



**Presidential Commission**  
*for the Study of Bioethical Issues*

**TRANSCRIPT**

**Commission Members**

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Amy Gutmann: Okay. Welcome back. This is the final session of this meeting and it's important for this session for us to go back to the fundamental question put to the commission.

President Obama asked for assurance that the rules governing federal research today adequately guard against abuses perpetrated in Guatemala in the 1940s. He also asked that, that being a low bar, but the bar which we began, right? He also asked for assurance that current rules and regulations protect people from harm and unethical treatment no matter where in the world U.S. supported research occurs, so both domestically and internationally.

And during our review we learned that since the 1940s major changes in the oversight and practice of research with human subjects have created a vastly different world for researchers and subjects alike. We have in place today regulations and professional standards that provide substantial protections for the health rights and welfare of research subjects, and in general can be said to protect people from harm or unethical treatment at a level far more adequate and higher than was in place.

Very little was in place actually in the late 1940s. And that's true when they volunteered to participate as subjects in scientific studies supported by the federal government, and true whether it be in the U. S. or internationally.

The commission's careful review of current rules we had input from the International Research Panel and input from excellent presentations and public input to the commission. All support that very general conclusion, but and this is an important thought, the currently limited ability of some government agencies to identify all of their human subjects research prevents the commission from saying that the system is capable of preventing all potential harms or unethical treatment.

And while it is true that there is no way to prevent all harms in research, particularly in medical research, and we have all acknowledged that it is not apparent that or let me—I will use a double negative, it is not apparent that the current system cannot be improved. Or we have found ways in which we are likely to recommend that the current system can be improved in several areas.

We think that there can be improvements to increase transparency and accountability, for example, which would enable people including prospective participants in research to know before they volunteer for it that there are protections in place. And also if we increase transparency and accountability we are also better able to expose and reduce the likelihood of harm or unethical treatment.

And so what we as a commission are setting out to do is to provide recommendations that would enable the federal government to establish more confidence in the system, as well as establish a system that clearly protects, and when I say clearly that it is not just insider knowledge the degree to which it protects human subjects in research. And so what I would like to do in this session is really discuss what kinds of details, more flesh to put on the bones of how we directly respond to the high level question before we set out in making the recommendations we are making.

I did a very broad outline here. I think it is true to all of our deliberations to date, but I would like members of the commission and I will begin, Jim, if you want to begin, say what kinds of findings, because this is the finding rather than the recommendations, what kinds of findings do you think is most important that we put into the report?

James Wagner: I will say a couple things. Actually I hadn't anticipated that question except that is what we have been at—

Amy Gutmann: Yeah.

James Wagner: —at for this whole time. And I think I'm comfortable with some affirmative language about our confidence of not seeing another Guatemala. I must say I find us tempted often to comment and make recommendations that are more mechanical.

For example, I have not said this and I wouldn't be comfortable I suppose letting the report go forward this way, but even talking about a transparency, less about accountability, a transparency is a condition. It's a mechanism. What we are really trying to do are we not, is to insure there is availability of information and that there is trust, trust or confidence.

We really don't want ultimate transparency. We are not saying we ought to tear down the HIPPA rules.

Amy Gutmann: No.

James Wagner: And the recent cries and maybe these cries will stay for the duration of our report, but the recent cries that we hear from transparency as though it is a standalone virtue are really a way of saying that we don't trust you that trust is lacking and I need to be able to look over your shoulder. I think we are not using it that way I don't believe, but I think we are falling into a trap of saying such popular language of transparency is important and we should be using it.

So I do think that one of the things we have really been looking for we should say out loud is to what degree of confidence can we tell the President and what would change the—and what would enhance the confidence with which we could tell the President that circumstances that existed decades ago are no longer here and in fact we believe by making the following improvements and changes we could enhance that confidence. So that may sound as though it is merely linguistic in a jargony sort of comment, but it really is not.

Amy Gutmann: Yeah. Yes, and we had—

James Wagner: Feel about that.

Amy Gutmann: —an extensive discussion on the international research panel on precisely which we all agreed on precisely what you said, which is the end is not and indeed even the means isn't complete transparency. That is not one of the ethical principles we are working with, but it is accountability.

James Wagner: Yeah. That's [inaudible].

Amy Gutmann: And when federal agencies can't provide the basic data not for any nefarious reasons you don't have the basis on which to answer the President's charge which he really wants us to answer because he does want to give the American public confidence in the system. And we have every reason to believe the American public should have confidence in the system.

