



Presidential Commission
for the Study of Bioethical Issues

TRANSCRIPT

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DR. GUTMANN: Welcome, everybody. It's great to be in Atlanta. It's great to be at the CDC. It's great to be hosted by the President of Emory University, Jim Wagner. I want to say thank you to Jim. He is not only a great host of this meeting but a great Vice-Chair of this commission. And good morning to my fellow commission members.

I am Amy Gutmann. I am Chair of the Presidential Commission for the Study of Bioethical Issues and also the President of the University of Pennsylvania. I have to say it's beautifully sunny here today with a gorgeous view. Where I come from I'm told raining, so it's particularly nice to be here.

Before we continue, let me note the presence of our designated federal officer. I think of her, and we think of her as our Executive Director of the Commission, Lisa Lee. Lisa, please stand up. Thank you.

I also would like to ask Bioethics Commission members to introduce themselves, beginning if I may with Dr. Hauser.

DR. HAUSER: Stephen Hauser, University of California San Francisco;
Neurology.

DR. GRADY: Christine Grady from the NIH Clinical Center and Department of Bioethics.

DR. MICHAEL: Nelson Michael, an HIV/AIDS researcher from the Walter Reed Army Institute of Research.

DR. ATKINSON: Barbara Atkinson from the University of Nevada Las Vegas, the planning dean for a new school of medicine.

DR. WAGNER: Very exciting.

DR. SULMASY: Dan Sulmasy, the Department of Medicine and Divinity School at the University of Chicago and The MacLean Center for Clinical and Medical Ethics, and I would note amazingly our 17th time introducing ourselves.

DR. FARAHANY: Nita Farahany, Professor of Law and Philosophy at Duke University and the Director of Duke Science and Society.

DR. KUCHERLAPATI: Raju Kucherlapati, the Department of Genetics and Medicine at Harvard Medical School.

DR. ALLEN: Anita Allen, Vice Provost for Faculty at the University of Pennsylvania, and Professor of Law and Philosophy.

DR. ARRAS: I'm John Arras from the University of Virginia.

DR. GUTMANN: Thank you. We were just teasing on how many -- I'm known for drinking Diet Coke in the morning, but one is plenty. Thank you very much. Would anyone like a Diet Coke on the commission?

So during this meeting we will continue our work in response to President Obama's charge to review the ethical issues associated with neuroscience research and the application of neuroscience research findings.

This is part, but it also goes beyond the President's BRAIN Initiative. We were asked to be part of that initiative, but as being part of that initiative, our charge is actually to think about the ethical implications of neuroscience as well as the ethics of neuroscience research.

So last month in response to the charge and our own just frankly preexisting desire to look at neuroscience and its ethics, we released our first of two reports entitled "Gray Matters - Integrative Approaches for Neuroscience Ethics and Society." And for those who have

not yet seen it, you should rush out before it becomes a best seller, to help it become a best seller. It's available to download at bioethics.gov. Our report's analysis and recommendations focused on the importance of integrating ethics in neuroscience research from the outset at all stages of a research project. So if you want to think of two words that characterize the themes of the report, it is integrating ethics with science, so integrative, and proactive, doing it proactively, doing it before mistakes are made.

It is virtually impossible to predict where an ethical mistake will be made. What it is possible to predict is that some ethical mistakes are likely to be made if researchers don't take account of ethics in a proactive way. So we were very strongly supportive of having an integrated approach and a proactive approach to ethical practice in neuroscience. And that means that people who are trained and teach and do research on ethics should work with those who are most expert at the science itself so that neuroscientists can feel comfortable in integrating ethics in their research.

And as a byproduct of our recommendations we think that will minimize the need for new regulations in this area. Regulations tend to be abundant and they tend often to go beyond what any cost-benefit analysis would warrant, although it's very difficult, I should hasten to add, to do cost-benefit analyses of these.

So we are now turning out attention to the ethical and societal implications of neuroscience research and its applications more broadly. A strongly integrated research and ethics infrastructure, as we recommended, will be well equipped to address these ethical implications.

