



Presidential Commission
for the Study of Bioethical Issues

TRANSCRIPT

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SESSION 2: DEMOCRATIC DELIBERATION IN BIOETHICS

DR. GUTMANN: Welcome back, everybody. I'm sure our other Commission members will appear momentarily, so I'm just going to get started. We are going to continue our discussion of the role of deliberation in bioethics, and we have two distinguished speakers.

We'll begin with Dr. Daniel Davis, who is the Director of Bioethics at Geisinger Health Systems where he leads the systems' bioethics initiatives. Dr. Davis served as senior advisor for bioethics in the Office of Science Policy at the National Institutes of Health where he focused on ethical issues in biosecurity and on the reform of the common rule, which we have discussed in previous reports. Before taking up his post at the NIH, Dr. Davis served as Executive Director of our predecessor Commission, the Presidential -- the President's Council on Bioethics. Welcome.

DR. DAVIS: Thank you very much, Dr. Gutmann. And thanks to the Commission and to Lisa Lee, Elizabeth Fenton and Esther Yoo for their advice and their guidance in preparing these remarks. I'm honored to be here before a Commission whose work I very much admire.

In the next few minutes, I'm going to take on two tasks; first, to reflect on those three-plus years as Executive Director of the President's Council on Bioethics and, second, to push a bit on the meaning of an authentically public bioethics, a bioethics that takes seriously and seeks to practice what I will call accountable deliberative engagement. And with this second task, I'll draw on two other sources of experience, my experience as a medical school dean for evaluation and assessment and my more recent experience at Geisinger.

So let me just start with the fact that Dr. Pellegrino and I were the replacement team brought in to substitute, in Pellegrino's case, for Dr. Kass, who had stepped down as Chair and, in my case, for Yuval Levin, who had accepted a position on the President's Domestic Policy Council. We inherited a Council with a very broad, diverse presidential mandate.

The Council's charter made no reference to democratic deliberation, nor does the charter for this Commission, but unlike this Commission, the Council did not at the outset of its work under either Dr. Kass or Dr. Pellegrino underscore a commitment to democratic deliberation by identifying it as a key principle for its work.

In fact, although I was very well aware of the concept or idea of democratic deliberation, I cannot recall ever hearing it even mentioned in the three-plus years that I served the Council and was privy to its public discussions as well as to the exchanges that occurred behind the scenes as we, Dr. Pellegrino, I and other members of the staff explored strategies for, in a phrase, "bringing our work to the public and bringing the public to our work."

The plain fact of the matter was that our Chair held to a rather "parsimonious" -- and that was a word he loved -- or minimalist view of public engagement. The Council's first and foremost task was, in his mind, to quote, set out the issues as objectively as possible, provide sound arguments

for competing positions and present them publicly in a restrained, balanced way. Our purpose was to provide the basis for the kind of moral considerations upon which good policy rests.

As you may have probably surmised by now, I had a lingering discomfort with my beloved mentor's minimalist approach, a discomfort that was accentuated on an annual basis with the imperative to complete the mandatory FACA assessment of the Council's impact.

According to one prominent school of thought, and I think it fair to say that Pellegrino was an adherent of this school, a national bioethics commission is to function as a microcosm of the society, the public that it ultimately serves modeling at least one dimension of democratic deliberation as you've defined it in your reports, beginning with your first report, "New Directions," quotes, respectful debate of opposing views carried out through an ongoing public exchange of ideas in which competing views are advocated often passionately.

What was conspicuously lacking, at least with the Council's work, was another dimension of the principle as you've enunciated it, active participation by citizens.

For nine years, I was on the faculty at Georgetown Center for clinical Bioethics, which Dr. Pellegrino founded in 1992, and I was the School of Medicine's Associate Dean for evaluation and assessment.

The period from the late 1990s to the mid-2000s was one of significant ferment in American medical education as the accrediting bodies began to reshape the framework leaving aside structure and process and emphasizing in an unprecedented way the objectives and outcomes of physician education and along with those objectives and outcomes, evidence-based approaches to program evaluation and learner assessment.

Those of us who functioned as stewards of the educational process, deans and faculty, not only had to define clearly its anticipated -- its ideal objectives and outcomes, we also had to develop and institute assessment methods for enabling our learners to demonstrate that they had indeed achieved the objectives, attained the outcomes. More so than ever before, we had to be accountable.

This proved to be and continues to prove to be an exceptionally formidable challenge. How do we gather and produce evidence to assure us that a medical school graduate has attained a developmentally appropriate level of competence in his or her communication skills or, better yet, consistently exemplifies such professional attitudes as compassion or excellence or respect for other members of the healthcare team? We can't just throw up our hands and slight the formidable nature of the challenge. To be accountable and to prepare our graduates for a lifetime of such challenges, we have to devise workable, reliable methods of assessment.

I think that the same drive for accountability should animate a Bioethics Commission's thinking and practice with respect to that other dimension, the most challenging dimension of democratic deliberation as you've defined it, active participation by citizens.

There are, as you acknowledge, two aspects to this dimension: Public education, the focused effort to lead citizens to an informed understanding of some usually rather complex issue in biomedicine, an effort that might utilize any number of educational methods, and the direct engagement of an informed citizenry in deliberations as a Commission.

Let me begin to describe how this might be done and done in a way that would enable the Commission to assess the efficacy and outcomes of its educational initiatives and the impact of those initiatives on the capacity of citizens to be so engaged, as well as the impact of that engagement on your deliberations by turning to a more recent experience at Geisinger, and specifically with the axon sequencing project that I mentioned earlier in my remarks.

Geisinger established a biobank in 2006. And it established that biobank only after conducting a survey to assess the community's attitudes about biomedical research, in general, genetic research, in particular, and approaches to consent. And since then, almost every modification of the consent process and forms has only been undertaken after a similar engagement.

