



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

TRANSCRIPT

**Commission Members**

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Amy Gutmann: So here's what I—yes, here's what I suggest—we segue to Dan Sulmasy, who will introduce the topic of compensation on behalf of the commission and the thinking today about it. And—

James Wagner: [Inaudible].

Amy Gutmann: —Daniel and Karen, if you would like to stay at the table, we would be happy to include you in the discussion. I see nods, right? Good.

James Wagner: Let's do that.

Amy Gutmann: And let me just remind everybody who's attending that if you have any question or comment you would like to make, there are cards available if you look back there on one of our staff members, Michelle, has cards. Just get a card, write down your name and fill out the card with your question. They'll be passed up and we'll be able to—time permitting we'll go back and forth between commissioners and any questions or comments there.

Let me also say that we have a designated federal officer our Executive Director Val Bonham. Please stand up. And I'm going to take this opportunity to ask all of the staff members of the commission to stand up. So before we continue, just as a good segue, let us all thank them. They've done tremendous work.

[Applause]

Amy Gutmann: And with that, Dan, if you would present and we will—after Dan's presentation we'll continue with questions and deliberations on this.

Daniel Sulmasy: Well, first let me say this is radically incomplete. We had about a week and a half as opposed to two years to come up with about five pages instead of 150, but we've benefited greatly from the work of past commissions, from your work, Dan, and others.

There are lots of thorny details and practical barriers that I think we've heard a little bit about, but we felt that the first thing that we had to say was there's an ethical obligation that might make the effort worth it. And that's what I'll concentrate on.

So the first issue that we confronted was a possible complaint that our job is to protect people. How is this protection if they're actually already injured? And we tried to make the distinction between a sort of primary and secondary sense of protection that we think dovetails nicely with what Dan said. The analogy we used is to a lifeguard whose primary task is to eliminate risks that people might have of drowning, but also has an obligation of people do drown to save them under those circumstances. And that's broadly considered to be protection. And so we think that this falls under protection of human subjects.

Still, why would it be justified in human subjects research? Several facts—first that as was already mentioned, the benefits of the research redound to the common good while the risks are borne primarily by individual subjects. I think we all know that. And the risks are not readily foreseeable. And it's another way of saying some of what Dan said, but the way I've put it is that the uncertainty is an essential aspect of the justification for the research to begin with. And we have to recognize that's an absolutely fact.

Now the counterargument as you heard is that volunteers may be motivated—one of them is that—volunteers may be motivated for reasons other than the common good and they're not motivated for that. And the reply would be that regardless of the motive, they do contribute to the common good and they're contribution is morally significant.

Many have said that there's a need to compensate those harmed by responsibly-conducted research, 30 years of presidential of commissions, most of the developed nations, our own international task force on this issue raised the question of why we're not doing it. And the basis that's primarily used as Dan said is justice and fairness and the primary argument against this is that subjects freely consent to these risks and therefore they waive their claims to compensation as a sort of free assumption of risk argument.

The counterargument that we want to pose is that a just society can protect persons against bad deal contracts. And it's not paternalistic, but a determination that such an arrangement is just inherently unjust. Just as we protect subjects from unnecessary risk by preventing trials that are too dangerous, we can protect them as Dan just said, I'm almost on harmony here, we can protect them from signing away this form of secondary protection.

And the paradigm example for this kind of case I think would be the NIH-sponsored phase I trial for a sick patient without further therapeutic options, if you take that as the first paradigm to think about this. It's high risk. There's little individual benefit, you know, less than five percent historically, extreme uncertainty, again, that's the reason we're doing it. There's public benefit even if the trial is negative because then we learn from that. The subject is incredibly vulnerable. They may be biased in terms of their own optimism into this, either unrealistically or it may be a coping mechanism for them that would lead them into this trial. It may be that they're purely altruistic, although that's apparently fairly rare. Few are even aware that they've waived their right to compensation because of reasons we heard about before that even one of our presenters yesterday working in academic research said he didn't even know that people waived their risks because it's buried so deeply in the consent forms that they waive their rights to compensation. So I think in some ways their freedom is even compromised or they're making this heroic act of self-sacrifice and in either case I think it's fair to compensate them if they are injured.

