TRANSCRIPT

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OPENING REMARKS

DR. GUTMANN: We are going to catch up very quickly on our schedule because we have 15 minutes scheduled for opening remarks, and I am going to make them as brief as is legally possible.

Good morning. I am Amy Gutmann. I am Chair of the Presidential Commission on Study of Bioethical Issues, and President of the University of Pennsylvania.

Dr. Jim Wagner is Vice Chair and President of Emory University.

We welcome you to our 25th meeting. Wrap our minds around that. And I am going to begin by noting the presence of our designated federal official, who is Bioethics Commission Executive Director Lisa M. Lee.

Lisa, please stand.

MS. LEE: Good morning.

(Applause.)

DR. GUTMANN: Yay.

DR. WAGNER: She deserves more than --

DR. GUTMANN: Right. And I will explain how we take public comments. There are comment cards. Any staff member, raise your hands. Staff members have the cards. If anyone wants a card, just get one, write down your question or comment, and Lisa or a staff member will bring them up and, time permitting, we will read and answer them. Even if time doesn't permit, we will read them and get back to you on them.

Jim, would you like to say a few words?

DR. WAGNER: I think, in keeping with your instructions, I will keep
them brief.

First of all, welcome, colleagues. Welcome to those who are visiting with us. The conversations today about the impact over time and we hope into the future on things like policy and practice and scholarship and public awareness of the work of these kinds of commissions is an exciting topic to take on.

So it is wonderful to be with you. Thank you.

DR. GUTMANN: Great. So we are preparing a report focusing on key aspects of something that's been central to every single one of our report and meetings, and that is deliberation and education and bioethics. And that report will come out soon.

And we've often noted the need both for better and more deliberation, especially on controversial issues. That is more and more apparent in the environment in which we are living in, and we have tried to model that deliberation.

We have also noted the need for the improvement of bioethics education, and we have developed many pedagogical materials to accompany our topical reports and highlight ethical themes across our reports.

Our new report, which is going to come out later this month, will lay out a series of recommendations for advancing bioethics deliberation and education, including, I believe, it's a five-step program for deliberation on controversial issues.

At today’s meeting we are going to expand and enrich the Commission's work, and we're going to do that not in preparation for another report, but rather to learn from advisory bodies past and present, domestic and international, with the goal of elucidating the impact of national ethics advisory bodies and to consider their future role.
Since the 1970s, the U.S. has had a succession of national advisory bodies to provide the President or Congress with expert advice on topics related to bioethics. Other countries and regions also benefit from their own advisory bodies, often set up somewhat differently from the U.S., and they offer guidance also on bioethical issues.

We as a Commission have made a point of reaching out internationally and collaborating in many instances, and always we have asked for advice from international organizations and bodies. And many of us, if not all of us around this table and those of us who couldn't join us, have actually participated in some international efforts.

And that has been a sea change since the beginning of the first bioethics advisory body in the 1970s. There has also been a sea change in the development of science and technology. The field of bioethics was in its infancy, one might say, in the 1970s, and it has since expanded and its resources are readily available, not only domestically but internationally.

So looking back at what worked and why can help us imagine and reimagine the role of bioethics in shaping policies and practices that ensure ethically responsible development and use of science, medicine, and technology.

And since the 1990s, each of the past three Presidents has established Bioethics Commissions to explore ethical issues in science, medicine, and technology. Should the next President follow this precedent, the Bioethics Commission hopes that our reflections will help set the next advisory body on a path for success.

So before we get started on our first panel, I would like to ask our Advisory Commission to introduce themselves, and I will begin with Dr. Steve Hauser.

DR. HAUSER: Hi. Steve Hauser, Chair of Department of Neurology at
SESSION ONE: REFLECTING ON THE PAST, PRESENT, AND FUTURE IMPACT OF NATIONAL BIOETHICS ADVISORY BODIES

DR. GUTTMAN: Welcome. It is really great to have you all here.

So the first session will focus on the past, present, and future impact of national bioethics advisory bodies. As is our typical format, we will hear from each of our speakers, and then we will open it up for discussion.

We will hear first from Dr. Jason Schwartz, who is Assistant Professor of Health Policy and the History of Medicine at the Yale School of Public Health. Dr. Schwartz has a Ph.D. in the history and sociology of science, and a master's degree in
bioethics from the University of Pennsylvania.

Dr. Schwartz has written widely on vaccines and vaccination programs, decision-making in public health policy, and the structure and function of scientific expert advice to government.

Dr. Schwartz presented at our 21st meeting about deliberative processes employed by previous Commissions. Dr. Schwartz has also served as the Harold T. Shapiro Fellow in Bioethics at the Princeton University Center for Human Values, an Associate Fellow and lecturer in the Department of Medical Ethics and Health Policy at the University of Pennsylvania Perelman School of Medicine, and as a former staff member of our Presidential Commission.

Thank you for rejoining us this morning, Jason.

DR. SCHWARTZ: Thank you, Dr. Gutmann and Dr. Wagner, Commission members. Good morning. It is a great privilege to be back here with you today, and I'm delighted that you've chosen to spend time thinking about the form, function, and impact of bioethics advice to government, and national bioethics bodies in particular.

Whatever emerges from your work will surely offer valuable insights that will inform the decision-making of the next President and his or her administration as they consider whether to continue what has, in essence, become the standard practice of establishing a bioethics advisory body and, if they do, as they determine how exactly such a group should be designed.

And your work on this topic will also help all of us interested in the past, present and future of bioethics advice to government to better understand these groups, the contributions they have and can make to bioethical inquiry and public policy, and
the relationship to work in bioethics more generally over the past 40 years.

As you noted, about a year ago I spoke with you about how previously Bioethics Commissions incorporated public deliberation and their work as part of your project on education and deliberation in bioethics. Today my task and our task is much broader, as you have asked for reflections about, "how bioethics advisory bodies in this country and public bioethics generally have contributed to bioethics writ large in health policy."

I won't attempt to answer that question in these opening remarks in a commission-by-commission or topic-by-topic fashion, especially because the other guests you have invited today bring such remarkable breadth and depth of first-hand knowledge and experience with previous U.S. Bioethics Commissions and other international bodies.

Instead, I will try to situate my thoughts regarding your charge within the larger context of expert advice to government in the United States on matters related to science, health, and medicine over the past 50 years and in the present day.

When thinking about bioethics advisory bodies like this one in this broader context, the question I find it useful to consider is: What are the unique contributions that a standing national or Presidential Bioethics Advisory Commission in the model of this group or those of your two immediate predecessors can make that alternative models for organizing bioethics-related expert advice cannot?

Put another way, what are the comparative advantages of this model, both for the government in acquiring expert advice on bioethical issues and for commissions themselves in choosing where to invest their time and attention in those cases when they have some freedom to select their own topics?
One way of getting at this question is to think about the various ways in which the relationships between advisory bodies and the government officials whom they advise can be and are structured. In my work on expert advice to government in U.S. biomedical regulation and policy, I have identified three principal models for understanding these relationships which I’d like to briefly introduce this morning. I call them the collaborative model, the cooperative model, and the arm’s length model.

Each brings with it a spectrum of advantages and disadvantages for advisors and their government sponsors alike, and none are ideally suited to the full range of areas for which outside advice is sought and needed.

In essence, the three models reflect increasing levels of separation between government personnel and their expert advisors. In the collaborative model, government officials are heavily involved in identifying the particular questions, not simply the topics, for which advice is sought.

They are involved in gathering, organizing, and presenting the evidence and other materials on which advisory committee recommendations are to be based, and in some cases, they’re literally sitting at the table with their expert advisors throughout their meetings and deliberations and participating actively.

Examples of current advisory committees that employ the collaborative model, as I see it, include the Advisory Committee on Immunization Practices at the Centers for Disease Control and Prevention, the group that develops the recommended childhood and adult vaccination schedules; and the Advisory Committee to the Director of the National Institutes of Health, the group that provides the NIH Director with advice on agency-wide planning and priorities.

Among the principal advantages of this collaborative model are that it
facilitates the development of advice that is most sensitive to the specific challenges and practical implications of issues that a sponsoring agency faces, making subsequent advice more easily suited to adoption and implementation. Advisory committee recommendations are least likely to be publicly rejected or ignored for committees having this model.

On the other hand, committees in this collaborative model are most susceptible to real or perceived threats to the independence of the advice they offer, and a particular concern is that these committees may be used, at least in part, to validate or legitimize decisions that their sponsoring agencies would have made regardless.

The second model, the cooperative model, introduces a bit more distance between government policy makers or regulators and their advisory bodies. Here I'm thinking of groups like the advisory committees that review new drugs, biologics, or devices at the Food and Drug Administration, or, more closely related to the work of groups like yours, the President’s Council of Advisors on Science and Technology, or PCAST.

As before, personnel from sponsoring government agencies or departments are still very much involved in facilitating the work of these committees, framing issues, and at times specific questions, for which their counsel was sought, and working to ensure the committee deliberations benefit from a thorough understanding of the relevant evidence as well as the practical implications of various policy alternatives.

But we see less of a guiding hand from government sponsors with these committees as they proceed with their deliberations and eventual recommendations. As a result, these groups are less vulnerable to, although never fully immune from, questions regarding their independence, but it's more common than in the collaborative
model to see recommendations here ignored, rejected, or simply not adopted.