But we don't—that is we have—there is nothing that came to light that suggests there is anything like Guatemala that could be possible out there, nothing. However, there are human subjects research going on that the agencies themselves cannot report to us.

It is not that they don't want to.

James Wagner: Exactly.

Amy Gutmann: They cannot in a timely fashion report to us. So if we wanted to do or if the government wanted to do a random audit it couldn't do a random audit on the complete base that would be necessary.

James Wagner: Exactly. And I'm simply saying in order that we can say Mr. President to give you to be confident—

Amy Gutmann: Yes.

James Wagner: —we would recommend that there be accessibility and that there would be accountability and that definition [inaudible].

Amy Gutmann: And I think what we can do there in our findings is lay the groundwork for giving the ethical underpinnings which we do on our recommendations for the AMPRN, which will soon be the MPRN. And that moves in that direction.

James Wagner: And from my end, philosophically that the thinking extends to a very fine conversation we had in the last hour where we were able to say what is first and foremost our responsibility, what's first and foremost do we understand as the ethical goal and sort of tease ourselves away from the temptation to try to define the mechanisms. And I think asking others to look at the inventory of mechanisms and to make an assessment of whether the mechanisms that are in place meet the ethical requirements that we all agree are there, not asking to re-evaluate whether or not they are ethical requirements I think is another example of the same kind of thinking to try to stick to the highest purposes for which we were called.

Amy Gutmann: I'm open for commission members, Dan.

Daniel Wikler: The one caveat I have with the way of sort of framing even what the goal is here is that we ought to be just a little bit more temperate instead of saying what we are aiming at. And when we were sort of talking about preventing all harms and all unethical research Chesterton famously quipped that the only theological doctrine for which we have empirical proof is original sin, is no matter what rules just make sure we acknowledge very carefully that it has got to be an optimal system.

It is not that we can guarantee in all possible rules that we set up when no matter how much transparency we have, no matter how much access we have to data that we need to also as we said in the report emphasize virtue, and the training of the investigators and even that may fail, but that we are doing the best we can and have the most optimal system. I think we can say there is room to improve, but just to temper it a little, so—

Amy Gutmann: So the question was protection from harm or unethical treatment. And what we have been consistently saying is protection from avoidable harm or avoidable unethical treatment there, whether or not, whether original you subscribe to original sin or not.

Daniel Wikler: Human fallibility.

Amy Gutmann: It's we know that there will always be, first of all we know we are dealing with experiments in which there is risk, and some of the risk is unavoidable and some of it can't be compensated for either.

Daniel Wikler: And some of the unethical behavior can't be avoided either. I think that's important to say that we will never be able to eradicate all unethical behavior. I think we just have to state that plainly.

Amy Gutmann: Christine.

Christine: I would like to see us emphasize that research is a very valuable commodity in the world and it has—

Amy Gutmann: Enterprise.

Christine: Enterprise, benefits, [inaudible], also that especially if you are thinking of it since the Guatemala story it has gotten enormously more complex in terms of how it is carried out. And there are lots of layers of people and systems that are in place to oversee the ethical conduct of research and those systems are pretty robust.

And so those are all in place already. So in going back to something we talked about in the last session, is the system broken? Probably not. Can it be improved? Of course and maybe also recognizing that improvement, even if we make recommendations now for improvement there can constantly be more improvement in the future I guess is that I would say, so a little more recognizing that this is a constant process that needs to be undertaken.

Amy Gutmann: Yes, Raju.

Raju Kucherlapati: So with regard to this specific question that you are posing, Amy, I think that getting information from all of the different agencies about the numbers of studies that they conduct and how much money that they spend is important, but as we talked about yesterday having that information doesn't assure us that they are all being conducted ethically.

Amy Gutmann: Correct.

Raju Kucherlapati: And I think we should make a specific recommendation as once you have this information how can it be used to assess whether or not—

Amy Gutmann: Yeah.

Raju Kucherlapati: —then how can you tell the President that okay, we have now the data and now you need to use these mechanisms to show.

Amy Gutmann: So one of the things—this is important, one of the things that that we could add

in recommendations, but for shadow and findings is once the recommendation and the ANPRM is taken, to have a database available consisting of agencies moving forward. And I think, Nita, you suggested a two stage process that would be possible for that. It should be used to help find out whether human subjects research generally is conducted ethically.

Raju Kucherlapati: Just even before all of the information is available if audit is a mechanism—

Amy Gutmann: Yep, yes.

Raju Kucherlapati: —it can be done today.