It may be suggested then that since the motives of the investigators are mixed and they may be experimenting for profit and not the claims of the—and therefore their claims of the common good are false, that this argument doesn't work, but our counterargument there is that even in that case the subjects are recruited under the presumption that they're serving the common good. So even in the for-profit pharmacy research, the person said why are you signing up for this? Well, to help other patients who might be using this drug in the future. So even if the motives of the investigator are mixed, that's the claim that's being made to recruit the person as a volunteer. And, in fact, to the extent that the subject is recruited under the claim of serving the common good, but this is not truly the motive of the investigator, then a claim of justice might be even more significant because they might've been recruiting them under a sort of false pretense. The paradigm here might be the subject recruited to participate in a phase III trial of me-too drug by a pharmaceutical manufacturer. But I still think the claim for compensation works there.

Still another objection we considered could be that some research seems closer to the free market conditions of a laborer and an employer such that as phase I trials of a new cosmetic drug for baldness where the person was recruited and they're really unemployed and uninsured, right? So this is the, you know, subject as wage earner. Well, here if you adopt the wage earner model,

then you've got to ask how such subjects would be justly excluded from a workman's comp system, which if that's the model you're using, that's what ought to be here that society has deemed just and required of all other wage earners.

Now moreover besides these considerations of justice, to the extent that the research is biomedical, then clinical medical ethics I think commits us to beneficence and non-maleficence towards the individuals in these trials. And that would dictate that clinicians not engage in the research unless they can assure that there's protection for the subjects they're enrolling in the trials.

And finally I think general utility might best be served by such a system, first by reassuring potential subjects and therefore potentially increasing subjects' recruitment into trials, and lastly—secondly by reducing potentially and we heard maybe some suggestion of that the cost that would be associated with resorting always to torts as the way to do this. Torts require proof of negligence, and, again, shared uncertainty about risk is the ethical basis justifying the research in the first place, so you, you know, you can't sort of make the claim of negligence there. Strict liability as we heard yesterday I think is counterintuitive, requires the courts anyway, may not be the test way to go. We certainly stand as Amy has said open to the possibility of torts for other damages or claims of negligence.

Scope of coverage then became something—so I think our committee is sort of in agreement with that, although I've reframed my outline in a way that I'm not sure that Anita will recognize in terms of the way she wrote it up, but this is what I was intending when I wrote the outline.

Scope of coverage, we certainly want to include medical care and we would think including psychiatric care. We are open to the possibility of other things, but we heard some strong advice yesterday about maybe not wanting to go beyond medical care.

Next we distinguished and want to distinguish sharply between compensation for the costs of medical care by—for those harmed by responsible research and reparations towards those persons or communities who have been victims of unethical research. And we think that here is a distinction between those two that we wanted to draw.

And then we reached the part where we have very little consensus, at least among the three of us writing, is the design of such a system. Because of the practical considerations, questions about whether we should be making the sponsors responsible for this, questions about adding to the burdens now to the researchers, and the many models that are involved led us to not be able to actually as a committee of three actually come to a conclusion that we would endorse a system of compensation outside of what's already there. I mean, the argument essentially is, you know, there haven't been a lot of people coming forth saying they're complaining about this. Somehow all of the care is getting covered. You know, if's not broken, don't fix it is the sort of argument that we heard. And we were unable to come to a consensus that we do have a broken system.

And that's for our discussion. But I think we did come to a consensus that the persons who are harmed do deserve to have their care covered. The question of how to do that was something we were not able to come to consensus on.

Amy Gutmann: So let me just ask—well, let me just take from you suggested in your deliberations a possible recommendation because there is the overwhelming sense that compensation in principle is the right thing. So the possible recommendation was that the

federal government study the issue of research-related injuries to determine if there is a need for a compensation system. We—that could be even stronger—

Daniel Sulmasy: But it's pretty weak.

Amy Gutmann: —of possible—there is a need for one if you can create one, so having a pilot, figuring out how to create one is the challenge, right?

Daniel Sulmasy: Well, we were not—and maybe, again, Nita can speak. We were not even at the stage of saying that there is a need for anything to be done. And that was part of the dispute that this—that just going along as we are might be possible and maybe Nita can speak to that here.

Nita Farahany: Yeah, I—it may be worth hearing what the others—what the issues are from the subcommittee.

Amy Gutmann: Oh, of course, of course.

Nita Farahany: And why, so the—what you just read as a potential recommendation is something that I think we may have broader support on, but the stronger case is that we may not. So I think Dan is absolutely right that we seemed to reach a shared consensus that there may be an ethical case for compensating research subjects, but the concern that I had and that we discussed was the imprudence of recommending a tort—an alternative to the tort system without understanding a few things first.