It's the third model, what I call the arm's length model, that I think best reflects the character of Bioethics Commissions in the United States over the years. I would also include in this category groups like the U.S. Preventative Services Task Force, the group supported by the Agency for Health Care Research and Quality that evaluates evidence regarding disease screening interventions; and also in this category a special case I'll say more about in a moment, advice received from committees of the National Academies of Science, National Academy of Sciences, and as it's now known, the National Academy of Medicine.

For these groups in the arm's length model, while the government provides financial support for committee activities, in some cases staff or administrative support, and often specific requests of topics to examine. Once charged, these groups generally have broad latitude with respect to how they structure their deliberations and recommendations.

While government personnel may, and generally do, respond to requests for information or perspectives, the onus here is on the committee themselves most commonly to identify and seek out the kinds of expertise and evidence they deem relevant to their work.

For these groups in the arm's length model, the case for the independence of the recommendations, both real and perceived, is strongest, but perhaps not surprising, instances in which recommendations are ignored or rejected are most common.

Groups convened by the National Academies, most often working at the request of a federal agency, deserve special mention. I'd call them arm's length plus as
they have even more latitude, including over the very composition of their committees, and they're specifically excluded from the various provisions of the Federal Advisory Committee Act that shaped the work of essentially all other expert groups supported by the federal government, including this one.

So how might this taxonomy of scientific expert advice to government help us to think about the form and function of national bioethics advisory bodies? As I said, I think the arm's length model, with its advantages and disadvantages for committee and government alike, best describes the relationships between these groups and the Executive Branch, but I'm not sure it's the optimal model.

Returning to my earlier point about the comparative advantage of a national bioethics commission versus alternative models of bioethics advice to government, what makes these groups unique is the function they serve as a formal, visible, and ongoing link to the President, the White House, and the Executive Branch.

Other groups that may assemble and have assembled to consider topics at the intersection of bioethics and public policy, whether organized within academia, private organizations or even the National Academies, cannot make those claims formal, visible, and ongoing.

This provides a unique opportunity, as I see it, to provide bioethics advice that speaks directly to the policy and regulatory questions, large and small, facing the government. Such advice can and should, of course, remain sensitive to broader fundamental ethical questions and concerns, but it can also reflect a rich appreciation of the on-the-ground challenges of government policy-making activities in these areas.

That kind of work can be strengthened if a bioethics commission were to have closer links to government, science, medical, and health officials, more in the
mode of the cooperative model I described previously rather than the arm's length model which seems to better describe these relationships to date. Again, PCAST seems to be a useful example here.

I'll note that one unique feature of your design compared to that of your predecessors, the presence of Drs. Grady, Michael, and your former colleague, Dr. Garza, as current government employees also serving as members of the Commission, seems consistent with this general outlook. And if bioethics commissions are to continue in the future, it's a feature that I, for one, hope would be preserved.

There's little doubt that the prospect of closer ties between the work of a national bioethics commission and its sponsors in government would heighten concerns in some quarters about the independence of these groups and its recommendations. But whether real or perceived, those concerns about independence will always exist for any government-created and -supported body, be it bioethics-focused or otherwise.

The most effective rebuttal to those concerns is the quality and rigor of a commission's analyses and recommendations.

On balance, greater cooperation between bioethics advisory bodies and their government sponsors holds great promise to strengthen the work of these groups, make the most of their comparative advantage relative to other modes of policy-relevant bioethics work, and increase the likelihood that they will influence the development of policies in the areas on which they focus, even when their recommendations are not fully embraced as inevitable.

That brings me to the specific question of impact, on which I'll spend my remaining time. Setting aside, at least for now, the obvious impact of the Belmont Report from the National Commission of the 1970s and the report on the definition of
death from the President's Commission of the early 1980s, there have been numerous attempts to assess, often quantitatively, the impact of various other commission reports over the decades based on citations in the academic literature, legal opinions, legislative activities, and the like.

Such analyses can be helpful, but they might obscure other ways of assessing the role of national bioethics advisory bodies and public dialogues regarding science, medicine, and health. For one, these groups have played and continue to play an agenda-setting role, identifying or affirming issues for which ethical considerations are thought to be most pressing and most relevant to government efforts in biomedicine, broadly defined, or to bioethical inquiry in the various other contexts in which it occurs.

With respect to your interest in the impact of bioethics commissions on health policy, as you've asked, let's consider the topics of reports of U.S. bioethics commissions since their first appearance in the 1970s.

Overwhelmingly, commission reports have focused on one of two topics, and sometimes both concurrently, the first being issues related to biomedical, particularly clinical research and the protection of human subjects; and two, issues related to new or emerging biotechnologies, particularly those that have implications regarding the beginning or end of life.

Now, to be fair, two prior bioethics commissions, the National Commission of the 1970s and the Advisory Committee on Human Radiation Experiments of the 1990s, had mandates focused entirely on human subjects research, and other bodies, yours included, have issued reports focused substantially or entirely on other topics.

Your report on ethics in Ebola deserves mention, as do the report on
caregiving for the elderly from your immediate predecessor, the President's Council on Bioethics, and the report on securing access to healthcare from the President's Commission of the early 1980s.

But it is also fair, I think, to say that such reports have been relatively rare exceptions to the larger pattern I described. So if we ask, as you do, to consider the impact of bioethics advisory bodies on health policy, how we define health policy matters greatly.

If we define the term broadly, as I suspect you envisioned, to include policies related to all aspects of medical science, research, and practice that may affect human health, the record of these groups is fairly robust.

If, however, we define health policy in the manner that health policy departments, journals, textbooks, and courses typically do, for example, as I might use with my health policy students, the organization, financing and delivery of healthcare and its consequences for individual and population health, the record of these groups is far more modest.

With rare exceptions, we find little in the collective writings of these bodies on ethical aspects of healthcare access and affordability, healthcare quality, health disparities, mental health, pediatric health, the environment and environmental health, HIV/AIDS, disabilities, and any number of other issues in community, public, and population health.

Now, the issues which bioethics commissions have studied and reported on are, of course, important, and given the prominent federal role in oversight of human subject research and for biotechnology policy and the longstanding place of both of these areas in the history of bioethics, their consideration by federal advisory groups is
certainly appropriate and valuable, whether such advice comes from national bioethics commissions, NAS IOM committees, or the Secretary's Advisory Committee on Human Research Protections, depending on the issues involved.

But time, the time available to bioethics commissions, is very likely their most scarce resource, and difficult choices are inevitable regarding how they direct their attention among many worthy priorities, and in other cases, specific requests from government agencies to study a specific area, often with an abbreviated timetable, have altered their best laid plans.

But bioethics as a field has often been criticized for its relative silence until recently on many of those issues I listed a moment ago. And if we accept the agenda-setting role that bioethics commissions can play in bioethics writ large and the related role, it has been argued, that commissions have played in the growth and development of the field since the 1970s, it's at least worth considering whether trends in the topics which have or have not been seen as appropriate for study by the national bioethics commissions are themselves a reflection of longstanding patterns in the field or, in fact, contributors to such gaps and omissions in the overall discourse of bioethics.

So there are many other issues about the design, composition, and goals of bioethics advice to government that I'm sure we'll talk more about throughout the day. I could say more. I will say more, but I'll leave it there for now, again, with many thanks for the invitation to be here.

DR. GUTMANN: And thank you for a terrific presentation. Thank you.

(Applause.)

DR. GUTMANN: Next it's my pleasure to welcome Dr. James Childress, the John Allen Hollingsworth Professor of Ethics in the Department of Religious
Studies at the University of Virginia.

Dr. Childress is author of numerous articles and books in biomedical ethics, including theory and method and unjust war theory and pacifism.

Dr. Childress has been actively involved in several national committees examining ethics and public policy, including the Biomedical Ethics Advisory Committee, the Recombinant DNA Advisory Committee, the Human Gene Therapy Subcommittee, and he served as chair of the Health Science Policy Board of the Institutes of Medicine.

Dr. Childress was a consultant to the National Commission for the Protection of Human Subjects and a member of the National Bioethics Advisory Commission.

Dr. Childress has held the Guggenheim Fellowship, American Council of Learned Societies Fellowship, and many other honors.

Welcome, Dr. Childress.

DR. CHILDRESS: Thank you very much, Dr. Gutmann, Dr. Wagner, and Commissioners, for this opportunity to be with you.

But I must say I join you with some sadness since my late colleague is not at the table. I would have welcomed his first question and challenge, and it certainly would have been the first in a challenging way. We miss him.

So I was asked to talk about the work and the impact of the National Bioethics Advisory Commission, NBAC as I'll refer to it henceforth, which was established by President Clinton by Executive Order.

The order identified NBAC's first priority, and this is in line with some of the points Jason has made, as the protection of the rights and welfare of human research
subjects. And he connected this with the requirement that all Executive Branch departments and agencies that conduct, support, or regulate research review their protections of research subjects, taking into account the recommendations of the Advisory Committee on Human Radiation Experiments. Note the continuity with a predecessor committee. And these departments were also required to identify measures to enhance human subject protection. Now, these reports were to be provided to NBAC so that NBAC could pursue its number one priority.

So not surprisingly, then, much of NBAC's work focused on research involving human subjects or participants, derailed in part by development of new technologies, cloning and human embryonic stem cell research.

A second priority concerned issues in the management and use of genetic information including, but not limited to, human gene patenting. Even though the charter, in contrast to Executive Order, included this within the first priority as Part B, NBAC never fully developed it for various reasons.

