



Presidential Commission
for the Study of Bioethical Issues

TRANSCRIPT

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SESSION 3: REFLECTING ON THE PAST, PRESENT, AND FUTURE IMPACT OF NATIONAL BIOETHICS ADVISORY BODIES

DR. WAGNER: I think we'll go ahead and get underway. Fortunately, we've all had a chance to review everyone's bios and by the time I'm through reading, I suspect Steve will be with us. And we're going to continue our discussion this afternoon on the future impact of national bioethics advisory bodies.

DR. WAGNER: And to begin this next part of our discussion, it is my pleasure to introduce Dr. Ruth Macklin. She is Professor Emerita at Albert Einstein College of Medicine – retired from her full-time position just this past June after serving there only 39 years on the faculty. She is an – That's just wonderful. Congratulations and thank you. She's an advisor to the World Health Organization, an elected member of the National Academy of Medicine, and the chairperson of the UNAIDS Ethical Review Committee. She co-directs an NIH Fogarty International Center Training Program on research ethics, which takes place in Buenos Aires, Argentina and in the borough of the Bronx in New York City. Since the early '70s, she has lectured and published widely on research ethics, global health, stem cell research, reproductive health, public health ethics, and HIV/AIDS. She continues her research work at Albert Einstein College of Medicine and is a bioethics consultant.

DR. WAGNER: Dr. Macklin has served as President of the International Association of Bioethics (IAB) and is a former member of that organization's Board of Directors. She received an American Society for Bioethics and Humanities Lifetime Achievement

Award in 2002 and is a Fellow of The Hastings Center. In 2014, she received the Henry Beecher Award from The Hastings Center and an award from the Global Forum on Bioethics in Research for her contributions to progress in international research ethics. She served as a member of the Advisory Committee on Human Radiation Experiments for '94 to '95 under President Clinton. And we're just so pleased that you could be here. Thank you for joining us.

DR. MACKLIN: I probably will be somewhat repetitious because the wonderful panel this morning covered a lot of ground.

DR. WAGNER: I suspect that so many of you were sitting on your hands wanting to – so, we'll give you that opportunity now and also in our roundtable session.

DR, MACKLIN: Alright. So, I do – I apologize. I do have a prepared text so I could keep to the time.

DR. MACKLIN: My interest in presidential commissions goes back to the 1970s, as you can see by my age here. I've been around a long time, and reading the reports of the national commission with its shorter name, the National Commission for the Protection of Human Subjects, et cetera. In several of those reports, at least portions of those reports were actually adopted as part of U.S. federal regulations, not in the earlier regulations, but the children's regulations, for example, and the fetal thing.

DR. MACKLIN: This was a commission that did have impact and I was reminded this morning – actually by Alex's presentation and some things that Tom said about the

impact that the President's commissions reports also had. The Belmont report, of course, is widely known throughout the world and widely referred to often by people who don't fully understand they're saying but the fact is there was impact, great deal of impact, from that early year.

DR. MACKLIN: The work of the subsequent commissions probably with the exception of the President's Commission, which did have some more impact, had much less, in either legislation or regulations, much less impact. As Amy mentioned this morning, and this was one of the points that I intended to make, but of course, it was made – every single commission recommended that there be some kind of regulation, law embodied in the current regulations for compensation for injured subjects.

DR. MACKLIN: And here, it's interesting to look at our European colleagues, maybe Eugenijus might say something about that, where it's actually a requirement in the European countries that have this, that subjects who are injured in the course of research be compensated. And those are actually mandated as part of the clinical trials insurance. So, we can learn something from our European colleagues and then keep making the same recommendation year after year and perhaps eventually it will be accepted. To this day, the U.S. federal regulations for the protection of human subjects lack any such requirement.

DR. MACKLIN: So, my direct experience, I'm going to be as Tom Murray said, somewhat anecdotal and talk about a couple of topics that haven't been mentioned. My experience has been involvement with two presidential commissions: first, as a member

of the Advisory Committee on Human Radiation Experiments, ACHRE. That was not mentioned on anybody's charts earlier.

DR. MACKLIN: It was indeed a presidential commission but not like all the others. It was created for a specific purpose, and for a very narrow mandate, which was to look at the past and the present in light of the human radiation experiments that the United States conducted or financed during the cold war period. It was indeed a presidential commission and I can attest to that because I have a picture of myself shaking hands with Bill Clinton. So, this was a very special commission but it was indeed a presidential commission, but not one that lasted beyond its something like 18-month mandate.

DR. MACKLIN: My other connection was with NBAC, 1999 to 2000, but for just one report. My title was Senior Consultant to the commission for its international report. So, I'm going to begin with the ACHRE experience. I'll refer to it as ACHRE. It's not an easily pronounceable acronym.

DR. MACKLIN: It was extremely well funded by the U.S. Department of Energy, which succeeded the Atomic Energy Commission, and the creation of the commission was triggered by some newspaper reports that actually revealed for the first time to the public that the United States had financed and conducted a whole array of radiation experiments, many of which were unethical for a lot of reasons and for reasons that went well beyond the informed consent, which was much of the focus.

DR. MACKLIN: As this was a specialized commission, members of the commission included experts in the relevant fields having to do with human radiation. Nuclear medicine, radiation, other scientific areas as well as members with expertise in bioethics, law, public policy, public health, epidemiology, history of medicine, and government policy.

DR. MACKLIN: One key debate – and I think this is possible relevant to what the other commissions have said, but one key debate that kept recurring was how to word the recommendations...the recommendations to Congress. The alternatives that were presented were to say that, when the recommendations were being crafted, Congress “*should*” do this, that, or the other thing, and the other alternative was [Congress] “*should consider*” doing this, that, or the other thing.

DR. MACKLIN: Now, some of us – and I was one of them – argued [that] saying Congress “*should consider*” is too weak because Congress could consider anything and then reject it. So, we thought it would be bolder, essentially, to say, “This is what Congress *should*” do. And yet, those commission members who had experience in governmental affairs (and some had vast experience) cautioned us not to offend Congress by appearing to tell them what to do.

DR. MACKLIN: One of our strongest members was Jay Katz, who was known to very many people here. And Jay Katz argued that the members of Congress are our elected representatives and since this commission comprises citizens of the United States, that we are well within our rights to tell Congress what to do.

DR. MACKLIN: In the end – and of course, I looked back to see just what the wording was – in the end, most of the commission’s recommendations were addressed to a body that was created specifically for this purpose, which was the Human Radiation Interagency Working Group. This was itself interesting about the American government – that these people had never talked to each other before.

DR. MACKLIN: They were from – it was a cabinet-level group that was convened by President Bill Clinton. The members included the Secretaries of Defense, Energy, Health and Human Services, Veterans Affairs, the Attorney General of the United States, the Administrator of NASA (because NASA was also involved in these radiation experiments), the Director of the CIA, and the Director of the OMB, the Office of Management and Budget.