Amy Gutmann: Yes.

Raju Kucherlapati: You don't have to wait for two years for a portal to be developed and all of the information to be available.

Amy Gutmann: Yeah, yeah, although it is strange to audit only that which agencies can report, if they can't report some things. It creates a skew. But point well taken. John.

John Arras: Also, just piggybacking on these comments, I think it's important at some point for us to emphasize the importance of using all this available data and researchable information to try to improve the process of patient protection, in the sense of doing research on the very protections we enact. Are these effective, or are these just extra layers of bureaucracy which aren't really helping?

James Wagner: How it is that we want to make sure that ethical treatment of human subjects research is a value rather than a requirement, or worse yet a requirement that we imagine is satisfied by [inaudible] that absolves the individual of assuming—

Amy Gutmann: No, finish, please.

James Wagner: Actually, that's the point. We have elements in there, but I'm wondering if we should bundle these together, elements of education, etc.

Amy Gutman: So here's what I think we've been saying with regard to this. We're going to have a whole section on the importance and indeed several sections on the importance of pruning regulations that are unnecessary before the budding stage. And some other recommendations to this effect. However, I take this to say that in the summary response in the findings part of our report, we should mention that accompanying the very desirable development of rules protecting human subjects from harm or unethical treatment there is a concern that the rules not at the highest levels, but the way they've been implemented with sub rules and regulations may have gone beyond what's necessary and what's for the protection and to that extent, we're recommending, we will be recommending late in the report that there be attention and changes made so that rules don't become ends of themselves.

John Arras: So we could—

Amy Gutmann: Rules should be means to the protection of excellent scientific research. From the protection of subjects from harm and ethical treatment. They shouldn't and they have a tendency to become ends in themselves.

John Arras: Just to follow-up. I think we can make an analogy here with evidence-based medicine. You know I mean there's a big movement afoot now to make sure that there's some evidence for the medical services that we deploy rather than just using tradition, which doesn't turn out so well often. And I think an analogous argument could be made for a lot of ethical requirements. Do they really advance patient protection or do they simply make people like us feel better.

James Wagner: Exactly.

Amy Gutmann: Anita.

Anita Allen: This may be an idiosyncratic concern of mine, but it is one that I am concerned about. I assume that there is classified human subject research being conducted for very good reasons of national security and defense by our government. And that we will never have access through notions of transparency or full accountability of that research. I'm wondering whether or not we could have at least a sentence in our findings to the effect that we acknowledge that such research may be going on, is likely to be going on. And that we hope that appropriate human subject protections are being followed in the context of that research as well.

James Wagner: So you acknowledge the suspicion. We certainly can't acknowledge—

Anita Allen: I don't want to call it a suspicion.

James Wagner: We don't have any data.

Anita Allen: But I think that past history has shown that it is very common for our government, for very, very, very important and good reasons to engage in certain kinds of human subject research that the public is not made aware of at least not initially. So without some kind of paranoia or mere suspicion, to—in a positive way, indicate that we hope that human subject protections are being extended even in the context of appropriately classified or undisclosed human subject research.

Amy Gutmann: Val, do you want to say something? Do you want to come up and say something? Val actually for this purpose got top security clearance to—come on up and you explain it. She had it already.

Valerie Bonham: We did as Dr. Grady alluded yesterday, we heard back from every common rule agency which includes the CIA and the DOD and CIA—

Amy Gutmann: Val, you're going to have to use the microphone.

Valerie Bonham: Sorry.

Amy Gutmann: Thank you. So other people can--

Valerie Bonham: Fair point. I just—alluding to what was discussed yesterday in its data collection effort the commission heard responses from each common rule agency including the CIA which is the one people usually think about as well as the DOD. And CIA in specific and we have a letter that we will forward to you on this point and it will be in the report made clear that while they do not conduct classified research they do- and they only conduct research in the United States- they do follow common rule protections for it. So you heard a response.

Alexander Garza: And I will just add for the record as somebody who reviews research for the Department of Homeland Security including classified research that we follow all the applicable norms.

Amy Gutmann: On the foreshadowing on compensation, I want to just make sure we all or at least there's a consensus of unanimity of where we're going on that recommendation because I saw lots of nods and so on but for the—for this session I think it's important and I'm going to do the first part and then I'm going to ask Anita to—she's collected the language for the second part. The first part of our recommendation is to say that there is an ethical case for a system of compensation for research related injuries. Then the second part is—

Nita Farahany: [Inaudible] case system for compensation. There's an ethical case—

Nita Farahany: For compensation.