And then the Executive Order and charter provided criteria that we could use to take on other projects: the urgency of the bioethical issue for public health and public policy; the relation of the bioethical issue to the goals of the federal government's investment in science and technology; the absence of some other entity able to deliberate appropriately about this; and the extent of the interest within the federal government.

We submitted our reports to the National Science and Technology Council chaired by the President and then to appropriate committees of Congress and other entities.

I would note the charter added making this available to the public, but
that's really the extent, in terms of the Executive Order that set us up and the charter, about the relation to the public.

We had a remarkable chair, Harold Shapiro, then President of Princeton University, a superb set of Commissioners, and a strong staff.

We first met in October 1996, followed by a second meeting in February 1997, just after the announcement of Dolly's birth, which in many ways changed the course of our work. We were asked by President Clinton to provide recommendation to the White House on possible policies regarding cloning human beings within 90 days. So that became our first exercise.

And if you look at what I have on the screen, that topic was clearly specifically requested by President Clinton, as was the one related to human stem cell research. And then the last one there, ethical policy issues in research involving human participants, was clearly part of our overall charge.

The others we developed as specifications of the overall charge in relation to the criteria that I presented earlier.

Let me just say a word about the role of principles in moral reasoning in our endeavor, just a brief comment, because our charter called for us to identify broad overarching principles to govern the ethical conduct of research, and most of our recommendations for research involving human subjects for participants specified extended, deepened, commonly accepted principles from the Belmont Report and so forth.

We did debate whether to add some other principles. For example, a Commissioner at the time we started, Ezekiel Emanuel, proposed a principle of community, and we considered whether to adopt that or whether to think instead about
the role of community and the way we think about all of the principles, for example, thinking about harms and benefits to communities, respect for communities, and participation of communities in the design of research.

But most often in our work related to research, we specified the various principles, such as respect for persons, for the topic at hand.

Sometimes we had an overlapping consensus about proposed public policies, but only partial or incomplete agreement about the reasons, and this certainly occurred in our first report on cloning human beings. Some critics dismissed our report as a Bioethics Commission that simply copped out by basing much of its argument on safety.

I think that is a misguided critique because safety is an important ethical consideration, and if the science indicates that this would be unsafe for children, then that's certainly a reason for a ban.

But Commissioners were divided as to whether that reason was sufficient or whether the other social and ethical reasons that are so controversial related to cloning were important. So was one reason primary? The text suggested all of these were important, but we did punt to the future more careful consideration of the larger social and ethical reasons since it would have been impossible in 90 days as the first body, really, to address this topic to do much more than we did in identifying some of the issues and indicating a preliminary framework for thinking about them.

So what was the overall impact of NBAC as a public bioethics commission? Well, questions about the value and effectiveness of commissions focus, obviously, on their goals and their success in realizing those goals. We emphasized two main goals. One, and clearly this was present in the executive order and the charter,
was to contribute to public policy, and specifically starting with the White House, but then other federal agencies and departments, et cetera, congressional committees and the like.

So this is our primary function, to offer advice to the federal government. But a second goal was also central to our work, even if it was not so clearly part of our mandate, and that was contributing to public bioethical education and discourse.

In the process of our reports, we emphasized the importance of functioning as a public forum, a public deliberative body, as well as promoting continuing public bioethical discourse, and we conceived our reports as contributions to public discourse in bioethics.

So these were goals. How well did we do in achieving those goals? Well, two years after its charter expired in 2001, Elisa Eiseman of RAND Science and Technology Institute prepared an evaluative report entitled "National Bioethics Advisory Commission: Contributing to Public Policy," and the focus was on impact, short-term impact, obviously, given the time, in relation to public policy.

And according to Eiseman, evidence exists that NBAC's work stimulated informed public and policy discourse here and abroad about the topics they addressed. However, the record is mixed regarding direct public policy contributions.

At the time Eiseman prepared this report in 2003, no federal or state legislation had been passed based on any of our recommendations, though some federal and state bills reflected those recommendations.

Furthermore, we were aware at some times when we made proposals that they would not be accepted even by our primary target, the White House. This was certainly true when we were formulating our recommendations regarding federal
funding for the derivation of human embryonic stem cells and the use of those stem cells in research, that this would not be something the White House would be able to sign onto. So we were aware that there were certain barriers.

But then in thinking about the research involving human subjects, this report by Eiseman indicated that government agencies responsible for a major portion of federally funded involving human participants, NIH, FDA, CDC, adopted several of NBAC’s recommendations and issued guidelines based on them.

Furthermore, professional societies drew on NBAC's reports and recommendations for policy statements, guidance, and educational materials, and other countries and international organizations referred to the work, et cetera. And there were significant media responses, especially to the most controversial reports related to cloning human beings and human stem cell research.

And perhaps it is in relation to those that we had our greatest success in promoting meaningful public discourse, but as it was clear from Jason's very helpful presentation, it is very hard to measure this. We are talking about a qualitative matter.

Looking ahead to the future, and this will overlap with what Jason was proposing, or analyzing and proposing, there are three main types of institutional structures for national public bioethics focused on public policy, each with distinct advantages and disadvantages. And Jason pointed to some of the comparative advantages and disadvantages.

First is a standing national commission extending over time with a broad mandate and the opportunity to select some of its own topics, looking back at your Commission.

A second possibility is a series of commissions with more focused,
targeted, limited mandates, such as organ donation and allocation, human fetal tissue transplantation research, human embryo research, and so forth.

Now, let me look at those two first. A major advantage of a standing commission with a broad mandate is that the commission has time to mature as a deliberative body, to develop and improve practices of collective analysis and reasoning and prepare for new challenges, and so forth.

Unfortunately, as I suggested, we had 90 days in which to prepare our report and that was our first endeavor to look at human cloning.

A major advantage of a targeted, focused commission is that participants can be selected who are best suited for the specific task at hand, and the committee can pursue this with concentrated attention and effort.

But we should not overlook a third possibility: non-governmental committees that produce reports and recommendations for governmental bodies. I think in particular, as Jason mentioned, consensus studies undertaken by committees established by the Institute of Medicine, National Academy of Medicine, National Research Council, and the National Academies, the structure and nomenclature are changing, as you know.

Often in response to request and with support from federal departments and agencies, such as the FDA or NIH, these independent committees prepare single issue consensus reports -- for instance, a recent one on novel techniques for prevention of maternal transmission of mitochondrial DNA diseases.

Such committees may appear to be less political than a Presidential or Congressional commission, but there is a distinct disadvantage. Even though these committees often include public members, their process is not as publicly open and
transparent as with governmental bioethics commissions. They may appear more objective and impartial in one sense, but they are usually less open and transparent in their processes of deliberation.

Having served on all three types at one time or the other, I believe that each one can contribute to public policy formation and public education, public culture.

Unfortunately, and we may have to wait for Jason on this, we don't have a good comparative evaluation of their respective merits for different kinds of projects. And I would emphasize that last because it may make a great deal of difference what project we're talking about as to whether it's better dealt with by a standing national advisory commission, a focused, targeted national ad hoc commission, or one of the consensus committees from the National Academy of Medicine and other national academies.

And there are other possibilities as well, including broad or focused state bioethics commissions. So we have a lot of rich opportunities with a lot of uncertainty about which one, which mechanisms, would be the best to proceed for particular topics.

Let me stop there. Thank you.

DR. GUTMANN: Thank you very much.

We'll now hear from Michael Gazzaniga --

(Applause.)

DR. GUTMANN: Oh, yes. Thank you for that, too.

We'll now hear from Michael Gazzaniga, Professor of Psychology and Brain Science and Director of the SAGE Center for the Study of Mind at the University of California, Santa Barbara. He is credited with fathering the field of cognitive neuroscience and has played a key role in developing the field.
Dr. Gazzaniga has also served as Dean of the Faculty at Dartmouth College, and from 2002 to 2009, he served on the President's Council of Bioethics.

He's a member of the National Academy of Sciences, National Academy of Health and Medicine, and the American Academy of Arts and Sciences. He currently serves on the Board of Directors of the AAAS.

His most recent book, "Tales from Both Sides of the Brain" -- I love the title -- includes a brief discussion of his time on the President's Council of Bioethics.

Thank you very much for joining us. Welcome.

DR. GAZZANIGA: Well, good. Thank you very much, Chairs Gutmann and Wager.

Let me start by simply saying I fully support the idea that there should always be a bioethics council advising the President. I found it to be a place, a public forum, that was civil and yet where heartfelt beliefs ran up against some uncomfortable facts. And hashing that out in public is a good idea.

So my own story, I'll just tell it this way because it flavors how I would structure the committee, following up on Dr. Childress's remarks. When I got called to take part in the President's Bio Council, I didn't know the first thing about bioethics, and Dr. Kass, Leon Kass, who called, said, "Well, you don't have to know anything. It's about bioethics, but we're not asking bioethicists to run the committee. We want people from all professional ways."

So I read Al Johnson's book, "The Birth of Bioethics," and realized that this was a manageable problem. And our committee was full of philosophers, legal minds, scientists, people of different religious beliefs, the whole ball of wax.

It could be at times quite annoying.
(Laughter.)

DR. GAZZANIGA: To hear sentient human beings say the things they say that aren't consonant with yours is always challenging. But it was very lively and terrifically productive, and we were part of a perfect storm. And the example I'll use was we followed up and had the stem cell baby dropped in our lap, and it was a very -- as you can recall back in 2002, it was a very hot potato. We worked on it for six months. But the story I want to tell is that people changed their minds as a result of the public discourse that went on at that committee by finding a vocabulary that all people at the table could understand.