Before we get started I'd like to take a moment to explain, as I always do, how we will take public comments at this meeting. At the registration table and with all the staff

members of the commission we have cards, comment cards. Would the staff members of the commission stand up and wave your cards. Happy to pass them to any of you. Just ask them for one. Write down any comments you have on one of these cards, or questions you have, and Lisa or another member of the staff will pass them up to Jim or me at the appropriate times. All comments, whether we read them or not at the meeting, we will read and take into account, and if you have questions, we will try to get back to you on them.

With that, would our Vice-Chair like to say a few words of introduction, please?

DR. WAGNER: I would indeed, and again, welcome to everyone. Welcome to the commissioners. Our most usual venue is Washington, D.C., but it's been great over the years that we've been able to travel all around the country, and it's good to have you back in Atlanta. To our guests today, welcome to you. A special thanks to those who will address us as experts in their field. And special thanks to you, Amy. As Atlanta is home to Coca-Cola, and Emory is such a big beneficiary of that, I am pleased that you are having two Diet Cokes in the morning. I think it's terrific.

Volume One of "Gray Matters" does indeed seem to be a hit. As you say, it says, commissioners, I think that we are on the right track. We move in this session, as Amy said, to ethics in research and applications of neuroscience. I don't know about you, but as I look over the agenda and read the materials, I am impressed with the breadth of scope of what we're going to hear over the next day and a half, from the needs and promises and even a little bit of the hype for potential neuroscience research and applications as they might address more on behavioral and cognitive disorders and enhancements at different ages, at different stages. We'll talk a little bit about how we go about pursuing research to ensure ethically appropriate consent and what do

we do with the data from these kinds of studies, all coupled with the issues that arise in tandem with the promises of new technology.

I think, while we have a very specific charge from President Obama, it's helpful for me every now and then to step back and remember the large charge that he gave us years ago was to help ensure progress and to help ensure that the progress and benefits are secured in an ethically responsible manner. I think we've upheld that. I believe that we have upheld that strongly, and I'm not concerned about the breadth of information so long as we understand how it is that this broader assignment can be pursued in a way that I think sweeps all of those things in. So I'm very much looking forward to the testimony today and to our discussions in the next day and a half. Again, welcome to Emory.

DR. GUTMANN: So what we are going to do in this first session is deliberate as a commission around two working groups that we set up among ourselves. These working groups have engaged in prep work to inform the Bioethics Commission's discussions and deliberations. One working group is the Research and Integration Working Group, and that's focused on the first part of our charge, that is, to identify proactively a set of core ethical standards to guide neuroscience. And the second working group we call the Applications and Implications Working Group. It's focused on the second part of our charge which is to address some of the ethical dilemmas that may be raised by the application of neuroscience research findings. In some sense you can think of it as the input and the output of neuroscience, the input of the ethics that goes into the research, the output, which is what are the challenges to our everyday understandings of ethics and what are the ethical challenges to the neuroscientific understandings that come out of brain research.

So in the first session we'll hear updates from both working groups, and John Arras will start us off with an update from the Research and Integration Working Group. And what I would ask, John, you and then Steve, is to give a brief summary and open it up to discussion. I will moderate the discussion and be the Devil's advocate or the agent provocateur, as the case may be. John.

SESSION 1

DR. ARRAS: Thanks, Amy, and thanks, Jim, for your hospitality. It's great to be here. So my role here is to be the rapporteur of our little subgroup. As such, I was tempted to claim privilege of the rapporteur at some points, but I think I'm going to stifle that urge. So I'm going to just give you a very brief summary of our deliberations.

Our group is composed of Chris Grady, Nelson Michael, Barbara Atkinson, Raju, and myself, and our two co-chairs. And our task is to really articulate some of the major issues stemming from neuroscience and research ethics, and to do so in a way that basically tees up these questions for the larger commission and for our distinguished guests. So I want to be a bit provocative myself actually and raise some questions.

So we looked at two issues. One is data sharing, looking at the benefits and the ethical concerns raised by data sharing and neuroscience, and the second big issue was neuroscience research on patients with diminished capacity. So with regard to the first issue, data sharing, really the overarching question for our group was what's new here? And this is true for both of these segments, actually. That would be a good way I think to focus our mission with regard to this report.