The first is that past commissions have approached this issue quite prudently. They have recommended determining whether or not a system is actually needed and of so how to design it. Second, there's no evidence that the tort system and the status quo more generally, right, so systems like the University of Washington system, systems in hospitals more generally, the—what we heard about yesterday from industry that the present systems fails to compensate individuals, and not just through suits, but by its mere existence, which may cause settlements and whether or not in fact there are people who are not being served by the current system. So we think that's an important thing to understand.

Third, so past carve-outs of the tort system have either been ex-post under extraordinary circumstances or the ex-ante ones like vaccine or workers' compensation arose from special circumstances like the vaccine manufacturers who refused to stop making vaccines unless there was some alternative system. And those systems did serve as preemptive systems to the tort system rather than additive systems.

In addition, all of the past recommendations arose before the Affordable Care Act was enacted in an era when all US citizens and thereby—in an era where all US citizens and all research subjects will be insured, this is going to raise incredibly complicated issues about the cross-cutting between different insurance models. So as we just heard, Medicare won't cover injuries that arose from research if there is another form of compensation that's paid. And in an era when everybody will have health insurance, what this means, whether or not they're not going to be able to receive insurance as a result, needs to be studied.

And then there are reasons why it might be particularly costly and difficult to make it an administrative system. So unlike the vaccine cases, there's not a limited number of signature

adverse events. How do you define a compensable event—is it any adverse event, is it particularly severe adverse events? Research occurs in uncontrolled research environments where many people are asked to take medications at home outside of a clinical setting unlike the vaccine case where they're actually administered in a clinical setting, so issues of causation become even more complicated. And if the individuals that we're really worried about are just the uninsured rather than the insured, then what this might encourage is, in fact, the most vulnerable individuals who lack health insurance enrolling in research programs simply to have access to medical care.

So if—given all of these different issues, putting aside the fact that there may in fact be an ethical case for compensation—

James Wagner: I think there is an ethical case.

Amy Gutmann: There is an ethical case.

Nita Farahany: —it seems like there's a strong case for asking the government to study and see if a compensation system is needed in light of these issues and if so what that model should look like.

Amy Gutmann: So can I just modify one word or two words. There is an ethical case for compensation. Then the question is whether there is a need for something new to be done. There's no compelling set of arguments that would deny that there's an ethical case for compensation. And then we can go on from there.

[Crosstalk]

James Wagner: I happen to agree with you. I mean, are we ready as a commission or when would we be ready as a commission to deal only with the second issue because are we ready as a commission to say—

Nita Farahany: Well, I did say—

James Wagner: —to say that we are convinced based on the arguments of this group that there is in fact a compelling ethical case?

Nita Farahany: I did say if intentionally. And the reason I said if intentionally is because I do agree that there needs to be reasons explained for why this is a special carve-out as opposed to other areas in which people engage in socially beneficial activities. And so is there a justification for carving out this group of people, even if we think that healthcare should be covered for people who are injured, is there something special and unique about this group?

Amy Gutmann: Yes, yes, yes. And we've been hearing—

James Wagner: I think the whole argument of individual risk for public benefits, that's a very unusual circumstance. I guess I would be comfortable concluding the first part of that. And then arguing the second part.

Amy Gutmann: I think there's a huge amount of discussion about whether a better system could be designed. And I think that's the bulk—everything but those two words of may be, there may be an ethical case, is—could lead us to a broader discussion of how—what we want to recommend with regard to the second part, which I think there's a lot of discussion needed, but I think Jim is right. We should ask does the—

James Wagner: The commission [inaudible]—

Amy Gutmann: —is the commission convinced that there is an ethical case for compensation in this?

Female: Yes.

Female: Yes.

Raju Kucherlapati: Not necessarily.

Amy Gutmann: Okay, go ahead.

Raju Kucherlapati: I think the arguments have already been made. Dan already talked about the cases as to why if the patients were willing to enter into the trials and that they are assuming the risk, then there may not be a special need to make a case that you have to compensate them. And when you say compensation, it's also very important to define what the nature of the compensation is. When you general—when we use the general term of—

[Crosstalk]

Raju Kucherlapati: —compensation is much larger than—

Amy Gutmann: Yes, we've narrowed that.

Raju Kucherlapati: Right. But even with the medical expenses, I think there are lots of sets of issues. And with some of these trials, for example, the risk is very high that they, you know, patients may be severely injured or die. But how do—what do we deal—how do we deal with that?