The thinking about it went forward, and I can tell you that -- this was lost in the public reporting, which was strange to me -- but 10 out of the 17 members of that Commission did not have a problem with biomedical cloning on a question of a moral stance. Seven did, of course, but 10 did not.

And so that's not the way it started. The six months of discussion moved people around, people comparing it to what's the difference between a 14-day old blastocyst and a brain-dead person. We can do everything to a brain dead person, but this blastocyst which doesn't even have a brain we're all uptight about.

And those kinds of arguments could be generally understood. The other one that was really the show-stopper, that 38 percent of all natural pregnancies spontaneously abort. What? And all of that common-sense kind of scientific finding after testimonies and so forth really, you saw, move people's thinking around. So I'm a big believer in a diverse group. And many, many times right thinking, by which I mean correct thinking, takes over.

Secondly, and you know this as well as anybody, the fast moving nature of
bioethics. I was at the time -- at the time bioethics reasoning isn't physics, and the context of the decisions and the underlying scientific knowledge keeps changing as we go through time.

Back in 2004, William Safire had moved on to be President of the Dana Foundation, which was a very brain-oriented foundation, and he urged me to write a little book discussing the experience. So I wrote a little book called "The Ethical Brain," and it came out in 2005.

I would say that book in 2015 is utterly out of date because of the underlying change in norms, societal norms, findings, scientific findings. It just gives you a benchmark of how fast and how quickly things change and how there needs to be continuing evaluation. It is not a one-shot deal and we're over with this thing.

And then I would also like to point out that the embryo issue and stem cell with somatic cell nuclear transfer, which just got everybody going on our committee, is completely moot now with IPSP. Nobody even worries about it anymore. No one even uses it. And all of those kind of changes, examples you will hear, are well familiar with.

But just a little sidebar that it's interesting when you're on a committee, and I'm sure all of you have this impulse, you move from educating yourself and learning arguments that you've heard of but you haven't really thought about all that much, moving from that posture to becoming an advocate. And if you're not naturally an advocate, it's a funny feeling that all of sudden you are out there being an advocate. And I warn everybody who in the future goes on one of these committees that it is a very active process that you are taking on.

Finally, to future issues, there's a wonderful cartoon -- I don't know if you
saw it in the New Yorker a few weeks back -- of two Google cars pulled over to the side of the road, one a police car and one a regular car. And the cop gets out and says to the other guy, "Do you have any idea why your car pulled my car over?"

(Laughter.)

DR. GAZZANIGA: Or, "my car pulled your car over?" And so we are all deferring our mental processes to third parties, as it were, and the import of that and taking ownership of action is an issue, and the privacy violations that we all know about.

I heard from a very well-placed person that it used to be the case that when people went to work for Facebook and Google, they went to work for money. There was the gold rush, as you know, to California.

Now it's quite different. They work because they want to be part of -- and this is actually said -- be part of controlling consciousness. And when you think about it, what does that mean? Is that highfalutin' or what?

When you think about it, they have all the click-through data on every one of us in this room and how our biases are and where it shoots us off to thinking about certain things. And it is a very powerful posture to have, and that is something that has to be kept an eye on.

And I would put a lot of this under the rubric of, should this committee, the future committees, be more explicitly conclusive of what we might call digital ethics? Because I think it's coming on fast and furious. We don't have further to really go than to think about how we're now able, through various AI mechanisms and the rest, to control how we would have robots carry out various kinds of military activities.

We all know that robots are simply doing what humans tell them to do.
But there's a deeper problem, which is by externalizing the capturing and ownership of the act by the fact that a third party element is doing it, what does that do to the individual, and how easy do these decisions become, and all the rest that follows?

I think it's clear that there should be examination of these issues, and every one of us can think of a gazillion ways digital life is influencing us. I just don't think it's thought about enough.

And finally, in the Star Wars future, but Dan Rockmore, a professor of math at Dartmouth and Chairman of their Neukom Institute, is pointing out the mind-reading technologies that are with us. And these have always seemed fanciful to me, that we're going to have gadgets on our head that can clip off our thoughts and capture them and have them in a representation somewhere up in the cloud.

But it's not fanciful. Look at the last cover of Nature Magazine. There's the work of Jack Gallant at the University of California at Berkeley where he is able now to capture somatic thought in a representation of brain imaging. And can that information, if stored, be used by you? To you? Who owns it?

All these problems follow. And again, it's an example of the rapid, incredibly fast advances in technology which are growing also out of biology. They are coming together. I think that should be inclusive, too.

So any future commission has its work cut out for it, and there will be lots to talk about.

Thank you.

DR. GUTMANN: Thank you.

(Appplause.)

DR. GUTMANN: We close this absolutely marvelous session with our
final speaker, Nandini Kumar, the Dr. TMA Pai Endowment Chair at Manipal University and adjunct professor at Kasturba Medical College in Manipal, and the former Deputy Director General at the Indian Council of Medical Research.

After joining the Indian Council of Medical Research, headquartered in New Delhi, as a senior researcher, Dr. Kumar became a program officer for pharmacology, traditional medicine research, studentships and bioethics.

She's been a member of several of the council's national and international working groups and has organized several national and international agency sponsored workshops.

Dr. Kumar was a member of the Bioethics Commission's International Research Panel, which very importantly informed our recommendations in our Moral Science report. Her work also involves ethics committee activities in India for advisory bodies responsible for overseeing research involving human participants.

And I should say that that international research panel which we constituted is an example of how even a standing body can bring together an ad hoc group when very important to deliberate about an issue that came to light, in this case in the aftermath of the revelations, much belated revelations, of what happened with the U.S. government in Guatemala in the 1940s.

Thank you. I want to just take this added opportunity to thank you for being part of that and to welcome you back.

(Applause.)

DR. KUMAR: Thank you very much for that introduction, and also I would like to thank the Presidential Commission for inviting me to this meeting and be in the panel with eminent bioethicists and scientists.
Before I start talking about -- oh, sorry -- I would like to actually touch upon, in two slides, something about India. Of course it's not a strange country for most of you here, but if you look at the slide, it does show a big chunk of land among the Southeast Asian countries. And also it's big in terms of its population, reaching 1.3 billion in January 2016, although the previous census has shown a deceleration at the rate of 17.64 percent. It is a heterogeneous population comprising of ethnic groups, tribal groups. So it presents a good, rich gene pool. So genetic studies as well as genomic studies are very important in India.

And also it presents a large number of treatment-naive people. So drug development actually is a promising research in India.

When we talk of India, we think of an ancient civilization. And it is true that code of conduct started from then onward centuries back, and it was described in the Classical Scriptures and texts of the medical systems in India. And in present times, of course, we have the Ethical Guidelines.

When we consider the document, the report of what has been described as the Conduct of Physicians, the earliest one is in the 13th century BC, and it pertains to Siddha medicine, which is presently practiced in the southern part of India.

And then we also have the various textbooks which became treatises in the Ayurvedic science. And also then coming down to the Hippocratic Age, we have the modern medicine and the Unani medicine taking root from there. And the underlying principle, whether it is ancient India or is present times, is the "do no harm" principle, and that has been reflected in the guidelines throughout.

Coming to the Indian Council of Medical Research, which was set up by the British as Indian Research Fund Association for funding and coordinating research,
it got another name after independence as Indian Council of Medical Research. Presently it has 32 institutes and centers, six Regional Medical Research Centers, and 70 field stations.

In 2007, it was the NIH Director who actually inaugurated the function where the Department of Health Research was set up under the Health Ministry, and the ICMR, that is, the Indian Council of Medical Research, came under its control.

The first guidelines one year after the Belmont Report here was, "Policy Statement on Ethical Considerations Involved in the Research on Human Subjects." It had six points described there, each one with a small paragraph. It was a small pink booklet.

And then, of course, we had the science and technology developments. It was high time that we revised it. It took us 20 years to do that, and the first revision that came through was in 2000. The Central Ethics Committee on Human Research was actually set up under the chairmanship of the Chief Justice of India, retired Chief Justice of India, who was at that time the Chairman of the Human Rights Commission, and this, after a four-year public debate and calling in comments, et cetera, got released in 2000.

And after the release -- and again, this was released during an NIH-ICMR Policy Forum. So the association is there, but there was a committee. I mean, this committee actually had undertaken review of proposals submitted by the ICMR institutions, but at that time the chairperson said that we had better review this only after the guidelines come out. Then we have a framework to go by.

And thereafter it took up the role of advisory body, although it is not named as such, for policy-making and review of proposals having national significance -- for example, HIV research, research in tuberculosis, and any item that
may come up which requires a national consultation. It has around 20 members taken from every walk of life, scientists and social scientists there.

Besides that, there is a Bioethics Cell in the ICMR headquarters, which formulates and revises ethical guidelines, and is interested in furthering the education and training in bioethics; access a consultation cell, also; and also coordinates action between the Institutional Ethics Committees of the country if a problem comes up. And it's also a coordinating international collaborative agency, sort of, to resolve issues.

And coming to the guidelines, as you see lined up there, 1980, 2000, 2006, a bill was actually made based on the 2000 guideline and then it almost made it to the Ministry but got left out of there. And it was actually resurrected from there by another DG-ICMR, and it's hoped that probably this year it will be passed.

So besides the guidelines, these guidelines actually form the basis for the Indian Good Clinical Practice guidelines, which also had taken into account the ICH-GCP guidelines.