DR. MACKLIN: When the recommendations in the final report are addressed to that group alone, the wording is direct and it tells the working group what it should do. However, some recommendations are addressed to “this working group together with Congress”. That’s the way it was worded. These recommendations include the phrase “give serious consideration to”, thereby, adopting the more polite matter of telling Congress what it should do. It was never clear to and to this day why it’s acceptable to tell all those high-ranking cabinet members and directors like of the CIA, to tell them what to do but not to tell our elected representatives in the U.S. Congress. I don’t believe the recommendations – to whom they are addressed makes any difference on the impact.

DR. MACKLIN: The Advisory Committee on Human Radiation Experiments had a somewhat unique difficulty, which also this commission had, in making retrospective ethical judgments. I'm thinking particularly of the Guatemala report from this commission because this was a dilemma that was argued on both sides about historical, ethical relativism. That was really the debate among the commissioners and people who testified before the commission – whether it's wrong to criticize actions in the past when, to use the expression, “they didn't have our rules back then”, as if you need to have some rules in order to tell you what's the right thing to do.

DR. MACKLIN: There was a lot of discussion about the appropriateness of making historical retrospective ethical judgments. Even when members of the commission came to agree on making retrospective moral judgments, the commission stopped short of assigning moral blame to individuals, which I believe was basically the same as the – You did? Because I'm thinking of a paper I read on that. So, you did?

DR. GUTMANN: We named names and assigned moral culpability and we found a contemporaneous article in The New York Times “saying” that these experiments prospectively would be ethically impossible. And we actually determined that that was available to all the people who committed those crimes.

DR. MACKLIN: Alright. So, I stand corrected about that. But, in the end, the committee did come to consensus on the recommendations, with one exception, and one of our previous panelists mentioned a dissenter to one of the previous commission's recommendations and the same Jay Katz was initially reluctant to sign on to the report.

DR. MACKLIN: The commission spent a very long time discussion the appropriateness of a dissenting voice or writing a dissent because the argument was if you're going to serve on some of these commissions, one has to be ready to join a consensus, even if in some minor ways, one might disagree. But, this was a problem: that no one was actually clear on what a dissenting opinion meant and whether or not and whether or not it would weaken the force of the report. And that was one of the worries. Some even wondered whether it's the type of report that allows for a dissenting voice.

DR. MACKLIN: In the end, the issue was resolved by calling Jay Katz' piece a statement by individual committee member and it appears at the very end of the entire report, just before the glossary or the index. In Katz's own words, "The commission's task was to examine the past and to examine the present, but the commission did not judge the present with sufficient care", and that was Jay Katz's concern.

DR. MACKLIN: With the NBAC – and, of course, Harold is right there and can correct me on any mistakes I might make – but I thought it might be useful to talk a little bit about what my role was. This is the anecdotal part because I was a Senior Consultant and therefore, a member of the staff, not a commission member. And we heard some very good things about the staff (PCSBI staff) and all of those commissions, to my knowledge, have had really great staff.

DR. MACKLIN: My role consisted of: attending all the monthly meeting, listening to the commissioner's comments on the topic at hand, drafting a section of each chapter, and

then, presenting it in writing for discussion at the subsequent meeting so the commissioners could then see it. This was sometimes, at times, more than once, a frustrating experience because commissioners on occasion reversed their views.

DR. MACKLIN: I had a very able assistant who was a member of the staff, I think just for this project also. I was the only Senior Consultant for international project. Alice Page was a lawyer with an MPH degree and she was my assistant but we were coequal in the work. We prepared drafts on what we heard the commissioners say at the previous session, only to find that at the next session, they now disagreed with they had said earlier. Sometimes this happened over night.

DR. MACKLIN: On one memorable occasion, we presented written text. Commissioners disagreed with our position so we went back the same evening and rewrote the entire section. We presented the revised [versions] the next day and the same commissioners argued for the position that they had rejected the day before. You can imagine that's a little bit frustrating. However, a more important concern for me as a hired consultant was how to maintain intellectual and moral integrity.

DR. MACKLIN: Unlike writing scholarly papers where I can express my own views, when drafting text for a presidential commission, the commissioner's viewers take precedence. Not only do they have to reach consensus if possible, but they take precedence over anybody, any lowly staff member or even higher staff member who disagrees. So, I wondered how much I could apply to the commissioners' positions without compromising my own intellectual and moral integrity.

DR. MACKLIN: The reason I was invited to serve as a Senior Consultant was that I already had some considerable international experience with WHO and UNAIDS and I had published articles about ethics on international research. As Alice Page put it in retrospect when I spoke with her about this, “we were light years ahead of many of the commissioners on the social justice issues and the prior agreements in particular”.

DR. MACKLIN: This was a hot topic between 1999 and 2000, there were vigorous debates going on in the literature, among bioethicists, and the community as a whole about specifically about carrying out research in resource-poor nations and what is owed to particular to the participants in the research and to the countries or the communities from which they came afterwards. The Declaration of Helsinki was being revised at about that time, and so there was a lot of ferment in the area of international research.

DR. MACKLIN: The two issues that were the most contentious at the time were post-trial access to the successful products of research and the use of placebos, whereas the FDA and the NIH favored the controversial research that the U.S. government sponsored that did use placebos when there were effective, established treatments elsewhere. This was a matter of contention. On these two matters, I and actually, coincidentally Alice Page, who I was working with, took a position that was I suppose – I don’t whether it’s to the left of the rest of the commissioners and so that became a difficult issue to handle.

DR. MACKLIN: Finally, we’re left with the question, as was raised earlier and this was my main concern, with “What is the practical impact of the recommendations that are

made?” In part, it may depend upon to whom those recommendations are made, but because we know that legislation takes a very long time and is a very different process, and the regulations, because there is now before us, in the United States, a proposal to amend or change or revise the federal regulations and that now seems to have ground to a halt because of a report from the National Academy Medicine, so we’re left with question of how to try to make the impact, and on this, I guess I’m with Bob Cook-Deegan, when I think these commissions, the scholarly work is so good and the people are so thoughtful and the reports are so readable by the general public as well as by professionals there ought to be an impact.

DR. WAGNER: Ruth, thank you so much. Amazing sense of history there.

Turn next to you – Dr. Harold T. Shapiro, former President of Princeton University and also the University of Michigan; Professor of Economics and Public Affairs at Princeton still. He’s a member of the National Academy of Medicine and the American Philosophical Society, and a Fellow of the American Academy of Arts and Sciences. His fields of special interest include econometrics, mathematical economics, science policy, the evolution of higher education as a social institution, and bioethics, of course. He served as Chair of the National Bioethics Advisory Commission (NBAC) under President Bill Clinton and Chair of the National Academy of Medicine's Committee on Employer-Based Health Benefits, and as a member of the Council of Advisors on Science and Technology under President George W. Bush.

Harold, thanks for being here.

DR. SHAPIRO: Thank you very much. It's a pleasure to be here. I'd like to begin my remarks by expressing some gratitude to this commission for your reports, all of which I have read, some of which will be on my syllabus starting in January, and we really owe you a debt of thanks for all the intellectual effort you've put forth and time you took these last few years and it's, in my point of view, very much appreciated.

