern is it was said most recently in another context by Bill yesterday -- but if neuroscience is to go forward with an integrated approach, with ethics, law, and policy, there must be funding from the beginning for these interdisciplinary approaches.

And we have seen the -- from the beginning, the BRAIN Initiative wanted to say and said, very front and center, how important ethics is to it. And then there was

some initiatives with funding where there was -- ethics was nowhere to be found, and people who had expertise in it were nowhere to be found. And that's been repaired, in part, because of our urging. And I think it's just really important for the future of this initiative to have adequate funding for these kinds of multidisciplinary approaches.

Raju?

DR. KUCHERLAPATI: So, Amy, in Gray Matters Volume I, one of the first recommendations that we made is that, you know, all brain-related research must incorporate ethics. And we sort of felt that kind of a distributive model is the best way to be able to disseminate and incorporate ethics into thinking about science.

So, in regard to, you know, this recommendation, we should be consistent with that. And I like your second formulation of that. And to be able to -- not a single element, but to be able to say that, you know, the principles that we articulated are important, and that that goal can be accomplished, you know, in a distributive way.

DR. GUTMANN: Yeah. So we are going to make it a -- you know, there will be -- the intent is to fund multiple places. At the same time, we know -- and we're not saying that every bit of research that goes on -- I mean there is some research that goes on that is very specialized that would not benefit from this. But there has to be significant funding for this for it to happen. And I think we ought to say that very, very clearly, that without funding this is not going to happen.

Okay. Anything else? And we have -- you know, we are actually at our time for this, but I will take --

DR. WAGNER: Two very quick comments. One jumps right off of this, and I have made this comment before, and maybe this is just light-weight stuff. But I think, to the degree that we read through each of our recommendations as though they

are the only piece that's going to be read, two things come to mind.

One is specificity, and being specific, like this, about funding; being specific about which agency we anticipate having responsibility. I would like to urge that that get written in to every of our recommendations. But this conversation prompts that thought.

The second is -- goes back to something that John has said a couple of times, and he said it again earlier this morning, that so much of the meat and so much of the intent is in the text before these, that we ought to make sure, again, that if you read them alone, we haven't lost something. And I'm thinking specifically about the ethics content.

I'm not sure that, when I read a recommendation that says that we -- you know, we recognize that several lifestyles and public health interventions could be safer and more effective. I think that's a nice public health statement, but we're an ethics commission. And I think somewhere in that we ought to very briefly -- very briefly -- identify why there is an ethical consideration of that in what we're pushing, ethically. Otherwise -- and I fear that, even those who are going to be -- that those who pick up a report and spend time only on the recommendations may not fully understand what our contribution has been, and how we expect, specifically, for them to be carried out.

So those are two thoughts, okay? If you look for ethics content in each recommendation, and look for specificity in each recommendation.

DR. GUTMANN: Without -- but could I just say -- and this is a friendly amendment -- without just putting the word "ethics" over and over.

DR. WAGNER: No, no, right, right.

DR. GUTMANN: There are -- right? I mean --

DR. WAGNER: Thank you.

DR. GUTMANN: You don't need to say "ethics" for something to be clearly --

DR. WAGNER: But I just think -- right. I just don't think we've untangled any ethical dilemma, if you simply --

DR. GUTMANN: Can I just see which one, where it talks about --

DR. WAGNER: For example, here, "We recognize that several lifestyle interventions," et cetera.

DR. GUTMANN: Yeah, yeah.

DR. WAGNER: And there are others like that. And while it's actually a great statement, and it's true, yeah, it's more of a public health statement than it is a --

DR. GUTMANN: Yeah.

DR. WAGNER: -- ethics commission statement. Thank you.