Regarding the stem cell, in 2007 we had the guidelines with the title, "Guidelines for Stem Cell Research and Therapy," which was reduced to, "Guidelines for Stem Cell Research" in the revision of these guidelines in 2013 because it was believed that the word "therapy" was actually being misused. And only the hematological application is considered as therapy. The rest is considered as research still in its infancy.

So it will be taken up on case-by-case basis by the Apex Committee for the Stem cell Research in the country.

We have the other ICMR draft Guidelines in biobanking, mental health research, dataset protection, research related to disaster situations, and very recently,
research on children and tribal groups.

Most of these are now going to be incorporated in the revision that is presently taking place. By this year it is supposed to come out. And some of the sections that were included in that have got expanded as a separate section -- for example, informed consent, vulnerability, additional public health studies, the disaster situation, research in the disaster situation because of the recent Ebola and Zika epidemics, and also the responsible conduct of research.

The other areas which were not covered earlier, like social and behavioral sciences and the biobanking, which was a draft earlier, have been included.

And I would like to mention here about the datasets, as was highlighted earlier, about the digital age that we are going through. It was felt important that we do something about dataset protection.

With that, I would like to end my talk by referring to Mahatma Gandhi’s quote because some states in our country are actually in the election process, and also the U.S. is also in that. So I thought democracy, which had been actually talked about by Mahatma Gandhi, has relevance for even human rights and the public good.

"Democracy must in essence, therefore, mean the art and science of mobilizing the entire physical, economic and spiritual resources of all the various actions of the people in the service of the common good of all."

Thank you.

DR. GUTMANN: Thank you.

(Applause.)

DR. GUTMANN: Well, there is a lot of food for thought here, and reflections. I think I can say without any qualification that your reflections are aptly as
ours are forward-looking. I mean, they are reflections on what has worked better and worse, and all with an aim of thinking about what would best lie ahead.

So I'll begin with a question, and then we'll go around. I'll keep a running list of this.

Let me begin, because Jim Childress talked about the balance between, if you will, urgency when some hot topic like cloning and Dolly comes on and long-term -- being able to reflect in a reflective way with a group that brings itself together.

So a couple of questions. We can begin with Jim, but anyone who wants to reflect on that.

To what extent were the articulated principles important? So I ask that because you said, you had 90 days and you could all agree on safety and safety for children. And in my mind, immediately, having a philosophical mind, why couldn't you or could you all agree on respect for persons underlying the need to ensure the safety of children? That seems -- that's a principle that you mentioned and that we certainly came back to over and over again. So principles, how are they important?

And the second question is at the other end of the spectrum. How important was it to, in your deliberations and how important do you think it is in deliberations, to express respect for all those positions out there which you're not going to agree with in the end?

And just not to make anything a mystery here, I think we would -- all the members of our Commission would say that was an incredibly important role of the Commission in its public role, which a commission -- other bodies, Jason, like the ones you mentioned that are less transparent, just can't do.

I mean, we heard from individuals and bodies who radically disagreed
with what we ultimately concluded. But almost to a person and body, they were very appreciative that they were not only heard by us, but heard publicly.

So that's the second. Basically principles in respect for persons and respect for persons in the actual way we conduct our business, how important is that, both in your reflections backward and in moving forward?

DR. CHILDRESS: Okay. Thanks.

Let me start with the second one. This obviously became very important for us as we were thinking about cloning, but also stem cell research, because those are very divisive topics, particularly for religious communities. And so obviously at any time of public input for a commission like this or ours, people may speak from a variety of perspectives. There's no limit on the range of perspectives that can be used.

But we also specifically solicited input from religious communities. After all, at that point in thinking about cloning, the theologians and spokespersons for religious traditions had actually thought more about it than philosophers had because, after all, it was treated more as a science fiction matter.

I never included it in my courses until after the announcement of Dolly's birth. But there had been writings by Paul Ramsey and a variety of others in religious communities about these matters. So it was quite appropriate to invite spokespersons for those, along with philosophers and others, to help us think through these topics.

And then we actually also solicited a paper on religious perspectives since no matter how broadly you try to cast a public hearing, you will not get everyone. We tried to be broader than that.

But there is also a risk because critics did respond that actually, even though we had been open in trying to incorporate all voices, it's not clear, they thought,
that we had actually adequately dealt with their voices.

Now, sometimes in these exchanges you get a feeling that sometimes people are upset because their voices didn't actually result in the final conclusion. And this has two sorts of issues here. One is that no particular voice may be in that final conclusion since the Commission is trying to address something from the broadest standpoint of the societal values at stake.

But second, sometimes it appears that it's difficult to argue against a particular religious position on a particular topic because you seem to be attacking someone's faith. And that's just a complexity that I would note, whether it is on stem cell research or on cloning or some other topic that will surely come up in the future.

So that's a complication. But it seems to me that this respect for persons and for positions is exceedingly important. It should lead to a maximum diversity in input. But in the final analysis the Commission has to work from a set of principles and values that it takes to be embedded in the society and for the appropriate task before it. So that's the first one.

DR. GUTMANN: Terrific. Terrific.

DR. CHILDRESS: The second one, about our response on cloning, listing safety first, well, because the procedure was unsafe at the time, very clearly, but we knew that was probably a temporary matter to be overcome by scientific developments, but you can use a variety of principles here in thinking about these.

And we were thinking about it in terms of the principle in not harming or imposing risk of harm on people who could not consent to that, and that happened to include children who would be created this way.

So we were working from that as a starting point. Clearly, in relation to
cloning, and we saw this in particular -- Leon Kass, later chair of the President's Council was one of the persons who testified before NBAC on cloning, and he wrote and in his presentation discussed very nicely the revulsion people experienced in thinking about cloning human beings as a starting point.

Well, that revulsion was present for many members. However, that was maybe tempered a little bit because on the Commission we had two people who are identical twins and one, myself, a father of identical twins. And if you're thinking about cloning, you're thinking in part about a delayed identical twin. And so in some ways that's a psychological response from the other side that may temper matters a little bit.

DR. GUTMANN: Absolutely.

DR. CHILDRESS: So that may be part of our experience as a Commission that was relevant -- Harold Shapiro, the Chair, being an identical twin.

DR. GUTMANN: Another one, yes.

DR. CHILDRESS: Right. So then we've recognized that there were a variety of other issues that people were invoking -- concerned about identity, concerns about threats to autonomy, concerns about threats to the family -- and all of those were important. Again, we included all of those in our report and thought about them. But in the 90 days we could not as a group adequately address them.

DR. GUTMANN: Got it. That's terrific.

DR. CHILDRESS: For particular members though, those may have been as important or more important than the safety considerations.

DR. GUTMANN: Very helpful.

Michael, did you want to weigh in on this.

DR. GAZZANIGA: That all rings true, and I would just add that by
having a committee of 17, there was every kind of -- not every, but there were --

DR. GUTMANN: That's a big deliberative body.

DR. GAZZANIGA: So as it shook out, there were atheists who were against cloning. There were religious people who were for cloning. I couldn't figure it out. It was shifting all the time.

I mean, there were some people pretty set in their ways. But there as so much change, so much dissention.

DR. GUTMANN: That's part of the mix as well. Right?

DR. GAZZANIGA: That's part of the mix. And so I think if you're one-on-one with one point of view, you might run into the problems you are suggesting. But if you're 17 people with all of this mixture, you don't get hung up on one problem.

I mean, there are people who can't get around the idea that because a fertilized egg results in you and me, right, that therefore that has the moral status of you and me. They just say, "Well, that just follows." You can't do anything with that. That's a belief. But if you say to them, "If you have your computer there and you lose the computer, you don't care. If you lose your hard drive you care because that's where the stuff is. So it's the experience of life that makes us human, not the motherboard. Right?"

"Oh, well, you've got a point there," and so forth and so on. And so the rigidity of a position is moved by these metaphors people come up with. I think it's ultimately good to have it.

DR. GUTMANN: Jason.

DR. SCHWARTZ: Just very briefly, on the diversity of viewpoint. I like that distinction that Professor Childress brought out about the public forum role that
bodies such as this can play, that groups like the National Academies are more limited in their ability to include a diversity of views. And I think that is all the more important because these commissions have not been designed, I think correctly so, to include representatives, include members who are speaking for a certain constituency. These commissions have and are selected to have membership that comes from a diversity of backgrounds, but they're not speaking on behalf of the American Medical Association or the Nursing Association.

So having a venue where the range of views can come together is important. It serves the educational mission of these groups. It helps clarify their own thinking. And as a pragmatic role, it helps these groups help respond preemptively to criticisms of the views they ultimately arrive at.

So I think it's a very important measure of impact, another one that would be very hard to quantify if we're trying to look back and assess these groups.

DR. GUTMANN: Yes, yes.

DR. CHILDRESS: Can I just add one thing to this?

DR. GUTMANN: Please.

DR. CHILDRESS: So one of the things that interested us was overlap among different groups who were presenting before us, maybe from a variety of religious groups and nonreligious groups. So that was important.

But also it turned out, in terms of the way people responded to the issues -- and this, I think, is close to some of Michael's points -- the disunity among those presenting was also important. The fact that someone could say that, "Well, wait a minute. Really, there's, even on cloning, wide diversity among religious and philosophical perspectives." The great differences then meant that in some ways we
were freer to work out a position ourselves. And the same on the status of the embryo. The diversity is often very important.