DR. SHAPIRO: It also seems to me that you are almost overrun by NBAC alumni. You had Jim Childress here last time, we had two of my colleagues this morning, Alex and Tom, here, as well as myself, but I do want to say that Jim and Alex and Tom were really central member of NBAC and more importantly from a personal view, they were my teachers. They taught me about bioethics in a very intellectually and personally generous way and I want to take this opportunity to thank them for that.

DR. SHAPIRO: I would like to avoid raising issues that have already come up here. I'm going to just try to get to issues that are on my mind that haven't yet risen. I have read the minutes of your meeting last time, so I know pretty well what Jim and other members had to say. I listened with great interest to what my colleagues had to say today.

DR. SHAPIRO: I want to begin with a cautionary note. One of the things I'm worried about in bioethics is whether this discipline has actually defined itself, whether it has any borders. At times, I feel like bioethics is everything that has a coherent group of carbon molecules somehow follows within the aegis of bioethics. I think that's not a good trend for a discipline that's trying to establish itself – hasn't had really enough time to

intellectually think through just what it is going to be as a discipline, despite the enormous progress that has been made in the last generations. I think caution is necessary.

DR. SHAPIRO: My own advice regarding future bioethics commissions, whatever their name is and however they're structured, is to be rather cautious about the issues that they take on and to remind themselves what kind of expertise is being called upon here. It's very common in my classes: the first thing that comes up, I guarantee you, is social justice. That's what everybody wants to talk about. Social justice is an extremely important issue but a very complicated, very deep issue, over which there are centuries of scholarship and thinking on and it can't just be tossed into everything that comes along.

DR. SHAPIRO: I think social justice is fine, but social justice is a whole different bit – I don't need to lecture Amy on this or any of you, you ought to be careful because bioethics commissions often get seduced and say, look, it's much more important. 'Don't worry about the small, little things, human subject protection. Look – there's much bigger problems in the world.' Humanity certainly has much bigger problems than anything we have in bioethics, and we have to be cautious of that.

DR. SHAPIRO: It's more important for us to understand, identify what bioethics is, what it covers, and what it doesn't cover, and not just try to take on projects that are important for humanity, certainly, and more important than probably bioethics is. But, nevertheless, if you think of this as a field, you think of yourselves as a bioethics commission. Your commission, or NBAC when I was there, was not chartered to deal with those issues,

important as they are. And so I think we really have to be cautious about that. But with this – let me try to make maybe four or five points within this context.

DR. SHAPIRO: First of all, I want to underline a point made by, I think, Ruth Faden at your last meeting. Namely, when considering impact, focus first on changing patterns of practice rather than on legislation and policy. I think this is not – I think this is one of the defects we have in the literature here. It's not that the literature is empty of those issues. It's just – there is not enough focus on what's actually going on, whether it's in a clinic or in a research environment or in a hospital or wherever it may be. I think bioethics often treats these things as the same thing that legislation and policy is the same thing as practice, and it's simply not the case.

DR. SHAPIRO: Practice is, can be very different and it's my own judgment that focusing on practice is more insightful, actually, and may yield more insight on where the country is actually moving and whether these ethical issues that we care about are really playing a role – you'll find out by looking at practice.

You'll find out something by looking at legislation and policies, and I think legislation and policies are important, regulation's important, but I think, perhaps, we focus too much on that and not enough on what actually is going on.

DR. SHAPIRO: You've also focused on the issue of education deliberation. One can hardly take any exception to that, obviously, as your report points out, and as Amy has pointed out for a career, that deliberation, and so on, is really critical to the democratic

process. But we have to be much more specific. It doesn't really help very much to say that.

DR. SHAPIRO: We are overcome with information in our society. We are overwhelmed by it. We really have to have a much more specific idea of who we're trying to educate, why we're trying to educate those, and what kinds of educational programs or deliberative programs – Who's going to do all this deliberation? Right? We don't really foresee, you know, 300 million people deliberating every night on these issues or any other issues for that matter. And so, I think it would behoove us to just be much more specific about how to do it and, particularly, who it is that we want to do this.

DR. SHAPIRO: First of – second of all, I'd like to make a word – say a word about context. My own view is that context really matters; that in dealing, let's say, with biomedicine, the context is really very important and we don't often pay much attention to it. Let me give you an example. At least it's my own view, that what's generating and what's giving all the life and vitality and so on to the biomedical community, is that certain kinds of relationships in the – either in science, in the scientific community, or in the corporate community, they are really pushing the agenda here. And it's not – unfortunately, it is not, in my view, bioethicists. It's the – not necessarily the partnership, but both these forces working, you know, at very great speed with enormous and very, very fascinating results.

DR. SHAPIRO: So, for example, we have this – new ways of editing the gene, whether it's CRISPR or Cas9 or some other appropriate – some other suggested alternatives to

that. Bioethicists are beginning to discuss this matter and it's really a very important issue, but you open up any issue of *Science* or *Nature*, these prestigious science magazines, and there's corporations advertising on what they're going to do. They are not waiting for us to decide just how they should go about; and by the time we catch up to that, who knows where the scientific agenda is going to be and where the scientific frontier is going to be. So I think it's really very important for us to understand that context.

DR. SHAPIRO: You know, you could look, I think, vainly with the NBAC's report, certainly, and think all the other reports, how these reports really thought seriously about the context in which these – not the political context, but the societal context into which these suggestions are falling and, at least my reading of all these reports, including the NBAC reports, is they are innocent of that idea, and I think that that limits the impact of their suggestion.

DR. SHAPIRO: Now, I'd like to look – I guess in the last meeting you had, you had a meeting – an issue that was introduced, I think, by Jason Schwartz, if I'm correct, regarding he – let's see. He had a cooperative model, a collaborative model, the arm's length model or some distinction like that. These are interesting things to discuss.

However, I think in the point of view of impact of the commission's report, particularly if you look – want to look at the impact not only on practice, but on policy and regulation, [it] depends much more on what access the committee chair or committee chairs have to the people that really matter. That's really what matters.

DR. SHAPIRO: All these models could work. All these models adjacent [to this] could work with the right leadership, the right members. They could all work. I don't see any reason why – there's nothing fundamentally wrong with them. But, everything depends on access because let's put it this way: The federal bureaucracy can bury anything. It doesn't matter how wise it is; it can bury everything if it wishes to.

DR. SHAPIRO: And so it's very important that the leadership of these commissions have access to people who really matter. That's my experience, not only in the bioethics commission, but other commissions I've served as chair at, whether it's PCAST or other kinds of organizations like that. Everything depended on access. Where we had the access, it went well; where we didn't have the access, it didn't work well at all.

DR. SHAPIRO: Now, you also had some discussion at your last meeting on the difference between – or how impactful bioethics reports were, your reports were, or our reports, NBAC reports, versus the National Academy reports, for example – that was another – not the only one, but it was another one that was considered at the time. And I think there is something that we bioethics commissions of whatever variety can learn from National Academy.

My own view is the key thing that separates the National Academy reports from, let's say, NBAC's reports, reports of commissions like NBAC, is not agenda setting. Agenda setting for both the National Academy and for these bioethics commissions are a joint effort by sponsor and members of the commission and so on, but it has to do with the review process.