So what's new? Well, there's a familiar set of issues. In our previous report, genomics and genetics and privacy, we studied very carefully the tensions between achieving

great public benefit versus threats to individual interests, including privacy interests of the individual. And so one major issue for us as a commission and principally for our hard-working staff is to get a sense of how much guidance we're actually going to get from our previous work, "Privacy and Progress."

Now, there's some interesting sub-issues that were highlighted during our recent conference call. One of them was to look at the possible differences between biological samples of the sort that we saw in genomic research and neurological neuroscience data. Do those raise identical issues or do we have a new set of issues with neuroscience, with brain imaging, for example?

There was discussion about different types of data, aggregate neuromorphology versus digital data from neural images. I think it was at this point that I began to glaze over during the conference call. I'm going to need some help in figuring out what that is all about.

We made distinctions between identifiable versus anonymous data sets and samples, and in view of the reading that we had for today I think it's a very live and interesting question whether a lot of our traditional privacy concerns are still meaningful in an era of big data which can do and runs around the usual mechanisms for protecting privacy. And finally, there was an interest in pursuing empirical research of various kinds to get a sense of what the public's and professionals' attitudes are with regard to the sharing of data and access to data.

So that's the first issue. Second is the I think much more fraught question of diminished capacity. This is an extremely important question and an extremely difficult question. It's a question with a very tangled history. Lots of very vocal stakeholders in this debate with conflicting interests. Most disturbing of all, I think, is a history of policy failure with regard to this very question. Our staff, Kata Chillag, produced a really terrific summary of all previous

federal efforts to define and operationalize the notion of decisional capacity, so going way back to the President's Commission and back, and all the other commissions.

DR. GUTMANN: John, just so we make sure we don't -- the issue is what is the capacity necessary to give consent.

DR. ARRAS: Right. Sorry for the shorthand. So by diminished capacity we mean the ability or lack of the ability to consent to research or to consent to treatment. Sorry about that. So on this chart of all these august committees, NIH, Presidential level commissions, there was a column that talked about result, listed the result. And in every single one, the answer was no action taken. So this is a troubling history, and so we walk into this with great trepidation.

So the question is, against this background, what can we accomplish? I think the first thing we need to do is to really study that history and to learn where and how previous efforts got untracked. Our more sanguine members on the subcommittee believe that this is a serious opportunity for us as a commission to learn from past failures, an opportunity to reframe and refocus and narrow previous work done in this area.

So one big question that I would have here, and I think this is a question the group would want to discuss as well, is whether there's a need -- whether there are any issues raised in the neuroscience context that differ from standard, garden-variety capacity issues in other kinds of biomedical research. A large part of the population of neuroscience research will themselves be impaired, so the consenting organ will itself be impaired. Does this make a difference to our deliberations?

And neuroscience might contribute to better understanding of diminished capacity. Now, this might be true, but it's also true that capacity, at least as I understand it, is a multifaceted concept that is not strictly medical. It has to do with lots of other factors that are

contextual. So it may be that research into the brain can help us discern the physiological supports of capacity, and that could be a good thing, but I'm not sure what ethical issues are raised by that. So in a nutshell, that's what we did. I encourage my fellow subcommittee members to chime in at this point and elaborate.

DR. GUTMANN: So just dividing it into the two parts you did, John, thank you. It's really a lucid summary. On the data mining and privacy issue, it would be good if some member of the group would add to and actually clarify the distinction that the group is making between different kinds of data aggregation. Someone? Raju.

DR. KUCHERLAPATI: Amy, I think the discussion focused upon, as you pointed out, the different types of data that are always, clinical data that are commonly collected, and that the ability to collect the data and use the data and maintain privacy from such data has been established for a long period of time. And I think one of the newer aspects that we talked about and dealt with other aspects of the commission's work in the past is some of the newer technology such as whole genome sequencing or whole exome sequencing of the DNA and that it turns out that it is very difficult to be able to maintain privacy of such data. Even though there is no names or other types of features associated with it, a determined group of individuals or an individual, it is possible to be able to identify the person from that. So it poses special types of challenges.