James Wagner: Raju, are—do—are the subjects actually agreeing to assume the risk or agreeing to take a risk? And I think there's a difference. One—the former it seems to me implies that they are willing to assume also the consequences of taking a risk. And what we're really—when I think of—and what I think of instead is the subject saying that they agree to take the risk and particularly it would be helpful and it seems to me we would get—the subjects are more inclined to do that if in fact there are mechanisms in place to help them assume the consequences of that risk. But I'm not sure. I'm curious of those—what the interpretation here is when a subject signs on to say I'm taking the risk or I am willing to assume all responsibility for it.

[Crosstalk]

Lonnie Ali: I still don't think that what he said, though, disqualifies what you asked about is it an ethical responsibility. Just because of what you said doesn't convince me that that's not ethical, that's not ethical to treat them. So was there something more?

Amy Gutmann: Both the Dans, both Dans made the argument that—and the argument has been made over and over again there's no—I see no effective counterargument in the literature that given the standing ethics of conducting research on human subjects, whether you look at Nuremberg or anywhere beyond, informed consent is not the only criterion. It's also because you—there is an ethical requirement not to subject human subjects to unnecessary risk or non-protection of the harms coming in, you know, in injury.

So that's, I mean, that's the argument that's been made over and over again. Whether some of the things you raise, indeed all of the specifics you raise are questions of what kind of system you can devise that's practical and affordable.

Raju Kucherlapati: Well, the clinical studies, you know, they're wide-ranging. And one end of the extreme, for example, in certain types of cancer trials, for example, that the kind of risks that the patient is assuming actually death. And I don't think that there is anything greater risk than death. And yet they actually willingly come and join those trials and, of course, the idea that you need to do everything to protect them is—still stands. But—so the question about assuming risk, the fact is they could actually die from whether it is treatment-associated or not or sometimes it may be treatment-associated.

Amy Gutmann: [Inaudible] Lonnie and then I'm going to let Anita say something—

[Crosstalk]

Lonnie Ali: I understand what you're saying, but usually people who—and correct me if I'm wrong, who enter into those types of trials have no alternative. It's a last-ditch effort to save their life, extend their life. But what you could say, and it—and just because they're in that trial and they're n there for a reason that is—that mainly benefits them, too, hopefully, if it doesn't benefit them and they know they're taking the risk and they know that it's going to advance your understanding of the drug and what it will do for other people who may get cancer for the public good, that's not to say that there's not some responsibility if it doesn't work. What are you going to do?

I mean, you talk about what is the responsibility, what kind of care are you going to give them, you're just talking about medical care. It may be just giving them palliative care, making them comfortable or something of that nature. But I understand what you're saying because I've thought about that, too. It's what do people enter a clinical trial and really the risk is death? I mean, because—but they know that without it they're going to die anyway.

So it's really, you know, it's one or the other, but with what you're doing in the clinical trial, there might be an opportunity to live longer, to have a better quality of life or to make some kind of advancement. So I understand what you're saying, but there's still I think an ethical responsibility even if you know that that clinical trial or that drug did not work for that individual

and it's not working, you're still going to make them as comfortable as you can until the end, correct? I mean, as far as assume that kind of cost of the care? Does that make sense?

Amy Gutmann: Raj, do you want to [inaudible]—

Raju Kucherlapati: I'm listening to the argument.

Amy Gutmann: Okay, okay. Anita. Anita.

[Crosstalk]

Amy Gutmann: —and we are going—I will at some point soon move on to the question of systems because that's—there's a lot to be done there and our time is limited and we obviously can come back, but Anita is also on the subgroup that spent a lot of time on this. So, Anita, why don't you—

Anita Allen: Thank you. And I enjoyed very much and learned a lot from working with Nita and Dan on this issue. I have reached a conclusion that Dan has reached that compensation of research subjects is just, it's fair, it's humane, it's ethical. But I also agree with Nita that there are a long list of practical concerns about implementing a system of compensation. And I think that what we heard yesterday from Mr. Feinberg, what we heard today from Karen, that these considerations are maybe even in some ways more complicated than I thought three days ago.