DR. SHAPIRO: The National Academy review process, as all of you know who have been part of that, it's very bothersome when you get to it. It's very irksome to have to go through this, but they really improve the reports a lot. I've served as Chair of many of these commissions from the NRC and the National Academy. It's that review process that takes – just to use a quick statement – it takes these reports from a kind of “B/B+” into the “A” range because they always inevitably have something really important to say that causes us to change our minds.

DR. SHAPIRO: Now, I'm quite aware that in many cases you are under a deadline, 90 days or some other – where this would be impossible. But, I have seen these review processes at the National Academy work very expeditiously. If you prepare in advance, if the referees know in advance that they have only a week, et cetera, et cetera, it can be very expeditious. So I think that's something that future commissions ought to consider.

DR. SHAPIRO: I guess the last thing I want to say, and, again, I'm trying to avoid what's already been said here. I think, Amy, you may be the one that brought this up last time because a committee such as yours or NBAC – and, evidently, these were controversial issues – and, moreover, these controversial – controversies are not settled by thoughtful deliberation. After you've cleared up all the logic, after you've cleared all the misunderstandings, after you've cleared up all the other stuff that can cause misunderstandings, there's still a fundamental difference between thoughtful, well-meaning people who really want to do the right thing. And I think that's the issue that you brought up – Amy, you brought up last time.

DR. SHAPIRO: And I think finding the language, you've got to come down on one side or the other eventually, right? But finding the language that can signal to the other side that you respect them as moral individuals is at least one way to try to make this happen in a way in which people can say, all right, we live for another day. We can accept this for now, but, you know, there'll be another day and maybe we'll win the next time around. That is very important.

DR. SHAPIRO: And when you think – I had one example, I think. I don't know that it succeeded, but it's an example. When we made our report on stem cells, we carefully said that we thought that stem cell research ought to go on, but only if you use embryos that were initially intended for a reproductive project; that is, you could not just use embryos that were only for research and create them only for research only to destroy them.

DR. SHAPIRO: Now, it wasn't because we thought that was a – the way of – you know, we would have liked it, but we hoped that maybe someone would notice this small difference and say, okay, they understood us, they understood – now, in fact, I don't think we quite succeeded in that way or at least we weren't convincing in that way, but, nevertheless, the effort to try to incorporate others' moral perspectives in a manner that is respectful of them as individuals or as groups, I think really can be very helpful.

Now, I have to say that one puzzle that's left over – and I know I have only a minute-and-a-half here left – one puzzle that's left over, for me at least, from all these bioethics

commissions, and yours as well, is that you take on issues that are controversial everywhere. I mean, whether it's pro-life, pro-choice, all these issues that surround – they're controversial in every country that I know about.

DR. SHAPIRO: And the question that I've been asking myself is why does America have so much trouble dealing with these issues in a thoughtful and respectful way with each other? We want to demonize each other rather than to try to work together to find some kind of, if not common ground, at least respectful ground.

Now, some political scientists have suggested the reason is that we have too many veto points in our system of government, so anybody can veto anything as we go along. There's so many veto points; perhaps that's an explanation. I don't – I really don't know. But I have to confess – and this is not meant as a chauvinistic remark – that I look longingly at the recent Canadian discussion on assisted – on what we call "assisted suicide."

DR. SHAPIRO: And of course it's very controversial, but it issued very thoughtful reports, took action and guess what? It's happening and nothing – and the country didn't come apart. There were strong objections. The country didn't come apart. It was very thoughtful and so on. It's something which I think deserves the attention perhaps not of bioethics committees, but of people who are interested in government and things like that nature to why here, in America, we find it so difficult to come to rest on these controversial issues. Thank you very much. I've got five seconds left. I'll give it to my next –

DR. WAGNER: Harold, thank you.

DR. SHAPIRO: I'll give it to my next –

DR. WAGNER: You'll cede that to –

DR. SHAPIRO: I relayed it to you.

DR. WAGNER: You'll cede that to – cede that to Rebecca. Thank you so much. I appreciate that.

And Rebecca Dresser is our next speaker. She's the Daniel Noyes Kirby Professor of Law at the Washington University in St. Louis, serves as Chair of The Hastings Center Fellows Council, and is one of the “*At Law*” columnists for The Hastings Center Report.

Professor Dresser has written commissioned papers for the National Academy of Sciences and National Bioethics Advisory Committee. For over thirty years, she has taught medical and law students about legal and ethical issues in end-of-life care, biomedical research, genetics, assisted reproduction, and related topics. Before coming to WashU, she taught at Baylor College of Medicine and Case Western Reserve University. In 2003, she was a Visiting Research Scholar at the University of Tokyo, where she taught a short course in law and bioethics. Professor Dresser served as a member of the President’s Council on Bioethics under President George W. Bush from 2002 to 2009,

and as a member of the NIH Recombinant DNA Advisory Committee from 2011 until just last year.

Welcome.

PROF. DRESSER: Thank you. I'm very grateful to be here and have this opportunity.

Oh, good. Some took care of my slides.

I have two slides.

I was a member of what I think was one of the most controversial national bioethics councils so far. I have lots of horror stories but I'm going to talk mainly about what this taught me about the role that groups like this can play. We were a different kettle of fish in some ways and it started with an executive order.

PROF. DRESSER: If you look at that [referring to the Executive Order for the President's Council on Bioethics], you see policy in one little place, but the emphasis is on undertaking fundamental inquiry, exploring questions, and providing a forum for national discussion, facilitating greater understanding, and [looking into] international collaboration. We actually did have quite a few international participants in our meetings and so forth. Maybe we got off to a slow start but it did take place.

PROF. DRESSER: I think what was distinct for us was that we were set up not to focus as much on policy as other groups have, and then, there was a second distinctive part of

our order. I think all the commissions have tried to explore different positions in reports, but typically strive to reach consensus. This often produces some procedural measures, and then substantive principles that are acceptable to most if not all members, and I think this is entirely appropriate for policy, is probably what you have to do. But if you're talking about inquiry into bioethics, it produces a plain vanilla version.

PROF. DRESSER: The approach here was different in that we were told to articulate the array of views, sometimes competing, rather than trying to reach consensus. I think that the release from consensus really affected what we did. There was so much more emphasis on discussion and education, for better or worse. We did have quite a few reports with the consensus recommendations, but almost everyone at the end has personal statements. We may have had a few dissents but more often, we were all invited for every report to say [respond to the question]: "Is there anything you'd like to elaborate on?", and just present [our individual] take on [the issue].

PROF. DRESSER: In that way, we tried to diversify it and also, our first report on human cloning, because we continued the cloning wars – we had two different policy options, and a majority and minority position on cloning for research. Also, some of our reports had no recommendations, just analysis.

I think we were the first group that had a website with not just reports and transcripts, but lots of other supplementary material. Our [Executive] Order really pushed this education approach, and I was really happy to see you guys take that on. I hope that that will become something for future councils. One thing that hasn't happened in other councils –

we had four of our reports published by commercial publishers. [The reports] were more accessible because of that. Our most popular one was *Being Human*, the one that has excerpts from literature, so take that, as you will. That sold out overnight.