Those are the two types of data sets, and we are very mindful about the differences and how we need to deal with those.

DR. GUTMANN: Members of the group on the diminished capacity, anything on either -- and anybody, actually. It doesn't have to be a member of the group, because we are

deliberating as a commission and we haven't reached any conclusions. This is just an outline of what we want to do. Raju.

DR. KUCHERLAPATI: I just want to make one comment. This issue of diminished capacity is very important because there are clearly instances where the nature of the population that we want to study and to be able to help from research might be those individuals who do not have the capacity to be able to consent. For example, if you have a late-stage Alzheimer's patient and you want to be able to understand the medical or biological aspects of the disorder, and those are the kinds of people that you want to enroll in the study, then intrinsically there is a problem. So that's the kind of issue that we need to deal with, and that may be especially important in neuroscience. Even though other specialties of medicine also deal with that issue, in the case of neuroscience it becomes much more acute.

DR. GUTMANN: So I think there is one very important general point to make here which flows from a question that John raised, and you I think answered it in a way that I agree with, and I want to highlight it to see if we all agree with it or enough of us agree with it.

There are certain issues that are particularly acutely raised, certain ethical issues that become raised in acute form in neuroscience but they are not unique to neuroscience. And I think it's important that in our report we indicate that we're focusing on these because they are acutely raised by neuroscience, not because they are unique. It's not as if this issue has never come up, or, to put it even more accurately, it comes up frequently in other forms of research but not as frequently and as predictably as it will come up as neuroscience progresses because of the nature of the conditions and diseases that neuroscience research and the BRAIN Initiative want to focus on. They are in some cases conditions of diminished capacity. And so we should go back and mine the standards that we have and make sure that neuroscience researchers, Raju,

that neuroscience researchers are well educated in those standards for the sake of being able to move that research forward in a way that doesn't hit a land mine or call for having to create regulations that ought not to have to be created if the researchers take account of existing centers.

That said, there aren't bright lines here, but there are standards we've developed over the decades, so let me just give you one example of something that if you went back a hundred years didn't exist: advanced directives. There can be ways of people signaling ahead of time what they consent to or not. There's a big philosophical issue about whether they're precisely the same person or not, but that notwithstanding, you can have reasonable ethical, legal standards that are as good as you can get even without settling the philosophical issue. I think that's important.

Christine. Nelson, I have after that.

DR. GRADY: I want to agree that although this issue of diminished capacity is not unique to neuroscience, it is so prevalent in neuroscience research that it's really important that we do say something about it.

DR. GUTMANN: Right, which is why I said acute, to use a medical term.

DR. GRADY: And I actually think it's important to look back at what other commissions and other bodies have recommended and to see why it wasn't followed up on and to sort of make some very important points that I think we can make that would be helpful.

You've said some of them already, John. So one example is that capacity is multifaceted, that there are lots of different things that contextually come into play that help us determine whether somebody does or doesn't have capacity, and so the assessment of it has to be

carefully done and nuanced and people have to be trained how to do that. I mean, that's the kind of thing we probably could talk about.

I also think that research into advanced directives is a great idea. I think we need to talk about what are the other mechanisms in addition to that that would allow to us bring in the number of people that we need to bring in to the research studies to answer these important questions in neuroscience.

DR. GUTMANN: Advanced directives for organ donation are something that we have accepted as a society even though we haven't settled the philosophical issue about whether somebody remains the exact same self over time with different capacity. I saw actually Steve's hand up next, so let me ask Steve and then Nelson.

DR. HAUSER: Thank you, Amy. My point was very similar to Chris's, and it has to do with the nuanced nature of reduced capacity. And we think of reduced capacity as being in a position where one is unable to grasp the nuances of a decision, to have confidence in the ability to make the right decision. But in the neurologic disorders sometimes there is disrupted and altered cognition that can result in active decision making that is different than one would have otherwise, a distorted decision-making process.

Among the dementias this is less common in Alzheimer's disease but much more common in the frontal dementias, and, of course, in the psychiatric disorders.