The—notice how the use of the tort system is—that's the default in our country. And it's not perfect. It's slow. It's cumbersome. It—but it also has the disadvantage that it's really not going to help anybody unless the tort system changes. It's a fifty-state system and we have to wait for the slow process of judges to come around to the position that this very new thing ought to be covered. And so if we say well, there's always the tort system, we're really not being honest unless we're talking about negligent injuries or intentional injuries because there's right now not a single tort doctrine in any state that covers a investigational drug or device on a strict liability basis. So what are we saying when we say well, we could have a sequential process of tort plus compensation? We're saying maybe we'll settle with the people that try to use the tort system.

So in any event, I think that the justice of the compensation we can—I agree and I think most of us agree with a couple of exceptions. And on the—just the specific question of the voluntary consent, it's a very in a way American ideal, but someone should be able to autonomously as a moral agent agree to take on a non-compensable risk for the sake of healthcare or the public good. That's a very noble idea.

But we don't expect that of almost anybody, right? The soldiers and the sailors and the Marines who go into battle, they assume a grave risk of death, but we take care of them through the VA system, right, if they get injured. And the workers in heavy industry who get hurt on machines that we don't understand, they get workers' compensation even though they assumed the risk of those jobs.

So I understand the attractiveness of the notion that there should be voluntary informed consent. But I just don't think that's the way the world works in very many instances at all in our country. And I don't think that research subjects should be sort of treated as this category of

people who unlike soldiers and sailors and Marines and workers get nothing if something bad happens to them.

Male: But it has worked.

Nita Farahany: Amy, could I just clarify on that—what I said before? So I guess I'm somewhere between where Raju and Anita just spoke because I do think that there is a strong ethical case for reimbursing—or for paying for injuries for research-related injuries, but when I say that, that doesn't mean that I am comfortable saying that every injury should be covered or what that system is. And so to me it could be the case that the tort system already serves that purpose and that the existing model already serves that purpose, but I do think they should be compensated. The question is do we not do that adequately today.

Amy Gutmann: Excellent. Well, thank you for clarifying because I was really taking this—as chair I try to just get us—I don't have a prior on this about the system. I do have a prior because this is something I've read all of the literature about, heard these wonderful presentations, read what our subgroup is there is an ethical case for compensation. That does not determine, Raju, whether or not our present system is as good as it can get, speaking both ethically and practically. There is another set of issues that we've heard some testimony about and there is some, but far less literature on interestingly than the first question. So now at least I think—I want to—I'm very pleased and with your clarification because I think where we can at least set the first aside as a consensus, Raju, we'll talk and see if we can have a unanimity here, but we still—it opens the question of the—the question about how—what kind of system would work best.

Christine?

Christine Grady: Yes, thank you. I absolutely agree with the ethical basis. I have no question about that. So what I want to ask—I want to ask and offer a few suggestions for if the system isn't broken, why fix it?

And one is a question I think for Karen and maybe a comment that—to Nita's list of possible reasons that the current system might work. And that is as we've been studying this issue of the last months, it's clear that increasingly research is getting very complicated, multiple sites, cross borders, et cetera. So I'm wondering what happens to international participants of you, the University of Washington-sponsored studies? The care that they might need from an injury can't be absorbed by the system unless you bring them to Seattle. So what happens in those cases is part of the question and do we need to think about how our current status quo system deals with people in this increasingly complicated, multinational research environment that we are in.

The second question I have is about the one related to whether or not creating a system would push us to preferentially want to enroll people who are uninsured. And I think it's at least possible that the opposite is true that, you know, to the extent that people who are in research need care and need care independent of injury, but also when there's an injury, maybe there's an incentive already to exclude people who don't have insurance because there's—especially in systems that don't have a system like University of Washington, that they may say, you know, if we take—if we enroll people who don't have insurance and they get injured, we're stuck, whereas if we only enroll people who have insurance, then, you know, then we can have their insurance

take care of their care. And so I don't know if we know the answer to that question, but I think it's least possible that that is already happening.

So I don't know if you have anything to say about the international group and then that's—

Karen Moe: Yes, yes, sure. So anybody who is injured outside of the general Seattle area can always use the \$10,000 out-of-pocket reimbursement to fly to Seattle and obtain healthcare in the Seattle system if they want. Of course, that's not practical for most people. So what generally happens in other countries is it's on a case-by-case basis. If there is a national health insurance that we consider to be the primary payer and we expect our researchers or their local staff to assist the subject in navigating that system. We would then provide any out-of-pocket expenses over and above that out of the \$10,000 reimbursable component of our plan. And also many of our international research studies, not necessarily the ones that are funded by NIH, but the ones funded by the Gates Foundation, for example, have some sort of provision in those contracts in other countries to provide healthcare to anybody who's injured, usually by the researchers and their staff on the ground.