PROF. DRESSER: We had lots of college and university teachers bringing their classes to our meetings. We got lots of invitations to be in debates and speak at colleges and universities. There was one enterprising Mount Holyoke College professor who brought her students to our meeting – she had a graduate seminar and an undergraduate class. She assigned the class and the students in the seminar to play the roles of the different people in the council and had them conduct a meeting in front of the undergraduate biology class. Then, she wrote this up for a journal. It really drew in the students in a way that she said was something she'd never seen.

I got to meet the person who played me, which was fun. [Dresser laughs.]

DR. GUTMANN: We inherited that. She actually came to ours and did the same thing.

PROF. DRESSER: Okay! Good for her. Very creative.

Besides being less focused on policy, we were notable for having more conservatives that other groups have had, as well as more public intellectuals who had written on topics relevant to bioethics, but hadn't really focused on bioethics. We were born right after the divisive election and after the embryonic stem cell research controversy.

PROF. DRESSER: Before I joined the council, in retrospect, I can say I was an innocent. I was very naïve about what can happen when bioethics is conducted in the national spotlight, especially when the deliberations address issues that have become a part of partisan political debates. I learned a lot and a lot of it was positive, and I learned that people of goodwill with different values and positions can join together in civil debate over many of the bioethical issues can join together in civil debate over many of the bioethical issues that divide people in this country.

Being on the council taught me that it can be challenging, stimulating, and a lot of fun to talk about bioethics issues with people whose political views are quite different from mine. I also learned that thoughtful scholars with diverse disciplinary backgrounds and moral commitments who haven't focused their work on bioethics bring new insights to the table. In my view, future commissions should try to show people that it's possible and fascinating to engage in civil discourse with people who have disparate views and offer a model for people of goodwill in this country to speak together about the issues that can be so divisive.

PROF. DRESSER: I also learned some more painful lessons. One was that advocates with a stake in the government's resolution of a controversial ethical issue want you on their side. If you acknowledge the merits of a range of ethical issues, you'll be attacked by individuals and interest groups with a single agenda. Some people won't like it if you deviate from what your colleague Jonathan Moreno calls "the great bioethics compromise", in which he's adopted a philosophy that he describes as, "keep a close eye on scientific innovation for its societal implications, apply the brakes now and then as

needed through regulations or guidelines, or just declare public discussion and let the bioethicists be the ones to analyze how all this is going.”

PROF. DRESSER: So, people who are comfortable with the great bioethics compromise were vocal critics of a politically diverse council that dared to depart from this accepted approach. As a liberal democrat from mainstream bioethics, I was disheartened at the narrow-mindedness characterizing some, certainly not all, of the criticism. Although there were very important exceptions, too many critics prefer to rely on media reports and unfounded assertions about the council rather than the transcripts and reports that constituted our actual work.

PROF. DRESSER: I'm going to end with discussion of what we should do going forward. This has come up again and again. We have all these groups dealing with bioethics policy matters – Recombinant DNA Committee, the Secretary's Committee on Human Research Protections, private United Networks for Organ Sharing – all these groups which have specific policy tasks and then all of the National Academies projects and so forth. What we've got to ask is “What can a national advisory group really add to this?”

In a way, bioethics has succeeded so much; national commissions are in search of an identity. One thing I would really support – again referring to Dennis Thompson and Amy's work on deliberation – deliberation in bioethics should expand to include the voices as many possible of those now excluded. We hear plenty from bioethics experts,

from the researchers, from the physicians, and a little bit from members of the general public.

PROF. DRESSER: We hear very little from people who know what it's like to be a patient, a family member of a patient, or a research subject. I think we need to hear more from them; I think comments during this morning's discussion alluded to that. These comment periods that we have, they're just not nearly enough. People were talking about having a member of the press on the council but also, I would say, people who have personal experience as patients and subjects really need to be a parts of these things as well as a close advisory role or some mechanism where we could get their insights.

Maybe like a review as you were saying [Dresser turns toward Shapiro], like the National Academies' to look at the reports and say, "Well, this has nothing to do with what really happened to me." I know when I became a seriously ill patient and I was asked to participate in a cancer treatment trial, I learned so much about my field that I didn't know. This is why I'm pushing this.

PROF. DRESSER: I think I'll stop here. A couple small things – One is, I don't know about you all, but, I always felt very frustrated that I had this day job that I had spent a lot of time on and limited time free to work on this stuff. I thought – I wonder if there could ever be something like a grant where you could get 25% of your time compensated for working on your commission work or something like that. Maybe that's something you did, but that would be something to think about. Also, I know at the last meeting, you were talking about focusing disproportionate attention to cutting-edge science, research

issues. I think that makes sense because the federal government is much more involved in research than it is in clinical areas.

PROF. DRESSER: We actually did do a few reports on clinical issues. We also had a report about access to healthcare that was just about ready to go when we ended, which was really saying that everybody should have access to healthcare. We never got to put that out there, but we have another report called *Taking Care*, about caring for the frail elderly. To me, that's one of the most important issues we face. It hardly got any attention. When we were doing the cloning report we had C-SPAN, they had that camera going around when we were talking – full of media. When we issued *Taking Care*, the report for caring for the elderly, we had two, three people. It's also culture and the media in terms of what's hot and fun to talk about. We're influenced by that. Thank you.

DR. WAGNER: Thank you.

And finally for this panel anyway, before we open our discussion, is Dr. Eugenijus Gefenas. Welcome; it's good to have you here. He is Professor and Chair of the Department of Medical History and Ethics at Vilnius University in Lithuania. He is the Director of the Lithuanian Bioethics Committee and the Co-Director of the NIH Fogarty International Center-funded training program entitled “Advanced Certificate in Research Ethics in Central and Eastern Europe.” He is a member and the former Chair of the Committee on Bioethics at the Council of Europe and a member of the European Society for Philosophy of Medicine and Health Care. Dr. Gefenas, whose work focuses on ethical issues in human subjects research, graduated from the Medical Faculty of Vilnius

University in 1983 and obtained his Ph.D. in medical ethics from the Institute of Philosophy, Sociology and Law in 1993. From 2002 until 2009, he represented Lithuania as a member of the International Bioethics Committee (IBC) of the United Nations – UNESCO. In 2014, Dr. Gefenas was appointed to represent Lithuania at the Bureau of the Intergovernmental Bioethics Committee (IGBC) of UNESCO and was elected as the Committee’s chairperson just last year. Thank you for being with us today.

DR. GEFENAS: Thank you so much for this kind introduction. Thank you for inviting me to present my views here and I am particularly honored to be with you because The Hasting Center, which was mentioned by some of you a few times today, was also the place where I was introduced to bioethics, one of the places, in the early ‘90s. Also, I think your committee is the committee that serves as a model to many other countries to [understand] how the national ethics bodies should work.

I want to go back with the slides, because it’s already the third slide here. Okay.

Also, I think the point is that committed like the Nuffield Council on Bioethics or the national committee in your country, they serve as a model and, therefore, I thought that combining with my UNESCO experience, the topic would be international capacity building initiatives.