DR. GUTMANN: So if I would just take from that a point that you all implicitly made -- I think, Jason, you may have made explicitly -- unless there is that kind of disagreement, there's not a lot of value in our Commission. Our Commissions have the greatest value when there are either strong disagreements or big misunderstandings or a combination of the two, and really, it's the disagreements that are driving. Because if they're just technical misunderstandings, then it's a lot easier.

So we had that greatly in the testing children for anthrax vaccine. We heard from experts who radically disagreed with one another.

Jim.

DR. WAGNER: Nandini, did you want to say something to this?

DR. KUMAR: No.

DR. WAGNER: Thank you all. Very, very thought provoking and your reminiscences, as they will guide -- could, might guide the future are very, very helpful.

In fact, I was going through a mental experiment here. If we were going to write a letter to the White House, actually to the next White House, and say what these Commissions ought to do, there have been suggestions that we could and might highlight new issues, digital ethics on the board.

We would certainly, given the conversation we just had, talk about the importance of deliberation and collecting broad viewpoints. We would say, Jason, that it needs to be close enough and collaborative enough to make specific policy recommendations, such as anthrax that you just mentioned, but at arm's length enough to be able to contribute more broadly guidance, principles, public education.
We also might say there are mechanisms to focus on narrow areas -- the ad hoc committee approach that this Commission took; soliciting a review paper on a particular area might be another one.

The one thought that I -- I am wondering what else would go in that letter. And the one piece that I hadn't considered before, in part because of perhaps professional courtesy, was the mention of the need to update, as you were saying, as technology changes, as public norms change, as our broader understanding changes. As I say, there's almost a professional courtesy that says, "Well, gee, that was such good work by such-and-such a commission, maybe we shouldn't touch that."

Could you say a little more, any of you, about this value of recommending in such a letter that perhaps part of a charge of future Bioethics Commissions might be to look critically at updating the work in progress?

DR. GAZZANIGA: Well, one quick thought on that and an example. So I looked up on your website. Did you have a session on CRISPR or is that --

DR. GUTMANN: No, we did not.

DR. GAZZANIGA: You did not. This is obviously red hot.

DR. GUTMANN: And we actually offline considered it, and we had -- it was taken away from us -- I mean not explicitly, but we felt implicitly taken away from this group.

DR. GAZZANIGA: Right. Well, I mean, here's an example. I wrote a chapter in my ancient book 10 years ago on pre-genetic diagnosis and the problems with selection and building your child by what was known. Pick the sex, pick the -- Francis Collins came and testified. At the time he thought you could probably pick the intelligence by genetic analysis. I don't think that has panned out, but you get the idea.
Well, now -- and so there was a big to-do about that, and I think rightly so.

And now with CRISPR we're talking about constructing children the way you want them.

DR. WAGNER: Yes, but also everybody else's children.

DR. GAZZANIGA: And everybody else's, too, and then getting into the germ line, et cetera, et cetera, et cetera. That's just a totally new ballgame.

And so if you look at the building your own child kind of thing, the ultimate Yuppie ideal, it's a very volatile time. And I think that public discourse should go on.

DR. GUTMANN: Yes. Anything else on this? Jim.

DR. WAGNER: Given that interest that emerged in NBAC on revisiting the principles, particularly the Belmont Principles, we did devote some attention to that and actually set up and helped to sponsor a conference independent of that that led to a volume on revisiting Belmont that included not only Commissioners participating, but a variety of others, in part because I think that in the level of ethical frameworks, there needs to be constant attention to those to make sure -- and there are different ways to formulate different ethical concepts, and what's the best way to do it in terms of current philosophical reflection, in terms of what resonates societally, et cetera. That should be an ongoing process. So that's one level.

The second level -- a lot of what occurs in terms of the particular areas, though, will be updated by new technological developments that will, in effect, supersede the others. And so the updating will occur in part by addressing the new things that emerge, whether it's CRISPR or something else.

DR. GUTMANN: Yes. Our first report was on an area, synthetic biology,
that almost nobody had known deeply about. And those just come on very quickly, and generally are hot potatoes. They don't require new principles, but they do -- and that was the report that immediately got us working on what principles did we want to highlight and run with, because -- and responsible stewardship, which is not the highest level principle -- I mean, it's a midlevel principle -- was very important here, and I think will be for CRISPR and lots of new technologies because it's not present people who have to be respected. It's the stewardship of future people and generations of the planet for responsible human habitation.

DR. CHILDRESS: I think that's an important addition that also broadens from the Belmont Report that focused especially on research involving human subjects. And while that can well fit there, nevertheless it directs our attention to a broader range of concerns.


COL. MICHAEL: Dr. Schwartz, Jason, in your three models you describe a reciprocal emphasis of independence based on the three models, and predictability of impact on the U.S. government.

In Dr. Childress's discussion of NBAC, he focused on advice to U.S. government, but also on the impact on the general discussion of bioethics as done in the public domain, something we heavily favor on bioethics education.

Have you reflected on your three models in terms of -- other than impact on U.S. government, on the other facts that Dr. Childress raised?

DR. SCHWARTZ: So yes. I mean, they are interesting, and I think our framework, taxonomies, whatever you want to call them, are compatible because my question is thinking about if we're going to situate these sorts of advisory structures
within the government, how might they look? How might they be optimized in terms of structure and design?

But Professor Childress's companion framework, I think, raises really important and interesting questions in its own right in terms of when we have an issue that requires deliberation, how can we structure the expertise, whether it's within government or without, to have the right subject matter expertise at the table, the right range of voices, the right range of perspectives, and to give it the venue that is appropriate for the questions it raises.

We shouldn't underappreciate the fact that a Presidential Commission has a visibility that, aside from public participation and public access, signals the importance on the part of the government of an issue being considered there.

So I think there's a complex -- and I don't mean to dodge your answer, but there is a complex mix that is, as Professor Childress says, context-dependent on the issue, the question it raises, the technical questions it raises, and the normative questions it raises, with a little dose of politics -- we can't be naive -- mixed in as well.

DR. GUTMANN: But could I just push anybody a little bit more on this? Because I think what Nelson brings up is really important.

If it just raises technical issues, frankly, the public and the media are not going to be very interested in it. It's only when it raises real, at least apparently ethical, issues that there is going to be this great interest in it.

And I think that's one reason why the Presidential Commissions were not only set up, to begin with -- look at the radiation experiment -- but every President has felt the need for it because there needs to be at least something that is arm's length to have that credibility to it.
So back to Nelson's question. How does that figure into your assessment of the work of a commission?

DR. SCHWARTZ: Absolutely. The credibility matters. The idea that these groups can keep some degree of distance from the advisors who they've been asked to advise is integral to whether these groups will have any effect whatsoever.

So finding that balance between having the right voice, the right seat at the table there, is incredibly difficult. But it's things that both commissions and government sponsors in the future need to be attuned to because it really matters whether these groups can do what both the participants and their government sponsors want them to do. I think it's critical.

DR. WAGNER: If I could just comment.

DR. GUTMANN: Yes, go ahead.

DR. WAGNER: I think you may be treading too lightly on this. Are there not examples, historical examples, where we have had the government policy and direct public connection?

I'm thinking if you go back to the roots of agricultural extension, where everything from economic profitability to, more recently, climate sustainability and stewardship of natural resources, have come from people, all paid by the government in this case, but who actually are able to have that dual impact on what will policies be and what also it must inform, advise, and assist the public.

I think we should have a little more courage about the prospect that our commissions could do both of those things very, very powerfully.

DR. SCHWARTZ: I think they can, and I think they have, by and large. Absolutely. I don't disagree with you on that.
DR. GUTMANN: So, yes, it's something we've worked hard at and hope to pass on to future commissions. Great.

I have Barbara next on the list.

DR. ATKINSON: Hi. Thank you. A great panel.

I'm interested in the politics of it. This is political season, and as we're thinking about the next president and what that might mean, I really am interested in how you think that plays into it.

I can see, because it's presidential, it gets more visibility and more stature. But I think if you could make the National Academy of Medicine, for instance, be more openly deliberative or if you could put a commission that crosses administrations, would it make a difference? Or is there something better about this structure of each new president appoints his or her commission?

DR. GAZZANIGA: Well, I think Washington's full of highly reasoned reports that are never read.

DR. GUTMANN: Yes, that's true.

DR. GAZZANIGA: So as I said, the perfect storm of a public issue and a very public discussion of the issues, and this is going to come up continually, I think, in the next 15 years, in the topic you have examined, neuroscience and the law. I mean, the rate of information in that field is staggering, and it's going to very much impact people's thinking.

And while the various arguments that will be made in the legal system and their acceptance through the appellate system -- that's slow, and there's going to be a large public discourse that is going to want to know the answer to: Where are we placing responsibility? Are we going to keep it on the individual or are we going to
have excuses expanded, et cetera, et cetera, et cetera?

These are hot issues. And if you can imagine, somebody commits an egregious crime and there's this incredible defense based on neuroscience that happens to be true, where is that going?

That will be red hot, I think.

DR. GUTMANN: So one of the really interesting points that you just made, I think, is a big divide between the past and the future. There is no single public anymore as far as listening to the news and digesting the news. So that issue will definitely get a public's attention. If there's something with regard to children or mental illness or cloning, that will get a public's attention, but it won't be the same public.

In the past if something were on the network news a pretty much single public listened to it. That is ancient history now, and it will never be recreated in our lifetimes. There are multiple publics. We've seen it for each of our reports on controversial issues, whether it's Guatemala or neuroscience or anthrax vaccine or synthetic biology. Those all got a lot of press, but the people who -- except for the science reporters and the -- even academia is much more fragmented than it used to be.