Christina Grady: Thank you.

Nita Farahany: Can I address your second?

Christina Grady: Sure.

Nita Farahany: So I think that maybe the case today, right, it could be the case that people look for people who are insured such that they are not stuck with their care unless insurance starts to have the policy of if you have a system of compensation, then we won't actually pay you for research-related.

What I was imagining under the Affordable Care Act, everybody is supposed to purchase insurance. If not, you get penalized for not doing so. Some people may choose to nevertheless not have insurance. Those people I'm imagining would be the most vulnerable and most likely to then enroll because everybody else would in fact be insured. Now it might be that you're right, which is at the other end the investigators would exclude them and so therefore it wouldn't be as much of an issue.

Amy Gutmann: Yes, Raju?

Raju Kucherlapati: So I want to pick up on this issue that Christine just talked about as to whether the system is broken and whether we need to fix it. So one of the questions that I wanted to ask is that we won't say how long ago the other Presidential Commission made the recommendation, but made the recommendations, and I think it's a long period of time, and that those have not been implemented. And so we have now experienced, you know, the society as a whole moving along with the current, existing system, and I think it is important to be able to document that not implementing this system has harmed the society in some way and not only in a qualitative way, but in a quantitative way and say that if we had the system that we would have done something. And I haven't heard any information about what is the damage that has been done. I mean, if a law is passed, if you want to take it to the Supreme Court, it's a—you need to

show that some damage has been done to somebody, somebody was injured as a result of the law. Otherwise they won't look at it. I mean, so is that—

Amy Gutmann: That's why we are not a legal commission. We are an ethics commission.

Raju Kucherlapati: I understand. No, I'm just making an analogy here that this is a responsible body asked by the President and so we're deliberating on this issue. So it's not enough to say that this is broken, but I think it's important to show how it's broken and that would to make a case, it would be good to find that.

Amy Gutmann: Well, since we kept Dan and Karen here, I'm going to pose this to Dan. The challenge is why you think the system is broken.

Daniel Wikler: I don't have a survey to hand you.

Amy Gutmann: I know that. I—

Daniel Wikler: The absence of documentation of problems that may have faced individuals who weren't compensated doesn't mean that there aren't such people. They just haven't surfaced. So it's not your place to hand the President a fully worked-out plan. But if you said that it would be irresponsible to continue without a compensation plan, unless you do the research and shows that actually there have not been such cases, a lot of such cases, for all we know there have been a lot. We just don't know. Now—

James Wagner: [Inaudible] on that. Christine is telling us it was \$250,000 over five years plus \$8,000 a year along with a research budget of \$1-1/2 billion doesn't seem to be a very big problem.

Daniel Wikler: Yes, that's right. so it would be—what it means is also it's a very low-cost fix. So we—if you don't know how much of a problem there is, all we have is the experience of one progressive institution, which it turns out—if I heard you right, this \$10,000 per person cap, you've paid out a total of \$8,000 in a given year for all of the subjects in this \$1 billion-plus research. Incredible, right?

James Wagner: [Inaudible].

Daniel Wikler: Now can I just throw in one extra thing here? The—you were asked a very important question of whether or not your plan could be imitated or instituted in much smaller systems. And the answer is well, I don't know. Do we really want as a country in which whether a human subject has this aspect of their care covered depends on how big the institution is that the researcher works for? What kind of justice could possibly be consistent with that?

[Crosstalk]

Daniel Wikler: And finally, one would hope that with just a sort of a national default system, all of the expenses that go into separating out your expenses versus other expenses and deciding

whether or not this patient is covered and that one's not given that all of the institutions sort of blur their research together, that would go away.

Nelson Lee Michael: Yes, well I wasn't asking an ethical question. I was asking a question about implementation. And that's why it's very relevant because a—an institution that has \$1.5 billion of research funding per year and has a world-class, huge medical care system has a different flexibility than, for example, the University of California at Riverside would to do the same thing. And that's really important for an implementation.

Daniel Wikler: It is, which shows that to say look, we have one great success, everybody else out there, if you think this is a problem, you do the same thing, that's not good advice. What it basically means is that the places that don't have that scale and all of that expertise, they're not going to do it, which means that it's going to be a patchwork of just and unjust contracts.

Amy Gutmann: Go ahead, Dan.