DR. GEFENAS: The Global Summit was mentioned as well a few times during this meeting, and Professor Capron noted that the first Global Summit was initiated by the Presidential Commission in ’96 together with the French national committee. This international capacity building initiative, if we understand capacity building in a broader

sense, is bringing countries together to share experiences. If we look at the slide, we [can] see [an] interesting increase in [the] countries participating in the Global Forum from 18 countries in '96 to almost 100 countries in Berlin [in 2016], the meeting some of you already attended as well.

Now, the question is “What does it tell us?” Does it tell us that the committees in these countries, they work efficiently? What is the model of the work? What are the problems? I think it’s quite a complex issue. I would like to spend my time today concentrating on the following issues: thinking about the incentives to establish national ethics committees, highlighting the role of UNESCO, and I will finish with the main challenges face next in the developed and developing countries.

DR. GEFENAS: With regard to UNESCO, I think this instrument, UNESCO’s Universal Declaration on Bioethics and Human Rights, Article 19, is a very relevant article for our discussion because I think this is the only global document, the only international document, which explicitly encourages member states to establish national ethics bioethics. There are instruments, documents, which particularly in the field of research ethics, we have quite strong documents encouraging or requiring [us] to establish IRBs or “regs” [regulations], but this is the only one with regard to national bioethics bodies and it also is explicit about the main features of the national ethics committees, namely independence, multidisciplinary, and pluralism. As well as – it already defines the main functions of the national ethics bodies like fostering debate and education, and preparing guidelines.

DR. GEFENAS: UNESCO works with the help of two important committees that [organize] with respect to bioethics. The Universal Declaration was developed by the International Bioethics Committee – IBC. This is [a] committee of independent experts; it does not represent government. The main tasks of this committee are reflection on bioethical issues [and] dissemination of principles. It is also important to note another committee – the Intergovernmental Bioethics Committee, IGBC – which works together with the IBC, International Bioethics Committee. However, this is the committee of representatives of governments.

DR. GEFENAS: And this way, the Intergovernmental Committee is supposed to give its opinion on the main documents of the IBC and also to express opinions on the agenda for the – for the following – for the future work. So in a way, this makes UNESCO instruments, at least in theory, implementable at the governmental level.

DR. GEFENAS: And then what is – what follows naturally from this institutional structure of UNESCO is this ABC, so-called ABC project, of assisting countries to establish bioethics [committees] because, as UNESCO notes in some of its documents, [the] majority of member states in the world, they do not have national ethics committees up-to-date.

DR. GEFENAS: So, there is this project. It starts with the exploration of the situation, with the technical support to establish an ethics committee, and then with the continued support – and there is, again, you can find the list of countries where these – these are developing countries, as we can see, where the committees have been established. The

problem is that if you – if we try to find some fluid information about the functioning of these committees, [and] there are no information available, what happens next?

DR. GEFENAS: So, it brings me to the European experience because Europe, in a way, is a good example for capacity building in bioethics committees, computing development in developing countries because Europe is very diverse. The countries are different in terms of socioeconomics and size.

What we find in Europe is that, on paper, all the national ethics committees and all the – EU member states would have national ethics bodies, and we will find these three functions, which are kind of classical functions, for national ethics bodies in their statutes. However, if we go and – if we try to see what is the actual functioning of these committees, they take more roles.

DR. GEFENAS: So, the bioethics, development of bioethics, is taken in a broader view in many European countries. For example, in a few countries I mentioned – I referred to in this slide, they are also involved in coordinating or approving multi-center research studies.

Now, if we try to get the broader view, this is interesting study, Satori study, conducted by the Secretary of the Austrian Bioethics Committee. And she studied [experiences] of almost ten European NECs, National Ethics Committees, Nuffield Council and also the Presidential Commission. And it was interesting to see what are the challenges, in a way, listed as the challenges for – in this case, for the developed countries.

DR. GEFENAS: The main challenges was – were related with the misinterpretation of NECs activities. There were mentioned by many speakers today that the same difficulties are also faced by your committee due to some misinterpretation by politicians or public policymakers or the public. Because there are some expectations, maybe not very relevant, because people expect that we have measurable results, that we have recommendations, which are easily implementable. So, this kind of legalistic model, is very, very viable; and also people try to see the opinions or reports offering definite solutions to dilemmatic situations.

DR. GEFENAS: So, these were concerns expressed by representatives of Austrian, German, French, Spanish, Slovenian bioethics committees, as well as Nuffield Council, and, also, I think somebody from the Presidential Commissions were also interviewed there.

Now, for the future challenges, again, the main task was to improve ways and possibilities to reach out [to] the public. So very similar what we hear around this table today. And, also, the Austrian Bioethics Committee noted the issue of emerging technology as the one which should feature on the agendas of the national committees of the developed countries.

DR. GEFENAS: Now, if we go to the developing world, I think we see [a] completely different picture because – and I have two slides listing – trying to describe the

challenges there. So, first of all, I would perhaps name the first one, the asymmetry between developing and developed countries in terms of resources available.

For example, resources in this country and [a] developing country would be very different in terms of money and human resources. But, also, more structural things are related to the difficulties to gain in a pluralistic discourse because many developing countries would have not very democratic societies and authoritarian governments. So imagine the bioethical debate in this context.

DR. GEFENAS: And, also, if we try to find information about the functioning of national ethics bodies in many countries, developing countries, we will find it quite difficult to find it in English, or the opinions which are the main feature of the – as a result of the output of the national ethics bodies would also be not always – will also – we will not always find this on the websites.

DR. GEFENAS: Another structural issue is that the issues prioritized by the developing countries would be very different from the developed [ones]. I assume that the note that emergent technologies as a priority in the developed world would not be priority, perhaps, in the developing countries because sometimes the issue of corruption would be phrased as a more relevant one.

And it happened to me to be in some Central Asian countries with this problem of establishing national ethics bodies. And it was quite – it took quite [a long] time to

switch from the corruption problem to the other issues we are talking today around this table.

DR. GEFENAS: And there is also another structural difficulty. I called it controversies of global approach, and the UNESCO applies this global approach with its Universal Declaration on Bioethics and Human Rights because it is supposed to be applied to all the countries of the world; however, developed countries are not always interested in this very general framework.

That was a criticism of the Universal Declaration on Bioethics and Human Rights, that it is too general and countries, developed countries, they have already quite sophisticated legislation and guidelines in many areas, so why do they need another abstract and general framework? On the other hand, for the developed – developing countries, even applying this general principle, principles, of informed consent and research can be a challenge.

DR. GEFENAS: So, my concluding remarks: I think that thinking about the capacity building incentives, and I think this committee is one of those, as I mentioned, stressed in the beginning, is an example of – [a committee] which can be used as an example of these initiatives.

We should be explicit and think about different challenges faced by national ethics bodies in different parts of the world and perhaps – this is just a suggestion – I was thinking

about European countries. The council of [European] countries, as I said, with very different sociocultural situations – I'm finishing in a few seconds.

DR. GEFENAS: These countries are struggling to create national ethics bodies and then perhaps we could have some broader – broader range of examples of how these national bioethics bodies could work in different sociocultural circumstances. So, thank you for your attention.