In 2013, for instance, we held a series of focus groups, and the purpose of those focus groups was to explore biobank participants' attitudes toward the return of genomic results. They had rather surprising results. There was almost overwhelming demand that every result be returned, no matter what its nature, and also included within the Electronic Health Record of those patients and participants and only on that basis did we then institute a change in our consent process to allow for return of results.

And with that, we commenced a project in 2014 in connection with -- or, rather, collaboration with, Regeneron Pharmaceuticals, a large biopharma based in Tarrytown, New York. We've recently announced that our project goal is to consent 500,000 Geisinger patients to participate in this project.

We also intend to return results to 2 to 3 percent of those participants who have a clinically actionable genomic result, and we're using the ACMG 2013 list in order to determine those results.

There are quite a few unresolved questions with this process. One set of questions concerns our approach to the fact that the genetic variance return to an individual participant will have implications for the health and healthcare of their family members. If our justification for returning results rests largely on a duty to care, doesn't that same justification compel us to care as well for the affected family members?

The other sets of questions concerns our approach to the return of results to My Codes -- and that's the name of the biobank -- pediatric participants. For example, should we inform a child or her parents here and now of her risk for an adult onset disease?

We've already set a precedent for engaging participants in questions like these, as I said, and basing our institutional policies on the outcomes of that engagement.

The previous survey and the two sets of focus groups were important vehicles for engagement, but on a relatively small scale. As we go forward, we've developed plans and sought funding for a strategy that will utilize deliberative engagement forums involving larger numbers of participants.

And it's important here that I acknowledge our debt to the work of Ruth Faden and Nancy Kass at Johns Hopkins Berman Institute of Bioethics where with funding from the Patient Centered Outcomes Research Institute, they've been utilizing deliberative engagement forums to educate and elicit citizen perspectives on alternative strategies for consent and disclosure in how systems-based quality improvement and comparative effectiveness are searched.

I was an invited participant at such a forum where the perspectives of organizational institutional stakeholders were elicited after a very succinct educational program. At least two other forums were held with hospital and health system patients as the participants, and one of the two was conducted at Geisinger for about 70 of our patients.

So let me bring my remarks to a conclusion -- I see I have less than two minutes -- by asking you to imagine with me that you've decided as a Commission to take up the pressing problems associated with the constrained supply of human organs and the ever-mounting demand, especially for kidneys. I checked this morning and the waiting list now numbers 123,000 individuals, while the annual number of donors continues to hover around 14,000, with 8,000 being deceased, five-plus being living donors.

Proposals for narrowing the gap between organ supply and organ demand range from moving from a first person to a presumed consent regime, offering financial incentives to donate to the family members of the newly deceased, establishing, in one form or another, a market in human organs.

Many of the proposals would alter the current ethical framework in ways that some applaud and others deplore. Imagine further that you have decided not only to invite expert testimony on this topic, not only to consider and debate the alternatives, the arguments pro and con in your public meetings, you've decided to bring American citizens, at least a few subsets of the citizenry, into direct engagement with you in the course of your deliberations.

Imagine further that you've decided to hold several deliberative engagement forums around the country, perhaps one in a rural area like my own, another in an urban area like this and so on. Each would begin with a focused educational program designed for the non-expert free of jargon and providing an introduction to the practice and outcomes of transplantation, its benefits, risks, and burdens as medical interventions, the dynamics of supply and demand and the current ethical and legal framework. There could be some way, then, of assaying the participants' understanding of the material as a prelude, then, to a structured exchange where the pros and cons of the various proposals were presented for discussion, debate and deliberation with the participating citizens directly engaged.

Any report, any recommendation that you as a Commission might decide to issue would bear the imprint of active citizen participation with an accounting of how -- to what extent that participation has shaped your findings and proposals.

Back in 1994, just before President Clinton established NBAC and ended a period of several years when there was no National Bioethics Commission, John Fletcher offered a rather bare bones definition of public bioethics as inquiries supported by Government to identify the major ethical considerations and public policy implications of controversial issues in biomedicine.

Given your commitment to democratic deliberation, especially to the dimension of active citizen participation, I think you could put a good deal more flesh on the meaning of public through an experiment along the lines I've suggested. Thank you once again for the honor of being here today.

DR. GUTMANN: I'll turn on my mic, as I always tell other people to.

Next, I welcome Dr. Jason Schwartz, who is the Harold T. Shapiro fellow in bioethics at Princeton University Center for Human Values. Jason holds an appointment as a lecturer there. His research examines policy, historical and ethical issues in medicine and public health. He has written widely on vaccines and vaccination programs, decision making in public health policy and the structure and function of scientific expert advice in Government, all of direct interest to this Commission.

Beginning in July 2015, Jason Schwartz will be Assistant Professor of health policy and management at the Yale University School of Public Health, with a secondary appointment in the section of the History of Medicine at the Yale School of Medicine. Thank you for joining us.

DR. SCHWARTZ: Thank you, Dr. Gutmann. Dr. Wagner, Commission members, it's a privilege to be here, as it was a privilege to support your work as a member of the Commission staff in its first year or so of work in 2010 and 2011.

I've been asked to discuss how National Bioethics Commissions have engaged in public deliberation in the past, whether explicitly or implicitly, and I take public deliberation to mean both deliberation in public among themselves and deliberation with the public, and to reflect on how those methods may have influenced their recommendations and their impact of those recommendations.

And I'll focus on the first four of these six National Bioethics Commissions, four of your predecessors here, very briefly. We could say more about them. We could say more about international Bioethics Commissions, other Commissions in Government agencies, state efforts, as well as groups that don't have ethics in their name, but nonetheless are doing ethical work in advising the Government.