Daniel Sulmasy: Yes, I was going to say that I think what you—what we probably have and we don't have the data on this is sort of a—already a patchwork of investigators who for various reasons try to do the right thing when these things happen, but without any specific funding for it, without any mandate to do it, with evidence already that insurance companies have begun to change the way in which they do it, and there's reason they can't make the next step of saying we're not going to pay for it all, Mom, and there's no guarantee that they will, sometimes study sections will require that there be redress within the grant so even on the kinds of survey research that I do that somebody—it says that if someone is upset by the questions you've asked them about dying that you must have them see a psychologist. But there's no payment for that by the government, you know, who's paying for this? It's out of the largesse of one institution that's really taking corporately its responsibilities seriously. Others, people try to patch it together. And that's sort of how we've I think limped along. And there may be more serious problems we haven't heard about. But I think that's what's happening now. But we don't have absolute data about it, but that's the kind of thing that under the radar is I'm sure happening.

Amy Gutmann: Karen?

Karen Moe: Sure. We don't have any hard-and-fast—

Amy Gutmann: Use the microphone.

Karen Moe: Yes, thank you. We don't have any hard-and-fast data about why or how the system doesn't work, but we do have a couple of observations I'd like to share with you. One is that most individuals are not served by the tort system well in our experience because most of the adverse events that we treat and cover with our compensation plan are small ones. I think we're focusing here in our discussion on these really large events and on death. But, in fact, most of our are things like some—I have a list of some of the most recent ones. Somebody was chewing on a vitamin wafer, fractured an old filling and crown on a tooth, saw her own dentist and we covered her dental bill for \$245. That's not going to go through the tort system.

The second point I'd like to make is to challenge the assumption that if somebody has private insurance that that insurance or Medicare will pick up the cost of reimbursing the injury or covering it. That's not correct in our experience. Medicare will cover the cost of "routine complications" for clinical trials that are covered. That doesn't cover a lot of unanticipated problems. Private insurers are even more reluctant to cover the costs of adverse events that occur in clinical trials.

Alexander Garza: Amy, if I may?

Amy Gutmann: Yes, please. Please.

Alexander Garza: So it's a—I think we're arguing over—we're sort of mixing the two questions, the first one of which I think most people have discussed, which is ethically are—should we be bound to compensate I would hate to say the word victim, but patients that are involved in research regardless, and so leave the payment part out of it. I think everybody fundamentally agrees on that, whether it's through a tort system or through a compensation system. And so as General Bradley said, novices talk strategy, professionals talk logistics. And so really I think what we're arguing about now is what is the best method in order to compensate people. And so I think we have to get over that first hurdle first. I think everybody agrees if somebody is harmed while participating in research that we should take care of them. Is there any argument about that?

Nita Farahany: I think the only question is for every single kind of harm, for every adverse event, or is it just—is this just a general statement, right?

Alexander Garza: That's the logistics.

Nita Farahany: Well, I mean, to—but so I think we can all agree at a high level, which is research subjects should be compensated. And then that doesn't necessarily mean every single thing from a dental filling to a nausea, everything else should be compensated.

Alexander Garza: Absolutely, yes.

Amy Gutmann: So the tentative—and I emphasize tentative because this is all subject to further revision—recommendation was beyond the strategy now, what you call the logistics, what I call the practical, to recommend that the federal government study the issue to determine whether we need a revised compensation system. In other words, here's—let me give the—let me frame it because the—I see we're coming—

James Wagner: That's okay. I think it's pretty important actually.

Amy Gutmann: —close, we're actually at 10:30, but I'm—we're going to be flexible and give ourselves another ten minutes on this and then we'll go on. Let me frame where we are. Many if not all—all of the commissions that have studied this subject before have recommended that—have agreed that there is an ethical case for compensation. The International Research Panel recommended that to us. We've heard a lot of arguments that are there's something wrong with

not having a system that says to people you will be compensated for research-related injuries. That's very broad. We've narrowed it in our discussions just to providing healthcare for people who are injured.

The federal government has been the recipient of that advice over time, over a period of decades. And there has been no response. Now administrations change, people in positions of authority have changed, so this is not somebody who's one administration, but it's been over a period of decades.

One of the things that the commission has agreed on is that the federal government should for its sake and for the sake of the American public should give a response and say if there are reasons why they think that the system is as good as it can get now, why that is, or if not, our recommendation, and this is the tentative is for them to actually conduct a study on alternative—what are alternate possible systems.