DR. WAGNER: Eugenijus, thank you very, very much. In fact, thank you all for your contributions. I've got three or four questions of my own that I – I would like to start with one, and I'm sure the others will get covered by my – by my colleagues here. And it is an extension of what you're talking about, how to set priorities and how priorities might be different in different socioeconomic contexts. But, I want to tie that back, actually, Harold, to a comment that you made that also seems to be related to the – not related to. It was – it was specifically about how one determines the scope of the challenges that we should entertain. You suggested that bioethics has yet to fully define itself.

And based on the example you used, you seemed to suggest that while we, bioethics commission should be addressing research and should be addressing the clinical dimensions, you seem less enthusiastic about the social dimensions. Am I misinterpreting? And is your comment a bit at odds with Eugenijus?

DR. SHAPIRO: I hadn't meant to imply that although, I can understand that it came across that way. Take, for example, the suggestion that Tom Beauchamp made at you last

meeting that bioethics, he said, had not taken up the issue of human rights. I don't think bioethics should take up human rights writ large. But, what it should take up is: Does it have the intellectual resources to find that intersection between human rights and bioethics that we could profitably address. These issues are way more important than anything – it's not that I'm not interested. But, for bioethics, the challenge is, 'Okay, of that big field,'

DR. WAGNER: Where is the narrow intersection that we should focus on?

DR. SHAPIRO: That's all I meant to say.

DR. WAGNER: Thank you. Thank makes me feel better actually. That was very good. Comments from colleagues here? Raju first, then Nelson.

DR. KUCHERLAPATI: So, I was very curious about these two different themes of notions, that one notion is that groups such as this should not make a specific recommendation and that we should provide just the options and leave it there. And the other view, and I think I represent our group, but we felt that it is absolutely essential that we take a stand on an issue. And, of course, you know, by virtue of the fact that this group can come to a consensus about that not only makes a case as to what this group thinks is the appropriate thing to do, but it also says that it is possible for diverse views to come together to bring to focus one of them. So, how do you think about that?

PROF. DRESSER: One interesting thing that our first Chairman, Leon Kass, said was – and he was much more interested in the objective of national education and fostering dialogue than specific policy advice. The only time we were asked for specific policy advice was for the [human] cloning. So, that was just not our assignment.

PROF. DRESSER: But he said he wanted our reports to be kind of like Supreme Court opinions. Sometimes there would be majority-minority, but what he really wanted was the best case for all of the major sides to be made so that people could read that and learn and thoughtfully develop their own positions on particular issues that concerned them as citizens.

PROF. DRESSER: Now, you may say, well, that's ridiculous for the commission, but I guess another thing to throw out is: Do commissions all have to be doing the same thing? I mean, we've talked about continuity, but maybe different commissions do different things at different times and what's wrong with that? So, I'll just throw that out there.

DR. GUTMANN: I think – just in the spirit of dialogue, I think given your commission's charge, which was not to actually make recommendations, that was your charge, but it is – Raju does speak for the commission. It is our view and our charge was to advise the government. And in the context of an ongoing sense – and it's not just a sense, but evidence – of gridlock in Washington that is enormously frustrating the American people, who we all loosely, if not strictly speaking, represent, we do think that if a group like ours, which was a dozen people, can't come to consensus on anything, then what hope – and I – it doesn't mean unanimity, necessarily, but a consensus, you know, enough to

make a recommendation – what hope is there to address the American public's legitimate sense of real concern that their government is not functioning?

So – and the analogy – I just would say the analogy to the Supreme Court is inapt – inapt for a body that doesn't try to make decisions. The Supreme Court strives in every one of its decisions to reach a unanimous decision if it can't – if it can; and if it can't, it always reaches a majority decision unless it has only eight members and is deadlocked four to four, which is very rare. It is happening now, but it's also happening in the context of the concern that the American people have for institutions of government not functioning.

So, I think you're absolutely right. Given the charge of your commission, there wasn't even – you would have to dissent from the charge to push for consensus on everything, but that was the exception rather than the rule on commissions, and certainly, we would have been letting not only the President down, but the American people down, I believe, if we hadn't strived for – not necessarily achieve. We did achieve unanimity and everything, but that wasn't a requirement. It was a goal, if possible, with integrity.

DR. WAGNER: I would say one of the – and just – one of the things I found very attractive about the charge to your commission, though, that bears on this is the language that you should articulate fully the competing moral positions. I think that's an extremely important thing to do, even as this commission then went forward to try to say having heard all of those, this is -- this is the – how will you – how will you come to resolve it. Who's next? Nelson.

COL. MICHAEL: Dr. Shapiro, you made a comment about some of your reports, when they went through a National Academy of Science vetting process, their – their report card improves. So I guess it begs the question, what was our GPA? But I won't – I won't ask you to answer that question. How would you – how would you operationalize that for a body like ours? I mean, so I guess, is the intrinsic value of the – of the National Academy of Science review process, is it the process itself, or is it specific expertise that simply exists in that body? So how would you – how would you convey that to a body like ours?

DR. SHAPIRO: I guess I got the wrong one.

DR. WAGNER: No, you're on. You're on. You had it right the first time.

DR. SHAPIRO: Okay. I believe you. I think that any committee such as yours, any commission such as yours, any group eventually can fall victim to losing sight of the – of the scene in which you're trying to operate. It's just inevitable, I think. And you can take advantage of people who are equally as expert as you are and see whether this makes sense to them or whether you've lost track of something on the way from your education to your recommendation.

So, it's not that the members of the National Academy, to take one committee, it's not that they have better experts somewhere. They just have different experts somewhere. And that gives you another sense of whether you've really done what you hope you did. And

just my experience, and others could have other experiences that this just dramatically improves the quality of what you're doing.

Now, there has to be an end to that. You could referee the referees. I mean, it's like the – who guards the guards problem all over again. But at least doing it once seems to me useful, if the time allows. When you have these 90-day constraints, obviously, that's very, very difficult.

DR. WAGNER: Let's have Anita, Dan and Christine and then we'll go to our break before reconvening on the roundtable. So, Anita.

DR. ALLEN: I appreciate all the comments. I was intrigued by the point that Harold made about social justice issues versus narrower bioethics issues, like human subject research or clinical ethics, and I was reminded, as I think was our leadership, of our report on Guatemala, *Ethically Impossible*. Which I think was one of our most important and emotionally wrenching reports and studies.

But, you know, in that context where you have research abuses happening in a developing country, you will sometimes have deeply connected issues of both of your – of your archetypical types.

So, yes, we were concerned about the issue, for example, of informed consent of research in subjects because the prisoners and sex workers and children and patients, leprosy patients there, did not give their informed consent and probably could not have to be research subjects.

On the other hand, to talk about that instance, which is a classic bioethics sort of case, and not talk about social justice would have been impossible because unless you really understood, say, the context of U.S. agribusiness in a developing country, it would have been hard to make sense of why it happened, why it was allowed to happen there, why it was ethically impossible in the United States but ethically easy in Guatemala. So, I think – I appreciate the distinction. I totally agree with you that, you know, one can't define human rights, you know, in its entirety as – as a – as bioethics and vice versa, but – but that it is equally important that we not forget or not overlook the social justice and even the human rights implications of so many of our classic bioethics problems and errors.