So I think that's another reason to have a standing commission that speaks -- that can bring different expertise from different areas, but actually doesn't fragment, doesn't contribute more than necessary to the further fragmentation of the public.

Jim.

DR. CHILDRESS: Can I respond also? There's no way obviously to avoid the political context, and it seems to me one thing that probably your upcoming report will do, and some broader discussions have tried to do also, is actually to shape
the way in which such a commission is actually conceived and structured.

DR. GUTMANN: Right.

DR. CHILDRESS: That I think is exceedingly important.

First of all, we expect the President to appoint a commission that will be closer to his or her values. Okay? That we expect. But if that's structured in such a way that best practices get built in from previous commissions as to how things might work, and if we keep in mind the role -- and you are right. The public is fragmented, publics -- but still, there is a matter of public justification that occurs.

DR. GUTMANN: Absolutely.

DR. CHILDRESS: And so that may tie into different publics. But nevertheless, it's an important part of the process. So any commission which present its report that has already involved public input, but now it's presenting it to the public and there is in the report and the follow-up a justificatory process that I would never underestimate, that helps to keep it probably from getting too extreme on one side or the other.

DR. GUTMANN: I think that's extremely important, to use "extreme" in a positive way. It's just essential that any body, a commission, speak to the broadest possible public by using principles and justifications. And that would apply to, certainly, law and neuroscience. We have worked really hard to do that.

Okay. Next, Christine.

DR. GRADY: So first, thank you all.

I was thinking, along the lines of trying to articulate the goals of the commission like this, it seems really interesting to think about the selection of topics. And in so many cases as you described them, somebody said -- I think maybe Jim said -
- most commissions have looked at human subjects research or emerging technologies.

Or maybe Jason said that.

DR. GUTMANN: Uh-huh, Jason.

DR. GRADY: When you think about the topics that you all spoke to, your respective points of view spoke to, and also the topics that we've taken on, they are often a newer, novel, public-scaring technology, or a thing like human subjects research that constantly the public worries about.

And so maybe the goal of commissions like this is, at least very strongly, to help explain to the public how to think about it in a way or how to think about the issues.

But what got me worried was something I think Jason said, and that is that, therefore, the constant enduring issues like health disparities or access to healthcare don't get taken up by these commissions

And I know John Arras -- and speaking of him, he wanted us to do that. He kept bringing it up. But there's always a more pressing or more urgent kind of issue.

So what do you think? What should happen to those more enduring issues? What kind of a body should take those up? And should it be a public commission or should it be some other kind of group?

DR. GUTMANN: Just since this is a public record, we did bring it up in almost every report in which it was relevant.

DR. GRADY: Oh, no, I know. But I mean as a topic.

DR. GUTMANN: I'm not correcting. I'm just saying that the difference is -- well, Christine's question is: Should it be brought up as its own topic as opposed to or in addition to having it a principle, which we had of justice and distribution of the fruits
of synthetic biology, and the way in which human subjects are protected across all the board? Should it be its own, and how would that work? Because we actually talked about that a lot, but I'd be interested in what you think on that.

Jason, you brought it up. So maybe you should address it.

DR. SCHWARTZ: No. I think it's -- my own inclination is to agree with Professor Arras's view and the one that Christine is relaying, that there are opportunities here. Time is limited, as I've said in my remarks, and these choices are often constrained on commissions both by the emerging, literally emerging issues for which a request is specifically asked or, in the founding documents of these commissions -- the President's Commission of the 1980s, the NBAC of the 1990s -- where the charter specifically gave a list of issue.

So often the choices, the available time and freedom to go off in directions that the commissioners themselves feel are germane and timely and worthy of the forum that these commissions provide, it is often not of their own doing that the list of topics, if you look at 40 years of reports, looks the way that I've summarized.

But I think there's a real venue. About seven years ago your predecessor had a similar hearing to look back and look ahead as it was concluding its work. And Nancy Kass from the Johns Hopkins School of Public Health spoke very eloquently and persuasively about the role that public health issues raised that a commission like this could weigh in on fruitfully, and I agree with those views.

But these are tough choices. That's not minimize the importance of the work these commissions have done. But trying to figure out where its resources can most fruitfully go to thinking about the health of the population are difficult questions.

DR. GRADY: Maybe there needs to be more than one.
DR. CHILDRESS: Perhaps, or maybe an especially targeted one. That may be one that we bring together. I mean, there may be a reason for bringing together experts and members of the public who could deliberate specifically about this.

DR. GUTMANN: Yes.

DR. CHILDRESS: But I am sure that what you recommend going forward in terms of future commissions, there needs to be -- obviously there will be directions provided. But there needs to be some flexibility in terms of the commission being able to take up its own tasks. And again, we did that, but it fell under the larger rubrics to which we were assigned.

One exception historically that I think is important is the President's Council in the early 1980s decided to take up a topic that was outside their mandate, and that was foregoing life-sustaining treatment. It became one of the very influential reports on that.

Now, that's a much narrower topic. But at the time it was huge and underdeveloped. That ended up being a significant document going forward for helping think through the distinctions and actually helping get the society to what it is at this point.

This is a much harder topic and one that I think is -- when you're in constant crisis, how do you bring it to the attention of the public then and make it something that is -- so I very much agree with that. And I know from speaking with Bill May, a member of the President's Council, that he argued for this, too, as a direction for the President's Council. So we have the voices along the way about the importance of this, but I'm not sure we have the structure or, more importantly, the political will to make that go forward.
DR. GUTMANN: So I think this is worth just dwelling on for a moment. There is nothing in our charge that precluded us from taking on the distribution -- so the topic we're talking about is the just distribution of healthcare. Nothing in our charge that precluded us from doing it, and we had it as a principle, and we deliberated about it publicly and actually highlighted it in all our reports.

The question, and it's still an open question in my mind because I've written on this, but my first foray and one of my most cited articles is, "For and Against Equal Access to Health Care."

The question in our mind is what we would accomplish by doing it, and it's in the context that we've been in over the last seven years. What would we accomplish?

And it was we collectively, not unanimously, but we collectively thought we wouldn't accomplish very much. That is, we could either -- so just think of the context we're in. We could either simply endorse Obamacare. We could be critics of Obamacare and say how it could be improved. Right? Or we could recreate -- and I say this strictly speaking -- we could recreate one of several theories of justice out there in the distribution of healthcare which would -- because there are -- that would bear little resemblance to Obamacare or -- it wouldn't be a criticism of Obamacare. And it's not clear how we could do that in seven years.

So you have to be -- what I'm suggesting is if you're interested, as we all are, in the distribution of healthcare, you've got to zero in on something specific if you're not going to either recreate the academic literature, which is the third option, endorse what's happening, or be a critic of what's happening, which feeds into a terrible political situation, since I'm also a political scientist, that we're in.
DR. WAGNER: Absent a context in which you can make specific recommendations, which is the fourth thing. I'm sorry.

DR. GUTMANN: There is no -- in the seven years we have been in session, there is no specific recommendation about Obamacare other than fix the darn Internet system, the web thing, that had any chance of having any reception out there other than people saying, "We told you Obamacare is broken," "We told you Obamacare is right," or, "We told you there should be a single payer system or some version of that."

Yes?

DR. GRADY: I think my point was even broader than just distribution of healthcare in that it seems as if commissions have historically responded to -- I don't know if crises are the right word, but some new finding that raised a lot of people's hackles.

And so that's what a lot of commissions have focused on. And you're right. There are opportunity costs. You can't do everything. But it does make you wonder that the longstanding, enduring issues don't get attended to by public bodies. Now, they do get attended to by academics, hopefully, and there are other -- there are venues. But there's not a public deliberation or public education role that deals with this sort of --

DR. GUTMANN: Right, and that's a serious issue about what publics or the public will pay attention to. We'll see. Our bioethics education and deliberation is a longstanding issue, and you'll see how much public attention it gets because it's not hot button.

DR. GRADY: Yes.
DR. CHILDRESS: There was one exception, and that was the President's Commission in the early 1980s on securing access to healthcare. And that was an interesting one because it included people who had been appointed, as I recall, by Carter, but also by Reagan, and so you actually got an overlapping consensus. It wasn't fully satisfactory, but nevertheless it did, for the time, did for the time help move the discussion a little.

DR. GUTMANN: Yes, at a time when it was a -- there wasn't what there is now. And 1980 is ancient history as far as public attention goes.

I want Anita and Nita to have a chance. So Anita.

DR. ALLEN: Me first?

DR. GUTMANN: Anita was first, yes.

DR. ALLEN: Okay. Well, so much of what I would like to engage the panel about has already been discussed. So I'll just talk about a couple things that are on my mind.

I just want to thank you all for coming and let you know that for me, being a member of this Commission has been a true highlight of my career. I'm really grateful for the President for appointing me.

So I was recently in Berlin at a world summit of bioethics, National Bioethics Commissioners. It was very, very interesting. And one of the things which happened to me there is it made me feel even sadder about leaving this Commission and about the fact that we don't have a standing commission instead, professionals who work for the government for a long, long, long time to build expertise, to build relationships, and to be able to delve into a lot more topics.

So I feel like I would like somehow or other for the issue to be on the
agenda that maybe the United States should have a more enduring bioethics body. I think it would be very beneficial. I do think that bringing in fresh expertise is a very helpful thing, but I don't think what I'm saying is inconsistent with the idea of a diverse, evolving membership.