James Wagner: And inventorying existing systems.

Amy Gutmann: What?

James Wagner: And inventory existing systems in that process.

Amy Gutmann: Yes. Is that—

Nita Farahany: Amy, that seems a little bit different than how we have framed it or discussed it in the subcommittee. So we had framed it not as a single issue, but as to say study the issue of whether or not compensation—a new compensation system is needed. And if you decide that a new compensation system is needed, then to engage in a pilot study after having studied possible mechanisms.

Amy Gutmann: That's fine.

[Crosstalk]

Amy Gutmann: But wait, wait, okay, let her finish.

Nita Farahany: And then a second independent recommendation is given that this is the same recommendation that both NBAC and the earlier commission provided, why is it that there has not been a response? Please give reasons for that—

Amy Gutmann: I just reversed the order, but it's the same package.

Nita Farahany: Well, but not if they provide reasons, not that that necessarily kicks in adopting a new pilot study for mechanisms. That's the only thing—the mixing was the only thing that I was—

Amy Gutmann: No, I didn't—it was unintentional. I meant that there should be a response with—and the response will either be action, actually conducting something, or a set of reasons for inaction. That's the only thing I—that is the reason I put it first is for—in my mind, it is in

some sense the highest priority that there be a response after there have been so many bodies who've been asked by the government to advise and there—we—there is nothing in writing that we or the American people can read in response. But I totally agree with the other parts subject to obviously we're not drafting orally. We have to sit down do this after this meeting.

Christine and then Dan and I know we're going to take the two comments from the audience and we'll read them ourselves and get back to the people on this just because of time constraints. This is really—it's important. Christine and Dan.

Christine Grady: I know we're not drafting, so this may sound like I'm worried about that, but I think that the—a recommendation, since recommendations often stand alone, that says that the federal government should study this in my view is not a strong enough recommendation. I would much rather say something more strongly about the ethical responsibility and say that the current system should be evaluated and other systems be evaluated, something that makes it a stronger recommendation.

James Wagner: To meet the ethical expectations.

Amy Gutmann: We're not going to draft, but we're—Dan. Dan.

Daniel Sulmasy: Yes, I was just going to say, yes, that the lead should be even before that something that consistent with many previous commissions, the—at least the consensus, if not the unanimous opinion of this commission is that there is an ethical obligation to provide compensation for medical care for persons who have been harmed in [inaudible]—

Amy Gutmann: We went—just to be clarify this—

Daniel Sulmasy: That should be part of the recommendation, yes.

Amy Gutmann: We got past the ethical questions.

Daniel Sulmasy: But in the recommendation, I think it needs to be—

Amy Gutmann: We weren't drafting the recommendation.

Daniel Sulmasy: —yes, but it needs to be stated so that it's—

[Crosstalk]

Amy Gutmann: Heard you. We are—before we adjourn for a break, I have one request. Because there are people here who weren't here yesterday, I'd like just the commission to go around and for you to introduce yourselves so everybody knows who was speaking. Nelson, would you begin? And then we're going to take a quick break.

Nelson Lee Michael: I'm Nelson Michael. I'm an AIDS researcher at the Walter Reed Army Institute of Research.

Stephen Hauser: Stephen Hauser, neurology, University of California, San Francisco.

Lonnie Ali: Hi. I'm Lonnie Ali.

Raju Kucherlapati: Raju Kucherlapati, genetics, Harvard Medical School.

Anita Allen, Professor of Law and Philosophy, University of Pennsylvania.

Alexander Garza: Dr. Garza, I'm the Assistant Secretary and the Chief Medical Officer at the Department of Homeland Security.

Barbara Atkinson: Barbara Atkinson, Executive Vice Chancellor, University of Kansas Medical Center.

John Arras: John Arras, teach philosophy and bioethics at the University of Virginia.

Christine Grady: Christine Grady, bioethics, NIH Clinical Center.

Daniel Sulmasy: Dan Sulmasy, medicine, divinity in the MacLean Center for Clinical Ethics at the University of Chicago.

Nita Farahany: Nita Farahany, law and philosophy at Vanderbilt University.

Amy Gutmann: And on behalf of the whole commission, Jim Wagner and I would like to thank Dan Wikler and Karen Moe for two excellent presentations and for staying with us for this whole deliberation. Thank you all.

[Applause]

James Wagner: Reconvene.

Amy Gutmann: We will reconvene in ten minutes.