DR. SHAPIRO: As I said before, I agree with that. It's just my plea – perhaps misunderstood – is just be cautious about what aspect of human rights is relevant for your particular study. I agree with everything you said about the Guatemala case. And I think it was very important to expand it to do that, but to do it in the context of understanding where do human rights and bioethics intersect.

DR. WAGNER: Yeah. Where they're combined. Thank you. Dan.

DR. SULMASY: Thanks. Two – two questions; one short directed one and then maybe a bigger one.

The first short question would be for Dr. Gefenas. Given your expertise nationally, I wonder if we could have, for the record here, whether the U.S. is an outlier in terms of

not having continuity in its National Commission. Are there any other commissions in which every successive government dismantles the previous one and starts a new one, or do they have continuity across governments?

DR. GEFENAS: Well, it's a very complex question. I'm not -- because you have to know all the practices of all these countries, but I don't -- I don't think that the United States would be cited as the example of discontinuity. That's -- that doesn't feature in the literature I read.

What features, really, is that the -- this is presidential model and some of the reports are really influential globally, like Belmont report. For example, the study I mentioned, the study -- the Satori study, it mentions the Belmont report as well as the *Definition of Death*, that was also the outcome of the commission, as mostly influential report, so...

DR. SULMASY: I'm sorry. It's a slightly different question. Not how are we regarded internationally, but whether there are any other countries that do it the way that we do, that you're aware of.

DR. GEFENAS: I think the countries where the commissions have a term and demanded ends and the commissions where the governments would then be responsible to create another body, to establish another body, would be very similar examples. Probably the difference is what you've already mentioned, that there were some discontinuity for the commission at some point where the commission was not established for a couple of years, if I remember correctly.

So, in other country – in other European countries, the commissions wouldn't have an interruption in terms of [their] time, but the different commissions would perhaps be representing different political views. And I think there is another point – an important point here, which was also mentioned in this report I cited, that it's – politicians, they are very keen to use the bioethics commission to promote their position. While sometimes, when we have dilemmatic issues, the reports could formulate majority and minority positions and then [that] is for politicians to choose.

So, I think that is important feature for national bioethics bodies because it – sometimes if you have a very controversial issue, there are different controversial positions, and then this is for the politicians to choose the trajectory, which is in line with this policy.

DR. WAGNER: Dan, given that your next question is likely to be provocative of more conversation and given the time, would it be appropriate to hold it for the roundtable and allow me to go to Christine?

DR. SULMASY: Yes.

DR. GRADY: Thank you. Thank you, all. I want to just follow up on something I think I asked the last time we met as well. I'm continuously struck by the fact that commissions don't do more clinical things. And I know that there are some exceptions, and Alex talked about those this morning, but Dr. Shapiro said, "We should focus more on practice than on policy and legislation." And in the world that I live in, some of the

clinical issues are the most compelling and the most difficult. And you would think that the public would be interested in those. You would think so.

But then we have, you know, the *Taking Care* report that nobody seemed to care about and the very infrequent taking up of clinical topics by commissions. So, I guess I'm just wondering if anybody has any thoughts about why you think that is.

And I also noticed on the UNESCO slide, it's [clinical practice] one of the lists of functions; and, yet, I think, if I understood you correctly, most national ethics committees don't deal with the clinical issues. They deal with the research issues. So, does anybody have any ideas about why?

DR. SHAPIRO: Let me press the right one. I think good ideas travel. And I think there is more influence that succession of bioethics committees had on clinical practice than we realize. The discipline, as a whole, doesn't do enough research on just what is happening out there in the clinical sphere, as an example, and it's really amazing to me.

I mean, there is probably more data on clinical practice than almost any other activity in the country. There are enormous quantities of data. We have this revolution in data analysis which is going on, so-called big data developments, which give you the tools to deal with that. And one looks very hard – maybe I just haven't come across the right material yet – to say, you know, what can we learn from that? We have all this data being accumulated. We have all these suggestions being made. Some things travel without regulation or legislation, believe it or not. That why I said it's important not to treat

regulation and policies the same thing. They're related, but they're not the same thing as what's going on, for example, in the clinical world. And I think that's a huge area for research if someone would like to start something, I think that would be terrific.

DR. WAGNER: Ruth.

DR. MACKLIN: Yeah, I don't want to speak – I don't want to speak to this internationally, but, for example, I mean, there are two things in the United States.

First of all, we don't have federal control over clinical matters. That's all a matter of the states. And if you look I mean, that govern the profession. So that's one difference: That a national body would be, in a sense, telling the states what they should do and not as much clinical practice. But the other, and I may be wrong about this and I'll get a lot of pushback, but, I mean, there has always been an effort on the part, at least in the medical profession – I don't know about nursing, but in the medical profession -- to be self-governing and essentially clean up its own house and take care of its own house and let everybody else stand back.

So, when you look at some of the kinds of things that can get physicians, essentially, to be cast out of the – of the realm, there are very, very few. I mean, there's a self-protective – they're like the police, in a way. A lot of self-protection and even when there's wrongdoing among clinicians, a clinician leaves one institution – a physician, for example – and the institution that he or she leaves doesn't tell the next institution what he did wrong. So, there is that self-governing aspect. And at least in the United States,

without any really national control in terms of legislation or regulation, there's a difference.

Now, other countries are different in that, and I can't explain, you know, what that would—

DR. GRADY: But even in the United States, I think the interesting question is, well, who's the audience? Because a lot of people have said the audience is the public. At least one of the audiences of national commissions is the public. And so I agree with you that there's less national control over clinical practice and there's a lot of things wrong with the way disciplines protect their own.

But the public should be – or I would think is – interested in these issues and maybe interested in how to think of them – think about them from a bioethical perspective; and, yet, it doesn't get any traction and it's just surprising.

DR. GUTMANN: So, I think the comments here together actually lead to some conclusions if we accept them. One is that it is true that clinical practice is decentralized by its very nature. We wouldn't want it to be otherwise, certainly.

But Harold's point, I think, goes directly to this that not everything that bioethics commissions productively, with impact, comment on or recommend on should be policy or law, but practice and certainly we have done, in other cases, where things are decentralized, made recommendations and looked at practices. And there is – the Federal

Government does have an education which is every bit as decentralized as clinical care, made recommendations and put resources for incentives. So, I think Ruth's observation is empirically correct, but, prescriptively, I think we followed Harold's view that we shouldn't look just – and commissions shouldn't look just at policy and law for, if no other reason, that it would be better if you didn't have to do, you know, a new law, a new regulation, if you could actually influence practice. And I think so looking more at clinical practice is important.

DR. WAGNER: That should be on the agenda.

DR. GUTMANN: Yeah.

DR. WAGNER: You folks, obviously, have left us with a lot more questions. That's why we want to invite you right back here for the roundtable. We will take the briefest break possible with a goal of reconvening as close to a quarter past the hour as possible, but not before we thank you all so much for your preparation and your contributions.

[Applause.]

DR. GUTMANN: So let's take a ten-minute break and reconvene.