Amy Gutmann: For research related injuries should be compensated.

Nita Farahany: Yes. Yes.

Amy Gutmann: The second part—

Anita Allen: And there's consensus on this group for medical in there because we don't want to unnecessarily open the door to broader types of compensation.

Female: That we really don't intend.

Amy Gutmann: Yes. Yes.

Anita Allen: I mean medical care.

Amy Gutmann: Yes.

Nita Farahany: And to that regard we might also need to say for qualified injuries.

Amy Gutmann: Yes.

Nita Farahany: I think where we also don't have consensus is what kinds of injuries—The second

part is to say that the federal government should study whether or not a new or different compensation system is needed and if it decides that one is needed to conduct a pilot study after having studied possible mechanisms for what that revised compensation system would look like and third part is then to say given that this is a recommendation merely verbatim that was made—I won't say the date—

Amy Gutmann: We don't need to draft it. We need general outlines—

Nita Farahany: As well as [inaudible] that the federal government should respond with reasons for why it both hasn't responded to past recommendations and if it chooses to not respond with action to this recommendation what its reason are for doing so. Either respond with action or respond for reasons for supporting the current system as being adequate to address the ethical compensation.

Amy Gutmann: Okay. I see everybody here nodding.

James Wagner: Is "needed" as good a word as "warranted"?

Amy Gutmann: Could we not try—that's okay. That's fine but this isn't going to be the exact wording.

James Wagner: The question has—

Amy Gutmann: We have the exact wording—

James Wagner: I wasn't really asking. I wasn't trying to wordsmith. I was trying to introduce the concept of priority.

Amy Gutmann: Yes.

James Wagner: If you said I've got X number of taxpayer money to address some of the biggest issues in healthcare right now, I don't know how this—I suspect people would say yes. There's a need. We can always do better.

Amy Gutmann: You mean like warranted or necessary?

James Wagner: You said the issue of priority is something that I have concern—

Amy Gutmann: The government can come back and say we think the case is a good case but we have other priorities and this takes low—if that's what they want to say. I just don't think we can—we are not in the position of weighing the need for the protection of human subjects against national security for example outside of the protection of human subjects. What we can say is that that's what we were asked to say. Does the present system adequately protect? And we're saying that there's an ethical case for compensation and we want the government—I won't repeat it. Anita has done the—

Anita Allen: That raises an interesting question, Amy. You say that we're asked to answer the

question of does the current system protect research subjects. That's part of the struggle that we're having and why we have this recommendation as a softer recommendation than some members would hope. Because you know we've heard some anecdotal evidence about why people may not be getting compensation adequately through existing tortes plus system and hospitals and other pharmaceutical companies have adopted. But to be able to say, can we go back to the president and say in fact there's a failing of compensation for individuals. I don't think that we can.

Amy Gutmann: We can say that individuals now are not guaranteed compensation for injury for research related medical.

Anita Allen: They're not receiving it. So they're not guaranteed it—

Amy Gutmann: We could—we could get cases where they're not receiving it, too. There are cases where they're not receiving it. What we can't say, and therefore we're asking the federal government to study is whether there's a better system for this. There are people who are not receiving it. Yes.

Christine Grady: I think we might also want to say that the federal government sponsored research is an outlier. Private sector is taking care of this and other countries are taking care of this.

Amy Gutmann: Yes.

Christine Grady: So that's—

Amy Gutmann: That's part of the finding not the recommendation.

Christine Grady: That's a good point.

Amy Gutmann: And that is in there and we'll make sure it's an important point. I just wanted to make sure we have consensus on that and we do. And we will redefine that.

Raju Kucherlapati: Question.

Amy Gutmann: Yes.

Raju Kucherlapati: Question about the [inaudible] recommendation. All of these reports are made to the president, whoever asked the question and the past reports are presented to different presidents, so is it reasonable to ask President Obama to answer as to why somebody else did or did not respond to a report?

Amy Gutmann: I don't think the question—and I haven't seen—this is being—we're not wording for—I don't think the it should be why hasn't it been previously responded to. I think the question is if the government chooses not to act, why has it chosen not to act? Just to give reasons on our recommendation.

Raju Kucherlapati: [Inaudible].

Amy Gutmann: Yes. On our recommendation. I think that's a friendly amendment. Friendly amendment.

Raju Kucherlapati: The previous recommendation then falls in the category of finding.

Amy Gutmann: Yes.