And in these problems where personality is affected early before language or memory, we have special problems. Also, in terms of advanced directives, for a number of these disorders the problem becomes even more complicated because the origin of the problem can precede the recognition by a long period of time. So this just adds to our challenge, I think.

DR. GUTMANN: So one of the things I wonder whether we are going to wind up recommending -- I'm just projecting. This is really not -- it's a question: Do we need more very contextually-based research in this area that is focused on answering the ethical question to help researchers figure out when consent is reasonable to accept? Because I don't see how as a commission we can go into the details of different kinds of cases of different diseases. I see nods, so I will go down my list. I have Nelson next.

DR. MICHAEL: So you just went precisely where I was going to go, Amy, which is I think that neuroscientists like Stephen and others are going to need to assist us to develop a more precise framework for how we have these ethical decisions in informed consent deliberations. Now that there's an initiative, there's momentum, you have funding, it's going to propel the field very quickly, and we want to make sure that our ethical considerations can be there when the science needs us to be there. Certainly there's nothing novel about special populations, and this commission has debated a lot on the special conditions of children with countermeasures for Anthrax attacks or other kinds of biowarfare issues. We talked a lot about prisoners and individuals in the military in our deliberations about Guatemala. So I think the ground is well trod in a general sense but not in a specific sense. So I would echo your thoughts about the need for research to help define that framework.

DR. GUTMANN: And specifically data-driven research that takes the standards that are established and applies them and shows how they apply to different diseases in different conditions and different contexts is what we're calling for, which is very specific. It's not to ask bioethicists to go off and question whether the standards, the ethical principles at that high level need to be changed, because that's what we've been working on, but rather data-driven research that is an application of existing ethical standards. Dan.

DR. SULMASY: So, yes, along those lines I was struck by seeing again a distinction that Scott Kim drew in his article, which is something that began with Dan Brudney in our philosophy department at the University of Chicago, and then Lois Snyder and I have written about it in the clinical sense, which is a distinction between autonomy and authenticity. And it may be that something like that may be an opportunity for a unique contribution from this commission to sort of think about, go back again to think what are the purposes of informed consent. One is to protect people from being exploited, and the second is to show respect for them as persons.

And in a clinical setting we know that advanced directives are not executed by many people, are terribly flawed, in a clinical setting. I think those problems are probably even amplified in the research setting, and that maybe, rather than asking whether or not the framework is, you know, is this the decision the person would have made were the person able to speak for himself or herself, which is a very fraught problem from an empirical point of view, from a philosophical point of view, to asking the question is this a decision which is true to the person, in that sense of authenticity. Is it true to them in terms of their values, their narrative history, et cetera? And maybe if we move towards making that kind of a distinction, we could help move some of this discussion forward at a theoretical level and it might help us in a very practical way as well. So I'd like to see us talk about that a bit more.

DR. GUTMANN: Jim.

DR. WAGNER: Nelson, I appreciate your bringing up the Anthrax involving children because I thought where you might go with that is that, in addition to this very fuzzy area as we go from full competence to compromised diminished capacity, we could also come from the other direction. It's quite plausible that there will be very important studies that could

help society that will absolutely involve people who are clearly and utterly incompetent. And we might -- I think it would behoove us to have some conversation about surrogates who can speak - - again, that's the case for children, right? That's where I thought you might be going, with parents and their children. And it might help us to move the argument from the other direction as well.

What do we do if we assume from the beginning incompetence and yet see value in certain kinds of studies? And how is it under what circumstances that we would let surrogates give consent for that kind of work?

DR. GUTMANN: I'm going to have to, if we're going to have time for the second group to report out, cut this and move to the second group, and we'll come back. We'll find some time to come back to this discussion, which is really important. I know who hasn't had a chance to participate, beginning with Nita when we get back to it.

Steve, why don't you present the second working group's discussion to date.

DR. HAUSER: Thank you, Amy. I'd like to begin by acknowledging my fellow working group members: Amy, Jim, Dan, Nita, and Anita. And as Amy said at the beginning of this session, the goal of this second working group was to lay the groundwork for discussion and deliberation by the full commission about the application and implications of neuroscience research findings.