And all of these groups did engage and do engage, of course, in some form of public deliberation in large part because they have to at the very least as committees subjects to the Federal Advisory Committee Act. This was a bill in the 1970s that did not have biomedicine and science

at its core as an impetus for why it was passed, but nonetheless has been very influential in dictating the establishment, the renewal, the reporting requirements of Federal advisory committees and requirements regarding public meetings, public deliberations, public access to meeting materials.

Now, of course, there's the letter of the law and the spirit of the law, and we see a wide variety in terms of how committees comply with this. In some cases, public meetings are closer to theater, public comments are closer to pro forma. I think, on balance, the National Bioethics Commissions have done quite well relative to other advisory committees.

But throughout the Federal Government, the -- and I see some clock issues here at the moment -- I see throughout the Federal Government there have been really enthusiasm for these groups, particularly in health agencies, in terms of opening up the decision-making process and also increasing the legitimacy of the decisions that are reached.

As far as your predecessors, the first National Bioethics Commission in the 1970s, the National Commission best known for the Belmont report, this quote from Brad Gray, the sociologist who was a member of both this Commission staff and its successor, noted that the divisiveness of the issues, fetal research chief among them, could have destroyed the possibility of respectful working relations, but the chemistry worked another way. Members took each other's views seriously and sought common ground on which to base recommendations. And those are things we see a lot when Commission members and staff reflect on their work with each other. The National Commission's meetings, like all of these groups, were open to the public. The federal register meeting announcement solicited ten-minute public comments that could be submitted in advance to the staff director for consideration at the National Commission's meetings.

But what about the Belmont report? What about the well-known four-day retreat that led to this -- perhaps the most influential document in the history of these National Bioethics Commissions? We have this quote to contend with from Al Johnson that noted that the Belmont Commissioners, the national commissioners, himself among them, wanted a closed retreat so that a free-wheeling discussion could be held. A theme we hear often, the concern that public deliberation might stifle an open discussion.

Even if this was permissible under FACA, it wouldn't necessarily send a great message that this most important document came about in a way, at least in part, deliberately excluded the public. It's not clear that that's entirely the full story in that the Federal Register announcement for the Belmont meeting did acknowledge in the top right there that the meeting was, at least nominally, open to the public and people could attend if they read the Federal Register in the 1970s and were willing to attend a four-day meeting in suburban Maryland. I'm not sure how widely the meeting was promoted beyond that and, of course, that makes a difference there and we don't hear a lot about the attendance of individuals outside the core group and members and staff.

But notwithstanding this, the National Commission members and staff when surveyed by Brad Gray for that paper I quoted earlier, referred to the open, honest and public process of debate as an explanation for whatever successes the National Commission had.

More briefly on the President's Commission that bridged the late 1970s and early 1980s, Alex Capron, its Executive Director, Morris Abram, its Chair, met incredibly frequently during the three-year period when it was most active, 28 two-day meetings in 38 months, cited a wide range of witnesses, commissioned background papers, broad public attendance, broad outreach.

But notably at the bottom, Alex Capron, in the 1980s looking back on the just-concluded Commission, referred to the challenges members saw in terms of doing ethics in public. And he recognized and the commissioners recognized that it promoted a need for responsible and thoughtful comments and deliberation, which, in turn, drove everyone involved toward accessibility in the format and content of the reports, in terms of their engagement and it drove toward consensus. And this is Alex Capron's quote at the time that "it encouraged Commission members to seek the common ground that best expresses the moral insights and values of America today in light of our shared albeit not uniform religious and philosophical traditions."

Moving quickly through our historical tour, the Advisory Committee on Human Radiation Experiments, a group you're well familiar with as part of your work on historical research abuses, Ruth Faden, its Commission Chair, referred to the group as an openness commission, and I really like that language because she meant it in reference to the Commission's mandate to shine light on research that had not been well publicized or not publicized at all.

But it also refers, I think, to the way the ACHRE, as its known, went about its work, opening its own processes, opening its own mind to all the individuals who were affected by this research in the 1940s and beyond. Multi-day meetings, going to Santa Fe and Cincinnati and other sites where research of question took place and trying to invite individuals and their families with histories to contribute, soliciting oral history, soliciting considerable interviews, all of which shine through in the Commission's report released 20 years ago this fall.

NBAC, the National Bioethics Advisory Committee of President Clinton, they're, I think, unique as far as I can tell in having public members as part of their charter, specifically requiring three public members who were not philosophers, lawyers, physicians, scientists or social scientists. And Eric Meslin, that Commission's Executive Director, really believed that that was an important part of the essence of NBAC, that public participation was baked into its essence, for lack of a better word.

Now these questions about public members or consumer-members on expert advisory committees is a challenging one. Who are these individuals? Who do they represent? Where do they come from? But it's seen as an important tool in many cases.

In terms of how they went about their work, this statement from NBAC's report on stem cells in the 1990s I thought seemed instructive to our conversation today. In a section titled, "The Importance of Shared Views," they noted that their outlook was to develop policies that demonstrate respect for all reasonable alternative points of view and that focus, when possible, on the shared fundamental values that divergent opinions seek to affirm.

They're not saying democratic deliberation, but this is a section that quotes Thomas Nagel or cites Thomas Nagel, rather, on the importance of legitimacy in decision-making procedures and

cites Dr. Gutmann and Dennis Thompson on the importance of seeking common ground whenever possible.

I'll skip past the President's Council and their unique mandate to provide a forum for national discussion, Part 3, and to facilitate a greater understanding of Part 4. Dan can certainly speak far more expertly about it than I can.