Raju Kucherlapati: Which is appropriate?

Amy Gutmann: Yes. Yes. Okay. Now again anything else on the findings part? Or are we fine with the findings?

Anita Allen: I do wonder whether we need to be more detailed along the lines Anita was suggesting about specific issues or problems that would be confronted by using some of the alternatives. Maybe we don't have to go that far, but I was just wondering whether we need more detail on what the issues might be. So as to inform the president and those who he relies about some of the key questions that we think and we've discovered are worth pursuing such as questions about causation, about the inadequacy of current tort doctrine and so forth.

Nita Farahany: I think so, Anita and I think maybe our subcommittee which has been working on this might want to take a revised attempt at making sure that we've included, both what we've heard and what we've been discussing.

Amy Gutmann: That's not the recommendation, but in what we say leading up to it. So I'm more focused on that since we can have work on all of the recommendations and giving more as much detail in the text as we think we're qualified and can give. Dan.

Daniel Sulmasy: Just in terms of the, again the more general findings, I wonder if we shouldn't say something along the lines of what Christine was saying before about the changed research environment since 1982. Just not only that it's become this sort of important commodity or whatever word you want to use.

Christine Grady: Enterprise.

Daniel Sulmasy: Enterprise but that it's bigger and more globalized. That there's a larger private for profit sector in human subject research and a—

Amy Gutmann: And a larger public sector—

Daniel Sulmasy: And a larger public sector. And partnerships. And then another thing that we haven't really spoken about but if you want to think of one thing that changes the environment from 1982 to now is the way that patient groups are now more likely to advocate for research than to fear it. I don't know whether that makes them more or less vulnerable. But the way in which after the AIDS epidemic, patient groups now look for research and it's I think something we've not spoken about but it's a big sea change from a very protectionist kind of view in the 80s to now people

saying I want access to research.

Amy Gutmann: I think it's really important that we say, and then we will elaborate elsewhere but we say that there's been an enormous expansion, and we can give some rough numbers about that and then elaborate on it elsewhere in the report. And I think that's very important. There's one recommendation that we talked about briefly yesterday and everybody I know is agreed to. I think it's just important to come back to it because it actually affects—it illuminates the findings as well and that's the follow-up, which is that we recommend that as a way of helping to inform those who remain reasonably concerned about these issues that OSTP or another delegated entity within the governed respond with reasons either for considering change or if it decides not to consider change for reasons for keeping things as they are. That recommendation comes out of our observation that in the past there has sometime been rather than a response silence and no record that we can see of why previous governments have decided to take or not to take recommendations and so that would just help everybody be confident about the accountability of government once recommendations are made.

Other—Any other things on the findings because we are close to completion? Yes?

Stephen Hauser: Returning to transparency and recognizing that our change is a focus on government sponsored research. I would just like to ask whether it might be worth discussing whether some statement about broadening reporting responsibilities for non-government sponsored research would further improve the security that something like Guatemala would not happen again.

Amy Gutmann: So I'd be interested in what people—we heard a lot of concern about non-government sponsored research both on the international research panel and on public comments to the commission. We also heard yesterday from two representatives saying what their standards are. Do you want to repeat what you think we would say in the findings?

James Wagner: I might ask others to weigh in, but just as one possibility, reporting of early phase clinical trials in gov trials.com.

Amy Gutmann: [clinicaltrials.gov](http://clinicaltrials.gov).

Stephen Hauser: [clinicaltrials.com](http://clinicaltrials.com). Yes.

James Wagner: When is that reported? We do know that the FDA has sufficient influence sort of after the fact, if you will; they're not going to market in this country unless they've adhered to the common [inaudible], but how early in the clinical trials process do things appear on [clinicaltrials.gov](http://clinicaltrials.gov)?

James Wagner: It is right from the very beginning.

Christine Grady: Two important issues. I think unless you're—I'm not sure which one Steve is addressing. One is right from the beginning people are required to register in [clinicaltrials.gov](http://clinicaltrials.gov). But the set of applicable clinical trials that are required to be registered is not universal.

Stephen Hauser: That's the point.

Christine Grady: So phase one trials for example are not required.

Stephen Hauser: So early phase trials not leading to applications for FDA approval.

Amy Gutmann: So we were not—one second and I will let you—we were not asked to give any detail on anything beyond federally sponsored research. However, we are saying very clearly that all ethical standards apply to publicly and privately funded research and all the same ethical standards apply domestically and internationally. So any recommendations we make that are simply required by ethics would apply to both, but there may be practical considerations that apply differently to publicly and privately funded research and that we haven't gotten into as a commission.