In our first report, "Gray Matters," we argued for the importance of integrating ethics throughout the life of all research endeavors and throughout the careers of all researchers. And it was I think quite interesting that it was clear in the first report that, as we reviewed current practices as well as innovative models, that many of the necessary foundations for ethical neuroscience research, at least the principles, appear to be already in place. By contrast, similar

robust scholarship does not really exist around how to consider the societal implications of neuroscience advances; hence, our working group. We've held recently a second conference call focused on two cases, and I would like to summarize our discussion that was quite animated.

The first case study involved deep brain stimulation to treat depression. Deep brain stimulation, or DBS, many of you know is a surgical procedure, a neurosurgical procedure involving implanting electrodes into specific regions of the brain. After the procedure the device remains in the brain and sends electrical impulses to that region of the brain at a calibrated frequency that one can adjust after placement to achieve the desired effect. Deep brain stimulation has shown considerable benefit for many people with abnormal movements such as tremor from Parkinson's disease, and especially when these movements are resistant to less invasive drug therapies. We discussed a preliminary study that demonstrated possible limited effectiveness of deep brain stimulation to treat treatment-resistant depression, which is a devastating and burdensome disease.

And we discussed some of the science behind this case, which was I think particularly important because this is an area that has generated great interest and attention by society but also with surprisingly little firm data. For example, the information that we have to date is largely uncontrolled. The data holds open the possibility that in addition to helping some people, we could be making some people more depressed, recognizing that we are currently doing very extreme and invasive things for people with extreme depression such as electroconvulsive activity. This is potentially a reasonable therapy but it's also likely a transient technology with less invasive similar technologies perhaps on the horizon.

So some of the ethically relevant considerations raised in our discussion involved how we manage expectations by patients, by families, by society, about benefits and risks,

concerns about justice and fairness in participant selection, how to ensure informed consent for a procedure that potentially could alter mood or personality. In addition, we discussed the importance of gathering adequate evidence, and the hype has been way ahead of the evidence in this arena, to move this procedure from the research setting to the clinical setting. Despite the great enthusiasm, translating these research findings into clinical practice needs of course to be justified by sufficient evidence.

The second case that we discussed was a case study dealing with direct-to-consumer neuroscience-related products, and in particular a brain training system called Cogmed that is marketed to patients, to clinical psychologists, and to schools, but largely bypasses professional societies. This training system claims to improve attention and memory in children, particularly those with ADHD. One group of researchers evaluated the evidence of these claims and concluded that they were overstated.

Our discussion here raised a number of ethically interesting considerations including heightened privacy concerns raised by direct-to-consumer neuroscience products like these, or other products.

These groups are not directly in the healthcare system and thus not covered formally by medical privacy laws. In addition, we discussed the vulnerability of consumers who purchase these kinds of products who might be suffering from stigmatizing illnesses or might otherwise be reluctant to enter a traditional medical setting.

And this case raised for us key questions about the ethical responsibility of companies offering health-related products outside of the traditional clinician-patient relationship. The case also brought up issues about cognitive enhancement more broadly and its

overlap with direct-to-consumer products and the related critically important issue of justice and fairness.

So to close, these two case studies each raised a number of key questions that we all feel are extremely helpful as starting-off points for a more complete discussion.

DR. GUTMANN: Questions and comments about this, and if other members of the working group want to weigh in. Let me just say on cognitive enhancement, the more I think about the issues of cognitive enhancement the more I see this striking irony with the hype parts of DTC and others, which is the following: The more hype there is for these Cogmeds and others, in other words, the less they can deliver actually, the less concern there is that people who have fewer means aren't able to purchase them, because a lot of them are all hype and very little reality. The more reality there is in being able to enhance cognitive function, the more one cares about there being access to it by people who have lesser means, not just by people with greater means. It's not unique to this, but, again, it becomes more acute when it's a matter of being able to actually get the best positions in society, get entry to colleges and universities that are desirable, do well in colleges and universities that are desirable, and get desirable jobs. So the issues of distributive justice come into play the more advanced the capacity there is for cognitive enhancement. The less advanced the capacity the more we're concerned about the normal problems of snake oil salesmen in the commercial realm. John.