I'll also just for one international point just acknowledge very briefly the Nuffield Council on Bioethics most recent report that I think you're familiar with and the remarkable range of public engagement activities that they solicited both as part of their report as well as ongoing, as I understand it, from stakeholder groups to public consultations, surveys, exercises, really interesting examples, I think, that could be learned from these comparative studies.

Well, my last two slides turn to the question of impact and turn to the question of what this means today. How we think about the impact of these bodies has been a historically challenging exercise. Do we look in terms of specific policy accomplishments that we can perhaps count or measure or appearances in court opinions? Do we think about how these groups might change a scholarly debate, again, perhaps through quantitative metrics or qualitative ones?

This paper in the Kennedy Institute Journal from two political theorists in 2004 said that, yes, those are important, but we should also think about Bioethics Commissions as public forums. So we should look at their ability to address public concerns, to engage the public in moral decision making and to inform and encourage public reflection are all critical indicators of the success of a Bioethics Commissions at fulfilling democratic purposes.

That seems right to me. It seems right to me because no matter the efforts that a Bioethics Commission can go to in terms of trying to promote policy relevance and scholarly relevance of their work, some elements of that are out of any Commission's control. But in terms of whether a Commission functions as a public forum, that's entirely within the Commission's control and seems to be an important part of what these groups can uniquely add to national conversations on the issues that they look at.

My final slide picks up on the final words written in the final report by the President's Commission, the early 1980s group, summing up a wonderful report that I know you've been thinking about and looking at as part of your own work, and I think it's a great statement that's worth reading in my final 20 seconds; that "In a pluralistic society, a Commission on bioethical issues can serve as more than a forum for airing of differences. It can articulate broad area of agreement that already exists and if it is fortunate, provide the means for enlarging the field of common agreement. It can play an important part in engendering and encouraging the process by which a vibrant and ever-developing society reexamines, revises and reaffirms its systems of values and belief." It says "a report" in the passage. It doesn't, again, refer to democratic deliberation explicitly, but certainly captures several themes at its core and I think holds up very well 32 years now after it was written.

So with that, thanks very much for the invitation and looking forward to the rest of the day.

DR. GUTMANN: Thank you very much.

And we are open for questions and comments. I'm going to begin just to give -- Jason, I'm going to pull a page out of an article that you've written which really caught my attention and in the most positive way. You break down the way the work of national ethics Commissions have approached their work, in general, and deliberation, in particular, into six models. And I just want to -- under two distinct classes; one you call a rigid grid class and the other a flexible focus class. And it's clear, at least from reading this, that you have some affinity towards the flexible focus class. But I wanted you -- under that, you have two models. Okay? One is ethics as a focal framework, where moral expertise is valued with respect to framing questions and issues at stake. I'm reading this because -- to just to refresh everybody's memory. And so that's ethics as a focal framework. And the other is ethics as a focal and normative framework, which is ethical expertise valued in framing the issues and developing recommendations as well as for justifying the overall moral framework.

And in this, I think it's just important for us as a Commission to -- as a record, you see our Commission as explicitly having ethics as a focal framework, but as not fully trying to justify the -- you know, the foundations of the framework itself, which would be going into a full philosophical defense of the framework.

Okay? So if I've -- have I characterized it accurately? This is a question for both Dan and Jason. So if we are, as we are, committed to being, you know, a public -- having some public influence, right, is it -- what are the pros and cons of trying to justify the framework as well as to articulate the framework?

So just so we all know, the framework are our principles, which we have set out at the beginning. We use them flexibly because different issues or different principles are more relevant. And we say, I think quite generally, that lots of different moral philosophies converge on these principles. So in some sense, they don't require anyone to subscribe to one particular comprehensive doctrine.

So my question is: Should a commission do more than that consistently with wanting to be a public deliberative forum?

DR. SCHWARTZ: Thank you. Yes. So this is a paper that's forthcoming in the Kennedy Institute of Journal and I want to acknowledge Harold Schmitt from here, University of Pennsylvania, who is the lead author on this piece. And we were trying to sort through how ethics figure into the work of National Bioethics Commissions, and it is this question in terms of where should ethical principles and theories, how much work should they do, how -- to what degree they should be articulated? And then particularly in terms of justifying why any given principles that may inform a Commission's review of any given issue are the right ones, whether others should be included or excluded.

And I think my thought, speaking only for myself here, that it comes down to what these kinds of groups can make in terms of a unique contribution. Where can they directly contribute to the translation of these ethical debates into policy actions by the various audiences who their

recommendations reach? That's an area where these Bioethics Commissions can make unique contributions by their structure and nature and I think lends itself to the kinds of reports that keep those audiences in mind and keep that unique contribution in mind, knowing that there are other venues, both for the commissioners individually and in the broader academic communities, to articulate in its fullness why these ethical principles are adequate or inadequate or necessary or sufficient there. And I think that's that balance that so many of these Commissions have faced, but I think it comes back to this unique contribution that these groups can add.

DR. GUTMANN: Good. Dan.

DR. DAVIS: I certainly think you have to explain as fully as you can why you've adopted the principles that you've chosen to adopt as you did at the outset of your work simply in the interest of accountability. I think when you start to look at the various alternative ways in which we might resolve a particular policy issue and really begin to drill down into the pros and cons of those various ways, you might find yourself going beneath the justification you've offered for those principles. And I think you have to go where your inquiry leads you.

But I think, at the outset, doing as you did is a very smart idea. It gives you some sense of what sort of compass we're going to use on the map ahead, given the fact that the terrain is unknown. And we may adjust it as we go forward. But just so I think you're transparent about that, you have served really one of the key requirements as far as I'm concerned as a public body.

DR. GUTMANN: Right. Thanks.

Could I now ask a, in some sense, tougher question for us? And then I'm going to open it up. We live in a very polarized political environment. And one of our invited speakers, who, alas, couldn't be here because she fell ill, Jenny Mansbridge, would have done a presentation which she shared some of which -- and, Lisa, we can put this on record, right -- in framing what a Bioethics Commission's work is in the context of being in a very polarized political situation.