James Wagner: Except we are going to recommend a minimum number of categories of data? Weren't we going to try to identify a data set?

Amy Gutmann: Yes.

James Wagner: Would it be let me just blurt this out. Would we recommend working with industry groups to determine a minimum set of data that would allow earlier posting on [clinicaltrials.gov](http://clinicaltrials.gov) that does not compromise their competitive positions?

Amy Gutmann: We wouldn't do that.

James Wagner: We'd recommend.

Amy Gutmann: We'd recommend that the government does that.

James Wagner: That the government do that.

Amy Gutmann: The FDA.

James Wagner: The FDA would do that in order that we might be able to cover what the ethical concerns we have our without asking industry to compromise its competitive advantage by publishing? You don't think so Barbara?

Barbara Atkinson: I'd hate to go there.

James Wagner: Okay.

Barbara Atkinson: I think it's again if it's not broken, don't fix it. I'm really not sure that there is any reason to think that something is happening at that level.

James Wagner: Except we're concerned that we don't have the right data for government—the ready data for government sponsors our research and we just heard that there's twice as much money being spent on industry sponsored research.

Barbara Atkinson: Right.

James Wagner: You don't think—you're—

Barbara Atkinson: I guess I'm—

James Wagner: Phase two is early enough is that what you're—

Barbara Atkinson: That's sort of what I'm saying.

Amy Gutmann: It's getting too late to try to wade into a territory that we're—we don't have—

James Wagner: Fair enough.

Amy Gutmann: We weren't either asked to and don't have the background of data—

Barbara Atkinson: And the only piece you'd be missing is for things that didn't make it to phase two. Once it makes it to phase two then phase one will say—

James Wagner: Phase one is the safety and—the safety issue.

Barbara Atkinson: It is the safety issue.

James Wagner: It's the place where you're most likely to have the greatest subject danger.

Barbara Atkinson: Yes.

James Wagner: I'm just—

Daniel Sulmasy: I was just going to say on this question that it may be worthwhile just to have some sort of caveat on the report saying that we did not look into and cannot comment on these things but there are legitimate ethical questions to be asked and we also believe that our ethical standards should apply very much to private research as well as to public sponsored research.

Amy Gutmann: We have said that but there's an added yes. Okay. Christine.

Christine Grady: I'm just building on that same thing. It's possible in the sort of the language that we were using with respect to compensation to say that the principle that we're trying to achieve is more knowledge about the landscape of research across the board and one of the possible ways that one might even the federal agencies might consider developing their databases is to build on what's already in [clinicaltrials.gov](http://clinicaltrials.gov) and so we could raise the question of the you know at least considering the possibility of widening the applicable pool that gets put in like studying it rather than doing it. I don't know if everyone would agree to that but that's one way to handle it.

Amy Gutmann: My worry is the more the priorities of our recommendations that we've really spent

time on and the more you put in there the more you I mean at this late date I would be reluctant to put in—

Christine Grady: Although I do think Steve has a good point and if our goal is you can't start to assess the protections until you know what's out there, there's a whole. There's a group of studies that are not—

Amy Gutmann: So we should alert the government to that and say there's a concern out there and on our part that this should be studied as to whether to include that. I think that's fine. Good. I would like to thank everybody on the commission, every member of the public who has contributed to our deliberations in response to the president's charge. We held four public meetings on this subject. We convened the international research panel and the international research panel met three times. We've heard from many excellent speakers and we've heard from many members of the concerned public on this topic and we've heard from citizens of countless countries as well as our own and we've conducted an empirical research project which enabled us to see how readily available data are from the federal government. We've heard from private as well as public representatives and I think we've received tremendous insight from all of the comments and the deliberations. Our charge I think couldn't be more important because it's about protecting human beings from harm or unethical treatment and we I think are well positioned to respond to the president and I know members of the commission and members of the staff will be working very hard over the next few weeks to complete our report. I thank everybody who came today for your participation and your involvement and I know Jim Wagner and I on behalf of the entire commission also want to just take this opportunity once again to thank our staff and Val Bonham our executive director. Thank you.

[Applause]

James Wagner: And as is always necessary. You're so gracious in thanking everyone; it is my pleasure and responsibly on behalf of the entire commission to thank you for your leadership.

Amy Gutmann: Thank you very much.

[Applause]

Amy Gutmann: That's not necessary. But thank you. We stand adjourned and safe travels everybody.