DR. ARRAS: Thanks for that, Amy. I agree completely. You don't get the really hard problems until medicine succeeds.

DR. GUTMANN: Of distributive justice. In other words --

DR. ARRAS: Yeah. So continuing, Stephen, the theme of what's new here with regard to the deep brain stimulation, a question that comes to my mind is how is that question,

that case study, different from innumerable case studies in orthopedic research, in internal medicine, you know, the introduction of any new medical procedure where there's promising science on the horizon that current research is going to yield something, patients might be desperate. You see this in cancer treatment a lot, right? And people have to tread very carefully not to hype it and elevate expectations, proceed cautiously. How is this problem different in the neuroscience area such that we would really need to focus on it?

DR. GUTMANN: So Nita would like to actually answer, and Steve could answer too but I'll call on Nita since she was next on my list previously.

DR. FARAHANY: I think it's perfectly fair, John, to say that new medical interventions raise some of the same problems, whether it's a new implant, a new heart valve, or deep brain stimulation. But I also think it's importantly different in a few ways. One is some of the conditions that we talked about with neurological conditions cut much more to a person's self and self-identity. And it's far more likely to interfere with the things that we're really concerned about like the ability to have continuity of self, the ability to have adequate capacity to be able to consent, to be able to have continuing consent. And some of the ways in which these can debilitate a person and really change the kind of authenticity, as Dan said, of a person is more pronounced.

So in the spirit of some of the things that we've said, which is neuroscience puts a finer lens and a greater scrutiny on some of the issues that we've had before, but it does so in a way in some of these areas that's really a difference in kind, not just degree, because of the way in which it impacts an individual's ability to continue to function, to continue to make choices, to continue to be a fully capable and capacity-driven individually.

DR. ARRAS: May I follow up one second?

DR. GUTMANN: I just want to call on other people, so hold it, okay?

DR. ARRAS: Sure.

DR. GUTMANN: And then you can follow up.

Anita.

DR. ALLEN: I agree totally with what Nita just said. I just want to add that another thing that may be different is that it's a special history attached to psychosurgery, and that history gives us great concern about the issues of, well, what are we willing to do that might compromise personality and identity, as we've seen in the past, an extraordinary degree of scientific hubris when it comes to what we can do by invasive procedures regarding the brain. So I think we have a very, very heightened concern here. Not to say that orthopedics can't raise very serious concerns, or cardiology, but I think when we talk about the brain, we are talking about a very special history and a very special assault on personality potentially.

DR. GUTMANN: John.

DR. ARRAS: Thank you. I think that really helps, and I think for me what's really important to ask with regard to a lot of these questions is not whether neuroscience will raise these questions a lot more frequently than other areas, as with the area of the problem of capacity to consent. I think for us the big question is whether neuroscience and neuroscience research raises these concerns in interesting new ways that make us think harder about the ethical issues.

Simply because something is going to happen more often in the realm of neuroscience, to me is not a reason to really pursue it at length in a long document, but the kinds of reasons that we're coming up with here I think really are important and worth pursuing.

DR. GUTMANN: Let's not lose sight, though, of what Anita said. There is a history, a troubled history. John, you alluded to it in your introduction. Steve in his summary

indicated the reason we focused on a case of deep brain stimulation is here is a case of something that is being researched. It's being implemented. It doesn't have the characteristics, at least not the horrible characteristics, of some of the past treatments that were terrible, but it does share the fact that it's invasive, it's doing it on the brain. There aren't controlled experiments. We don't have controls. The amount of research findings that exist are very small that indicate positive results.

Those responsible research findings also indicate there are negative results there. The patients are desperate for treatment, or their families are desperate for treatment. It goes, as Nita said, to the very essence of, whether you're skeptical about essence or not, if there is an essence of who we are as people, it has to do with our brain functioning. Orthopedics doesn't share that, you know, those sets of characteristics. Now, indirectly it should be said we know that when people have diseases and they are physically impaired and get treatment, that can affect their brain functioning as well. So there's an indirect way in which the brain is affected by other forms of treatment.

But the fact is what we are focusing on is direct, and that's why when I used the word "acute" I meant it raises it acutely because it is qualitative as well as quantitatively different.