Given that, Jason mentioned one prior Commission had three public members. We actually had one public member in Lonnie Ali. And she was a wonderful -- absolutely wonderful member of the Commission and she only had to step down because of the care of Mohammad.

That said, no number of public members of a small Commission could substitute for deliberative polling at all what we heard earlier, right? And so how important do you see it, given the polarization of our politics, that a Commission like ours say something, do something, recommend something that would get a representative and deliberative understanding from the public rather than the polarized very unproductive politics that we're seeing writ large in the media, for example, and in some cases in -- you know, in some cases in our political institutions.

It's a very open-ended question, but I think it's critical for our work and it's very important -- let me just say when you do the history of Commissions, you have to take into account the rapidly evolving climate from the time the first Commissions were formed to our time.

DR. DAVIS: In a word, I think it's very important. I'm thinking back to Dr. Kim's, I thought, very insightful remarks about what happens in deliberative engagement forums to the participants themselves between the time that they enter and the time that they leave. In terms of the transformation of both their understanding and, I think, their capacity for engagement, which is a way of, in some ways, modeling something so different from the tenor of today's political discourse. And then modeling, as well, how that -- the outcomes of that engagement might be brought within the sphere of your deliberations. I mean, to me, I think that's a very important thing to try to do. That's why at the end of my remarks, I was trying to push a bit on how you might think about doing that.

And certainly a topic like organ transplantation is going to engage all colors of the political spectrum with regard to the issues of the day. But it might also offer an opportunity to really address and to show how this might be done in a civilized, respectful and substantive manner.

DR. SCHWARTZ: And to your point, I think, let me draw a little bit from vaccine policy issues and these kinds of questions so that a Principal Advisory Committee that provides Federal recommendations for vaccines has a single consumer member, as the title is called, and right now it's someone who works for the March of Dimes, so a very sympathetic champion for vaccination, as you could imagine.

In the past, that seat was filled by an individual from groups who are very, very skeptical of vaccine safety. So the question is how does having a single seat there, who does that -- what consumers are being spoken for and what not seems probably insufficient in terms of really meaningfully engaging the public. But so does the kinds of methods that many Federal advisory committees do and most of the examples I noted did in terms of bioethics Commissions of the kinds of engagement that says here we are, come tell us what you think either by attending meetings like this or sending in written comments, that that certainly engages the public -- the segments of the public who have a particular passion, as these vaccine meetings draw, whether, in that case, very supportive or very critical of vaccines, but it certainly doesn't capture a broader sentiment and that may obscure public opinions as much as inform it in terms of the individuals trying to make these kinds of recommendations.

DR. GUTMANN: Thank you.

I open it up for Commission members. Christine.

DR. GRADY: Thank you, both. I wanted to ask -- I think it was you, Dan, who said something about accountability, accountability for outcomes. And I wanted to ask you both whether you thought engaging the public is an outcome or -- in other words, is it an outcome or is it a method? Are we accountable for -- do you see the question? Sort of doing it because it's an important thing to do, or is it a method for getting to other outcomes or both? And how is it measured? In 30 seconds or less.

DR. DAVIS: Go ahead, Jason.

DR. SCHWARTZ: I think it's both. I think it's both something that these Commissions can do as bodies that are trying to capture, to some degree, the range of views that are available on contested and complicated issues. And also then translate that to its formal audiences in terms of the groups it advises, but also interpret that for the broader audiences who are consumers of these reports. So I think it should be a core part of what these groups do in addition to the writing reports and the advising.

But how do we measure it I think goes to the same kinds of challenges in terms of how we measure the impact by any metric there, that it's -- as you noted, it's very hard to do. I don't have an easy way to suggest how we can get there, but I think it's something that should be and rightfully is a core activity of many of these groups here.

DR. DAVIS: I also think it's both. And I suddenly find myself, you know, imagining that FACA form that you have to fill out after each year when you're in the position that Lisa is in.

I think you could -- you could probably find ways to measure the impact or the outcomes of the education that you would provide as part of a deliberative engagement form along the lines that I suggested. Certainly the measure of the impact of engagement on your work would consist in how you justify your findings and your recommendations in light of the products of that engagement. So it may not be the most strictly qualitative or quantitative assessment, but you would give an account of -- I'm thinking back to the earlier sort of question about whether it's binding or just simply influential. My own thought is that it should be influential. But you should be able to specify it in fairly clear terms how it was or was not. And that, to my mind, would be the measure.

DR GUTMANN: Nelson.

DR. MICHAEL: Something a bit provocative and maybe it's a question to my fellow Commissioners as much as it is to you two gentlemen, but, you know, previous speakers spoke about the use of democratic deliberation more in a scientific or as a research tool. And Nita and I were talking about this a little bit as we walked off in terms of understanding, first, how expensive -- how valuable but also how expensive those tools are.

And two is: What do you do with this tool now that it's in your toolbox? You've given us the insight that you think that this approach as a tool is useful for a series of Commissions, not only our own. So maybe sort of looking forward, what recommendations could you give us about how we could potentially use these tools as a Commission not just to have some of our fellow commissioners populated by members of the public, as best as that can be described, and I think that you've tried to do that.

I loved your comment, Dr. Davis, about a civilized, respectful and deliberate engagement. I mean, it certainly harkens back to our comments about our colleague, John Arras. And much of the debate we have now in some of the politicized issues are anything but civilized and deliberate and respectful. They tend to be polarized and highly political.