The other thing which happened in Berlin that I found interesting is at one point the meeting became extremely tense because you had a contingent of representatives from Africa who were saying, "We should be talking about water and famine, not cyborgs and CRISPR and designer babies."

And there is this divide across the world. And as we're sitting here today talking about different models of bioethics commissions and issues that we talk about or are not talking about, I mean, if you put that same conversation in a global context, we are so far from agreeing about it, what we should be dealing with as bioethicists.

And it is absolutely important in some countries that they confront the ethics and justice issues around water and food. And maybe we have a luxury in the first world of talking about gene editing and cyborgs. And I think it is important to talk about gene editing and cyborgs. I really do. But as I do that now, having been to this world summit, I feel a bit more self-conscious about the fact that we have that luxury.

And one more thing I want to say. It kind of relates. And by the way, I love the reference to Gandhi, who is a big hero of mine. I do think that the public good and democracy are very important kind of framings for everything we talk about in connection with bioethics.

But I wanted to talk about the choice of topics, and we talked about it before. I just wanted to say one thing that also relates to my trip to Germany, and that is that I'm in this room displaying what the German Bioethics Commission has talked
about, and there's a thick pamphlet about the topic of intersex. And I thought, "Intersex?" I mean, I couldn't imagine the U.S. Bioethics Commission, any of us from Bush, Clinton to Obama talking about intersex as a topic for the commission.

But why not. Right? Here's a topic which they felt was a very clinically significant problem faced by physicians and families. What do you do when you have a child who's either phenotypically or genotypically ambiguous or uncertain or non-matched? What do you do about that? And how do we apply notions of autonomy, respect for persons, et cetera, to this kind of clinical issue?

There are lots of clinical issues that the commission could delve into. I know at one point some of us, maybe the two Nitas, thought that talking about fertility as being a very important topic. I mean, fertility medicine is raising all kinds of important issues, not just for women, but for families and for the society as a whole. Why don't we focus on the clinical issues around that?

So I guess if I have a question it is: what do we do about the gap between practical clinical issues, some of which may involve controversies, and then these larger issues about justice and resource allocation? And how do we do it in a world which is both developed and underdeveloped?

DR. GUTMANN: Nandini, could you talk about the -- you come from a world that is both developed and underdeveloped in many ways.

DR. KUMAR: Yes, I was just thinking about that when I was listening to you because in India you get the highs and the lows and a lot of the middle, mediocre standards.

You talked about the intersex. I would like to point out that in the biomedical section we are actually talking about the LGBT and about emerging
technology. Of course, the report on synthetic biology was actually referred to, and we have included that as a section. But we are actually covering synthetic biology, nanotechnology, and devices with IT, information technology.

So we are restricted to that right now. Of course, the points that you had highlighted, we have reduced that into salient bullet points in that, which is workable, more reasonable, than talking about so many things in an elaborate manner about the technologies.

The water and food is a problem in many parts of the country. That is there. There are actually other projects trying to address that. There is a huge number of research projects involving this aspect in the country, but these are mostly funded by the NGOs and a little bit by the government. The Indian Council of Social Science Research doesn't fund that much, but the Indian Council of Medical Research funds a number of projects.

But the funding, the present government, the funding has not been increased. Actually, there is a lot of struggle about the funding. So we need a number of NGOs to step in or philanthropic societies to step in to cater to these aspects.

DR. GUTMANN: Nita, and then I would like Steve. Steve can have the last question.

DR. FARAHANY: Oh, Steve always gets the last word.

(Laughter.)

DR. FARAHANY: Thank you guys, everyone for coming today. It's nice to both reminisce about what's happened in the past as well as to give us a chance to hear your reflections on your experiences and for us to reflect on our own experiences on the Bioethics Commission. I'll remind us this is not our last meeting. So let's not let
this be our true last conversation about this.

I likewise have thought for quite a long time that the model of the Bioethics Commission as an executive order-created commission is problematic, for practical reasons, for impact reasons. Practically, we were talking just recently about where do our reports live after bioethics.gov is handed to the next one? And happily, Georgetown has been kind enough to create a repository, but certainly the public doesn't necessarily know about that.

And instead of having this kind of institutional knowledge that's kept and shared and passed on from commission to commission, you have go hunting and pecking to try to find these things, which I think is problematic.

But as we think about what it would look like to have a longstanding commission and what some of the tradeoffs might be, I hope we can reflect on that as we give a recommendation about having something like a longstanding commission.

The Nuffield Bioethics Council, I think, is an interesting model and certainly they are incredibly productive in the number of reports and topics that they take on.

I've been frustrated at times at our inability to take on, I think, some of the most controversial topics, whether it's healthcare access or fertility issues or really being able to forge some of those kinds of conversations. But I also appreciate that by sitting in the Executive Branch and being called the presidential commission, that that gives both convening power and the ability to really, I think, engage in the public's discourse in a way that we couldn't engage otherwise.

And so if you think about all the problems we've been talking about here, which include: How do you have a longstanding commission? Where would you place
it? Who would it be advising? Is it a congressional advising committee? Is it an Executive Branch? Where does it sit? And what would its charge be? I think some of the things we have consensus about like, for example, you'd want to have some changeover, and consistent changeover, in order to bring in fresh ideas.

But where would you put it given your experience, and what would you think it would be -- what would be the impact of where you would put it, given where you would put it?

DR. GUTMANN: And Nita's question is where would you put it, practically speaking. That is, it has to be able to be put where you recommend it would be put. So if you say Congress, for example, how is that going to happen? If you say --

DR. FARAHANY: This is influenced in part by being a lawyer. Right?

DR. GUTMANN: Right. Right.

DR. FARAHANY: So who creates it and for what purpose is it created?

DR. GUTMANN: So it's still visible.

DR. SCHWARTZ: So one historical point and then one point to this question. And what we're seeing of this presidentially executive order-created model seems to be an artifact of political debates over the 1980s. It was called the President's Commission of the 1980s, but it was congressionally chartered and had members from both commissions, and that led to awkwardness. There was another group in the late 1980s that didn't even get started because of the politics of abortion and membership issues.

So the model that some have advocated for is something like the Office of Technology Assessment, which is talked about nostalgically in many corners. It was created by Congress, housed within Congress. Something you cannot guess. You could
think about a model like the Congressional Budget Office or a group like that that is established by Congress that somehow exists somewhat removed from the politics of the day. If it's not going to be within the Executive Branch, I think that would be the next logical place, but brings, as your expression indicates, concerns of its own.

DR. FARAHANY: Right. So I appreciate that and also the historical context of it. There is a value to it being put into the Executive Branch. And we do have the National Academies, which serve a similar function or can serve a similar function.

So how do you give the stature, the presence, the convening power, and at the same time not end up with all of the political problems, et cetera? How do you create that perfect -- where do you situate it for the perfect commission?

DR. CHILDRESS: Having been a member of the Bioethics Advisory Commission, the congressional one, in the late '80s, I would suggest you not go in that direction because what happened with the abortion controversy was because a couple of members died and they could not agree on replacements. That ended it after a few meetings.

DR. GUTMANN: Steve.

DR. HAUSER: Well, Amy, my question is a little bit narrower.

DR. GUTMANN: No, please.

DR. HAUSER: So I'm sorry to end with a narrower question. But one of the issues that we've focused on since the beginning, and will on the last report, is education. And education across the lifespan is one component of education.

Michael, you mentioned Jack Gallant's recent work with these semantic atlases that he's creating, and it begs the question: How is this information
communicated in a way that's digestible and actually accessed by as many people as possible?

We've thought and recommended web-based, FactCheck, Neuroskeptic, that kind of thing, but I wonder if you, or any of you, have ideas moving forward of ways to give, more effectively, the correct information free of baloney to the general public.

DR. GAZZANIGA: Well, of course, there are a lot of organizations that think they do this. AAAS, the popular magazine "Scientific American," they constantly see as their task to translate information for the general reader.

So this is a big country with all kinds of outlets, and I don't think it has to funnel through one here at all. I think a lot of this stuff does get done very well.

What concerned me about the context of all these questions is that my experience on the Bioethics Council, when we came out with a report, there was always the opportunity for a minority report. Now, did you have that?

DR. GUTMANN: Yes, we had the opportunity. We actually aimed to see if we could reach consensus, and we did on all the issues, especially given the context of our time. We thought if we could it would be a great service to the issues and the public. But we could have had a minority report if we had wanted one, yes.

DR. GAZZANIGA: Yes. If you really are going to tackle the enduring questions, there's going to be a lot of disagreement about everything from healthcare to euthanasia to enhancing drugs. The list goes on and on. There are literally lots of points of view about it from smart people.

And we were always told that the American culture, or let's say the American people, do not like to be moralized to. Right? And so that was always the
rhetoric. Here's the way you should be thinking about this. Right?

So that's why such a council would probably have a richness. It would be a way to collect together the richness of opinions about difficult issues. If it was phrased that way, I think it would be highly accepted, but that's a very skilled task.

DR. GUTMANN: Steve ended on an actually broad -- broader on education. And we are going to conclude this session, not our work or this day, by really thanking you for an incredible set of comments and input into our ongoing deliberations, and real attempt to see how much outreach we can do with what we've done, and then think about what comes next for the country.

I should say for all of us it's a real honor to be asked by our President to serve, and we thank you for helping us in that. Hear, hear.

(Applause.)

DR. GUTMANN: We're going to adjourn for an early lunch, and reconvene at 12:30.