I have Dan and Raju.

DR. HAUSER: One thing that this case does have in common with orthopedics, and it's something that we discussed last time, is the relative lack of strict regulation for devices compared with drugs. And I think that one additional area where neuroscience may be a little bit different -- in "Gray Matters" I think we said these problems come into sharper focus even though in genomics one has most of the same menu of issues -- is because so much of the

leading edge of society's, all of our interests in capturing slightly better performance seems to be focused on the neurosciences. And I'm remembered of, and I'll paraphrase a statement by Bill McKibben that, "One should never underestimate the length that we will go to for marginal gain."

DR. GUTMANN: Dan.

DR. SULMASY: I was going to offer potentially a way to answer John's questions again which maybe helps us avoid getting into essentialism with respect to the brain. And that's in a recent conversation with Martha Nussbaum about the importance of consciousness in care at the end of life, she was sort of pushing back from me, and then I asked her how many of those capabilities depend upon being conscious and cognitively aware. And it's sort of after life and bodily integrity, it's three through ten, right? So the rest of them sort of -- I think that's part of what it is. The simpler way to say it is that most of the sort of capabilities that we value about humans are dependent upon consciousness and cognition, and that's a way to avoid essentialism and answer the question.

DR. GUTMANN: Right. And when we spoke about it in "Gray Matters," we said that over and over again, that the importance of what we are focusing on has in part to do, in large part to do with the fact that this research goes to the core of who we are, research on the brain. May not be all of who we are. It isn't all of who we are, but it is the core.

Nita, and then Raju.

DR. FARAHANY: I just want to pick up on a strain that I think ties both the earlier conversation as well as Stephen's remarks and some that Dan said earlier about capacities and the degree to which that's an empirical question versus an ethical question or actually a combined question. I think the way that Dan framed it, which is to say there is an aspect,

certainly an ethics question, which is authenticity, I think is right. I don't think this is a purely empirical question. I think one thing that we could do that would be extraordinarily useful but certainly it's not something we can do alone and requires a lot of participation, empirical research and other research, is to understand the different contexts and the different capacities that are needed for different contexts of decision making. So with deep brain stimulation where a person has deep and intractable depression, the question is what kinds of capacity for consent are needed in order to be able to fully and autonomously, and kind of the other questions we might have, be able to consent to that kind of treatment, and is that different from, for example, withdrawal of end-of-life support for decision making where there's a lot of really interesting neuroscience research that shows there may be conscious awareness but no other types of functions.

And so being able to recognize what capacities do we think are essential to self, to personhood, to being able to make decisions to me seems to be an ethics question. Whether or not it exists in different contexts and the extent to which those capacities are ones that exist when you have deep and intractable depression or you lack awareness is an empirical question, but being able to set the standards I think advancing that conversation would be a valuable thing for us to do.

DR. GUTMANN: Raju.

DR. KUCHERLAPATI: Amy, I just want to point out one aspect that actually cuts across both the research and applications and that has been brought up by Steve, Nelson, and Jim talked about this: Infants and children. Obviously there are a number of instances that in the case of countermeasures we talked about children, and I think that we, the commission, made a Solomonic recommendation about how to approach that problem. But I think in the neuroscience

and infants it causes a special problem that you cannot circumvent, this issue of directly dealing with infants.

There is intense amount of interest in trying to understand what is the age at which infants and children recognize personhood and when do they develop some of the essential features of human beings such as anger or cooperation or competition, all these types of things. And many of those types of research aspects are being done now by observation, but it is not too far away to conceive that that observation could result in next step would be interventions about them and what the implications of those are. And absolutely we know that infants and children are not capable of providing consent, and there have been questions raised as to whether the parents or the surrogates for them are indeed capable of providing the kinds of consent that would be necessary and whether societal intervention is necessary to be able to establish the guiding principles of ethics in doing both the research and the applications.

DR. GUTMANN: We need to end this session with that important, interesting, challenging question, because we have another session which is on neuroscience research across life stages, interestingly enough. So that is the perfect segue to our next session which Jim will introduce and moderate.