Do you think that Commissions like ourselves should potentially recommend that expensive experiments be done to poll the public in terms of issues that we would want insight into? Usually these are the purview of political action groups that form focus groups that are politically driven, they're not scientifically driven. So is that a bridge too far for our group to recommend that perhaps science should be taken in that kind of direction?

DR. DAVIS: I would at least like to explore the bridge. So my inclination, thinking on my feet, is to say, yes, I think you should think really hard about especially the dimension of active citizen participation in the work of bodies like this and have that be part of your legacy to the Commissions that come after you.

Just, you know, in the time that I've done this work and since my time on the Council, the word "public" bioethics, I continue to turn over and over and over again in my mind what that means. And it has to be more than doing it in public. It just has to.

We have had meetings with 400 participants, folks in the audience, and we had meetings with 10 people. I worried about what it meant to do ethics in public when there were only 10 people in the audience. So I think we have to push on that.

It is expensive. It's logistically challenging. There are -- Dr. Kim, I think, beautifully alluded to this, there are some really interesting methodological challenges. But my sense is that they're worth at least working your way through, at least hypothetically, and then trying to figure out what could we actually achieve in practice.

DR. SCHWARTZ: Yeah, I think there's something to be said for systematically trying to better understand the views of the public at large. For ethics, that's not going to lead us to the right answer by itself, but it may introduce perspectives or points of view that may otherwise not be seen by discussions with scientific or academic or political elites there. So in that role itself, whether it's the kinds of models we've seen -- we've heard earlier today or others that try and systematically understand the concerns, the hopes, the worries of citizens at large seems a good thing that should be part of the mix of what these Commissions do.

DR. GUTMANN: Jim?

DR. WAGNER: Could I do a quick, quick follow-up, then?

DR. GUTMANN: If you want to follow up, yes. And then I have Anita and then Nita.

DR. WAGNER: And so, Dan, what would have -- what do you wish you had done in your Commission service that would be an example for us as you call on us to provide -- as you both have called on us to provide examples for public engagement for future Commissions?

DR. DAVIS: Oh, I wish I had done a lot of things differently. And if -- you know, unfortunately, life has to live -- be lived forward, right, and understood backwards I think is the saying.

DR. WAGNER: So we can benefit from your understanding, yes?

DR. DAVID: Well, I -- so we kicked around ideas, for instance. We had a long but never published inquiry into organ transplantation. That's why it was on my mind. And I tried to push on my beloved Chair. One of the ideas I had was we needed to hear from folks who were recipients of living donor organs as well as from those who had been living donors. We had a lot of anecdotal evidence that was, frankly, concerning about the practice of living donation, but it was anecdotal. And it seemed, as a result, to be rather insufficient for, you know, making recommendations about a controversial practice.

And there was no registry of living donors, so there was no source of quantitative data that could help us sort of reckon with the risks and benefits. And we had a number of very, very articulate, strong advocates for markets in living donor organs. And it just seemed very important to sort of hear from those individuals in trying to craft -- or even the sources of information that would feed into the deliberative processes.

The same thing with newborn screening; I thought we should hear from parents about this practice, which most of them know nothing about, and about what we were then considering, which was an expansion of the uniform panel of disorders that were screened or that are to be screened. So I --

DR. WAGNER: Those are a couple of very good examples.

DR. DAVIS: -- thought we weren't --

DR. WAGNER: Thank you. That's helpful.

DR. GUTMANN: Anita.

DR. ALLEN: Hi. So I think I want to start, Jason, by commenting on your -- on your grid because it strikes me that the rigid grid class group of approaches, it has -- it has power for me because I think that sometimes these sort of principled approaches are heuristic for teasing out what may be more amorphous, more subtle ethical considerations that don't really fall neatly into any of the categories or neatly under any of the principles, but yet you wouldn't have gotten there had you not had a framework for beginning to think hard about ethical questions.

And so I'm not at all opposed to using rigid grid class type approaches, models, in order to help people begin to get to some of those more subtle questions. And I think that one of the things I learned from our colleague, John Arras, is that, you know, you do need to get to those more subtle questions.

I think as a Commission, we often have trouble taking some of our more nuanced conversations and then translating them back into something we can put into a report, and that's a limitation, I think. And so sometimes it looks like all we did was apply some pre-existing principles to a set of facts, when, in fact, we've had a very rich and broad gauging conversation among ourselves

and with people who've come to talk with us, and I think that's sort of an inevitable problem. Right?

The flexible focus class models, you know, they're very -- they seem more appealing and in some ways more sophisticated and in some ways more subtle. They have their own issues. One of them is this: I think that there needs to be some place in talking about deliberative democracy for acknowledging that for some people there's something automatically suspect about quote-unquote moralizing in public. Right? That there's something illiberal about it. It inevitably mires you in something that's subjective, that's personal, that's maybe hegemonic. And that's something we haven't talked much about, about the ways in which -- it just may not feel comfortable for a lot of folks to be drawn into a conversation in which they're asked in a public forum or for public purposes to talk about ethical and moral issues. And then -- and I want you to comment on this, and both of you, actually.

But then finally, when you began, Jason, you mentioned that we could talk about Commissions that moralize -- or sorry, Commissions that deliberate in public with the public. And then there's another sort of thing that we could talk about, too, which is, you know, ourselves as part of the public. We are consumers of healthcare, biomedical technology. We are people who have experienced illnesses and family problems, et cetera. And we have -- as was mentioned earlier, we had a representative member of the public on our Commission, a woman who runs a foundation that deals with neurological disorders and has a famous spouse, herself an MBA. But another kind of level of public bioethics might be where the commissioners kind of broke down some of those walls and would be very open with the community about their own experiences and perspectives and how they might affect their judgment.

So I just thought I'd love to hear your thoughts about anything that I just said, especially the latter points.

DR. SCHWARTZ: Yes. Three points, and I'll be very brief in responding in reverse order, the question about who is the public, we hear similar discussions about the public is in public health. Right? Sometimes public health is seen as the other, it's a group of bureaucrats or administrators or other agencies. But if we're thinking about public health, we're thinking about all of us, especially in a democracy. So these questions about the public not being the other, but being us I think resonates very much.

DR. ALLEN: And experts being the public. Experts are the public and the public are -- in some ways experts.

DR. SCHWARTZ: Definitely, in terms of those boundaries being at the very least fluid, if not non-existent.

In terms of the difficulties of moralizing in public, that would seem to me the kind of thing that is another potential asset of groups like this. In terms of trying to promote thinking through complicated, often politically divisive, complex issues related to health and biomedicine, that this can promote a spirit of openness and discussion by what these groups do both in terms of their formal proceedings as well as the kinds of activities they do beyond their meetings. So I

think you're right, but it seems something that these groups can also help promote that kind of discussion.

Finally, on the paper and the questions about -- referred to as rigid grid frameworks, which are a top down kind of model saying perhaps a Commission should start with a formal ethical framework, an existing one or one that they have defined from the start, and then apply that over the issues that they look at subsequently.

I think you've pinpointed what seems to be the strongest argument for such models, is it promotes clarity of what the Commission and its members stand for, where they're coming from in terms of the issues that matter most to them, and then doing that work and then thinking about how those issues apply to the particular topics under their investigation.

So we weren't necessarily -- certainly rigid and flexible have some connotations to them, but we were trying to sort of map the kinds of options that seem available to Commissions without necessarily looking at, well, which ones have fared better in terms of all the kinds of metrics, quantitative or qualitative, that we thought about. But I think you're right in terms of the value of making clear what you stand for from the start.

DR. DAVIS: You are members of the public, that's correct. But I do think that there's a significant difference. All of us around this table have lived and pursued careers that have shaped us in very conscious as well as unconscious ways with regard to the issues that we take up.

And that's not true of John and Jane Doe, who haven't been, you know, leading nurse bioethicists, like Christine, and political scientists and physicians. So I think it's -- although it's true, yes, I think it's important to keep that difference, that qualitative difference in mind.

And, also, the fact that we learn surprising things about our own biases when we engage the public. I keep thinking about return of genomic results and how genetics counselors and clinical geneticists and so on are very nervous. And the public is, like, what's the deal? Give it to us. And that, I think, just recent research has been published on that very fact.

So I think those of us who have been brought up in these professions with these attitudes need to hear from the public.

DR. GUTMANN: Nita.

DR. FARAHANY: Thank you for this. I've been deliberating about this principle both, you know, as we thought about bringing it as one of our next topics, but also in the context of some of our work at Duke on communicating science and the importance of communicating science.

First a comment on the conversation about the need to talk about why we chose particular principles. I think that's right. You know, the question is: To what extent do you need to do so? Right? So do you go through every different framework that you could adopt? We could adopt a human rights framework. We could adopt this framework. We could adopt that framework.

We decided to adopt this framework. You know, how much do you lay it out versus simply explaining the principles that you chose and explaining the value of those principles?

That's a separate question from a second kind of issue and comment that I have, which is in thinking about how this works in actuality. I mean, I think, of course we should be engaging the public as broadly as possible. Of course we should get as many viewpoints as possible. Of course that would lead to the vast and most informed views by us.

But on the concept of deliberative democracy, as we're rolling that out as a process by which the public is more engaged in the deliberation rather than informing our deliberation, I wonder, first, how you do that when we have a country that, you know, largely is somewhat apathetic in voting in general, right, in representational democracy let alone in specific issues.

Second, the extent to which people are unlikely to really invest in topics that don't directly touch them. So if they feel like it's remote as a concept or remote as a policy, the likelihood they'll really invest the time or thought, or is it just the people where it is actually touching them that day, that -- you know, that -- it's a topic that actually affects them, so it's rare disease and a family member has a rare disease or they have a rare disease. You know, this kind of thing.

I would think, you know, the best possible conversation would be one where you could actually get stakeholders involved at every stage in the process. But to what extent can we really expect that? And if we can expect that given the difficulties of engaging people more generally, what is the value? Aside from informing dialogue, what can we expect to achieve by that? Do we expect to have more evidence-based dialogues, as the previous speaker said? Do we expect people to feel better about the outcome and feel more invested in the outcome? Or is it simply kind of a principle of in order to do bioethics and ethics well, you have to engage, you know, the public more broadly? So understanding and kind of quantifying what is the outcome? What is the better outcome that you achieve as a result?

Sorry that those are relatively large and vague, but these are my ponderings about this issue.

DR. DAVIS: I mentioned one outcome and that is, I think, you might learn surprising things that you would otherwise not have learned without that process.

And it also seems to me if you define yourself in accord with principles that include the principle of democratic deliberation as you've defined it with that second dimension of active citizen participation, then I'd ask you what did you have in mind in really framing that principle and adopting it and saying this is what we're going to be about.

I think your questions are very, very good and difficult. But my sense is if you're going to be accountable to the framework you've adopted and laid out at the very outset, you have to struggle with that. And I would assume you had intuitions about the value of doing that.

To me, as I've mentioned, I think the value of doing that is you learn things you otherwise wouldn't learn. And that, to my mind, is the most important value. But, too, it really is in the

interest of accountability for we've said we're all about this. Now we need to demonstrate that we are all about this; otherwise why have the principle or that dimension of it?

DR. GUTMANN: So we did early on deliberate about this. And as with the principle of respect for persons, for example, there are multiple, as Nita was alluding -- there are multiple reasons that feed into it. In any given controversy, certain reasons take more -- wind up having more weight than others.

But in all cases, it is, as you say, a source of information which is important for us to have. And we don't -- to the extent that we want information about people's views and -- information about people's views and information about arguments that people give that you might not have thought about. To the extent that we want them, we want them in a non-skewed way so that we're not just tapping into those people who are most prone to come to a meeting or because they have an immediate family member at the moment affected. We hear from them and not from people who will be affected down the road. So one is information.

The second is legitimacy, that we are a public body and we are actually charged with learning about the broadest -- it's in our charge, and I will just paraphrase it, but learning about the broadest set of views in our society on this -- you know, on the issues that we -- and engaging, not only soliciting them, but engaging with them.

And the third ties in directly to respect for people, that it's a form of respect for people to hear them out, listen to them take into account their views even if you wind up disagreeing with them in the end. And there is good evidence that -- and we've seen it in our deliberations on testing anthrax vaccine in children where we couldn't possibly, nobody could, satisfy all the views out there because the views were contradictory and we heard from experts and citizens alike, but we didn't have the benefit of a deliberative poll which would have been time -- even more time consuming and expensive, but it would have been, I have no doubt, informative -- you know, a deliberative poll that actually set out the pros and the cons and so on and we heard back from people.

But that's, in some sense, the report that I think we're most proud of because it was so difficult and we found an answer that I think it's true none of us began with, which was the age de-escalation to keep minimal risk experiments on children -- keep to that standard and at the same time find a way of moving ahead.

And it was actually adopted. And it was in direct contradiction to a previous recommendation that the Government didn't just run with because they had the sense -- and this is Nita's point -- they had the sense, Nita, that there would have been a public outcry if they had just run with it.

And we didn't set out not to have a public outcry, but we set out in a more deliberative way, in a way that got more public input. Could we do that on every single issue and still get our work done? You know, no, because time is limited. And did we do it in the full deliberative polling? No, but we came as close as we could in the time -- in the time allotted to us.

So I just wanted to -- that's a more through way of saying, yes, we stand behind what our initial principles are, but there's still open questions about to what extent you can do this. To some extent, we have to do it. We absolutely have to for the reasons that we've stood behind.

And with that, I turn it over to Dan for the final question of this session before we take a break.

DR. SULMASY: Thanks.

One comment I have to make in light of your last ones, Amy, is that last night in our class on Paul Ramsey, one of my -- I gave the example of anthrax, and one of our graduate students actually spontaneously came up with the idea of age de-escalation as a solution. So it's really remarkable, the kind of students I have the privilege of teaching.

DR. GUTMANN: That's the glory of teaching.

DR. SULMASY: Yes, yes, it's wonderful, wonderful.

But thanks to the two of you for your reports, and building on some of what Amy just said and then Nelson's question about the use of these empirical technologies, I mean, it sort of raises the question for me for both of you to answer what you really think the role of national Commissions is vis-a-vis the entire process of deliberative democracy. Right?

Are we, in fact, supposed to be the forum in which deliberative democracy about these issues takes place? Or without being as minimalist as you've described your Commission, Dan, should we humbly say that we're a piece of the puzzle, a small part of the pantomime that we can call upon other people to do the deliberative polling, the citizen juries, as part of it? But that's really not our task to be the people who actually become the forum for all deliberative democracy about every bioethical issue we take up. So, you know, where do we go between minimalism and that grandiosity, which I think is sort of impossible?

DR. SCHWARTZ: I agree with the latter approach, that groups like this can be a very important -- very visible and very prominent, but can't be the exclusive home for these kinds of activities. I think the visibility of these groups, their place in advising the Federal Government provides important opportunities to undertake some of these activities.

But certainly there are things that are happening at the state and local level where there are important, unique and diverse characteristics that call for specific kinds of different inquiries, it would seem to me, that there can't be one-size-fits-all approaches to the issues we think about, but these groups have an important part in terms of thinking about the issues in a general sense and particularly with an eye to what the Federal Government can and should do in promoting them.

So I think a valuable and visible model for how these kinds of activities can happen and hopefully promoting their -- the dissemination to other kinds of venues down the line seems the right answer to me.

DR. DAVIS: I certainly don't think you can model it to the high degree that I'm suggesting on every issue, but I think it would be very dependent on the issue. If you were to go back, you know, to the mid '70s and think your way back there and Tuskegee has just been revealed, that to me would be a kind of issue.

And the challenge of trying to develop an ethical framework for human subjects research where you might decide you were going to model for the whole country a deliberative democratic approach to that issue or some other significant sort of watershed topic of that sort, but not on every issue by no means. It's too expensive. It's too logistically challenging. I just don't think you could do it, but. . .

DR. GUTMANN: Because we're in the -- in Philadelphia, in the birthplace of liberty as it humbly calls itself, it is worth recalling just before we break that the founders wisely, I believe -- and I say this as somebody who is a strong believer in deliberation, as they were -- but they wisely said that the Constitution would never have been created had it been -- had to be deliberated from the get-go in public.

That said, we operate as a Commission within that constitutional framework. So we don't have to create that constitutional framework. And were we to have to create it de novo, we would probably not be able to do so in public from the get-go.

And that's why the principles we articulate are not ones that we created as a Commission, but resonate within the Constitution of the United States. That Constitution had huge flaws, slavery being the biggest one, which we still haven't fully lived down. That's the biggest one or I should say one of the biggest ones. It also didn't enfranchise women, for example.

So we have to also realize that not deliberating in public is -- has got huge imperfections, as well. And the jury is still out as to whether the imperfections -- you know, how those imperfections.

That said, we want to thank you because we have no better alternative than to deliberate in public. And not only do we not have a better alternative, we fully embrace the alternative and we're looking for better and better ways of doing it. And you have helped us in that regard. So we thank you very, very much and we will take a break.

(Whereupon, a short recess was taken.)