



Presidential Commission
for the Study of Bioethical Issues

TRANSCRIPT

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Amy Gutmann: Thank you. I'm going to wait until Mr. Ken Feinberg arrives, and I know he's here so—so let me set the context for this session, and we are extremely pleased to have a special guest with us, and here's the context. The International Research Panel, which I was asked to constitute by the President to advise the commission, produced a list of recommendations for the full commission to consider, and one of these recommendations related to compensation for research related injuries, and the recommendation was that the US should have a system by which human subjects who are harmed or injured in research could get compensation for that injury without a showing of negligence. And past commissions have also recommended that compensation for research related injuries without resort to the tort system, which depends on a showing of negligence, to be put into effect in some way. But nothing concrete has been done, nor—and I think we will recognize this very likely to recognize this in a report, nor have reasons been offered for doing nothing. So at minimum, it is likely that the commission will ask, although we're likely to do more than the minimum, but we're going to ask that whatever the government decides to do, it offer reasons for why they do it or not do it. In other words, this is an issue of public concern that this commission has heard repeatedly about.

So various countries around the world have increasingly required that sponsors of research ensure that injured research subjects receive free medical care and financial compensation for injuries related to—resulting from the research. Current US law and most federal agencies do not require that injured research subjects receive free care or financial compensation for medical care caused by research related injury. Notable exceptions include the Department of Veteran Affairs and NIH Clinical Center, both of whom provide care for adverse medical events resulting from trial participation.

And so to some leading medical centers in the United States, such as the University of Washington—and we will learn more about that tomorrow—the concern in—made too simple, but let me just make it too simply, because I know our guest will make it more complicated—is that compensation through the tort system does not cover non negligent cause of an injury, and the question arises about whether current policy can satisfy moral obligations to research subjects. There is no question that we have been asked that it doesn't satisfy legal obligations. The question is about moral obligations, which is the charge of our commission. Are we as a society obligated to ensure that those who accept the conditional risks of research are not also charged to accept financial risk associated with adverse events?

So we are now eager and pleased and honored to have Kenneth Feinberg with us today to talk about compensation in general and any thoughts he might share with us about compensation for research injury. Give a very brief introduction to Mr. Feinberg. He is the managing partner of Fienberg Rosen LLP. In addition, he is the administrator for the Gulf Coast Claims Facility, which he was designated by the Obama administration and British Petroleum in 2010. Before this, Mr. Feinberg was appointed by the Secretary of the Treasury to be the special master for the TARP executive compensation. In addition, he was appointed by the Attorney General to be special master for September 11 victim compensation funds in 2001, a position he kept until 2004, and I should just add on behalf of the entire commission personally we are honored and pleased to have you here today, and in admiring of the work that you have done above and beyond the call of duty. So thank you and welcome, Mr. Feinberg.

Kenneth Feinberg: Thank you very, very much. I wear two hats here today. I was a member of President Clinton's commission on bioethics involving the unwitting testing of American citizens back in the 1950s, radiation testing chaired by the distinguished Ruth Faden of Johns Hopkins,

and my other hat that I am wearing as the chair points out over the past 25 years I've been occasionally called on to come up with plans to compensate victims of Vietnam veterans exposed to Agent Orange while serving in Vietnam, the 9/11 victim compensation fund, the Hokey Spirit Memorial fund, arising out of the shootings at Virginia Tech. And now, the BP oil spill fund.

Now that may seem a little far afield from what you are doing, but really it is not, because the fundamental question to me when it comes to compensation involving any individual or collective tragedy is whether or not you rely on the tort system, time honored, works pretty well in this country, has for over 200 years. Do you go to court with your gripe? With all due respect to the chair, who I admire greatly, the tort system recognizes many, many claims where negligence need not be proven—strict liability, product defect, breach of warranty. You do not need to show negligence as between the manufacturer of the product and the injured victim, society concludes the injured victim should recover from the deep pocket, even if the deep pocket it proves to be not negligent, acting very, very reasonably. That's the law; it has been the law for decades.

The question that we dealt with in Chair Faden's commission involving radiation testing was whether or not the tort system should be available for the victims of research gone wrong—negligence, although in the radiation cases, there was direct intentional conduct—or whether in lieu of tort or anticipatory of tort you first go through a different system. Maybe tort is your—it is not one or the other. Maybe tort is your court of last resort, but as we have had on the books now for 40 years, for example, vaccine legislation on the books, federal law. If you are the victim of a vaccine inoculation gone wrong, before you can go to court, you have to go through a rather complex arbitration process, where arbitration is the preferred remedy in trying to compensate the victim. Now what I've learned, and I don't want to take too much time, because I'm sure there will be a lot of questions from this incredible panel. I am amazed that on this rainy day in Boston, you have nothing else to do, I guess.

Here are the issues that come up all the time in my work. Let me just mention them. They may not have any relevance to you, but they may. One, should there be compensation at all? Where is it written that if non-negligent accidental reasonable action is taken that goes wrong, there should be any type of compensation? That is a policy question. Two, if you want to compensate, what form of compensation? Does it mean money? Does it mean a life plan for somebody who is quadriplegic or in a coma? Does it mean service, medical treatment as compensation? Or does it mean a check? Three, if it means a check, who is paying for it? Who is paying for it? If the federal government funding this? Private insurance? It is a very important question that if you are going to pay actual cash to certain victims, what is the source of the funding?

Next, how much funding? What will it take? Do you in a non-tort regimen provide compensation as if it was tort, as we did on the 9/11 fund? Congress and the 9/11 fund made it very clear that even though there was a non-tort alternative, I should pay out compensation as if the victim had been in the tort system. They just didn't have to go to court. So the 9/11 fund ended up paying on average for a death claim arising out of 9/11 tax-free \$2 million. There's never been anything like that in American history, and I doubt there ever will be again. It was a one-off response to a very unique catastrophe. So how much are you going to pay?

Then the very very important question in all of these cases, what are the criteria that triggered the payment? This is the point raised by the chair. Should there have to be negligence or recklessness or, in the case of the radiation experiments, intention? What is the mental state,

the culpability that should be required to trigger compensation, or should it be strict liability, no negligence, doesn't matter? Or, and in addition, not only what is the mental state of the researcher, what other criteria should be imposed in deciding appropriate compensation? Are you paying only for medical treatment, out-of-pocket medical treatment? Are you paying economic loss for loss of future wage capability? Are you paying only the victim, or are you paying the victims dependents? Are you paying regardless of collateral sources of income, need? Are you going to pay the banker more than the waiter or the busboy, the way the tort system does? Somebody gets hit by an automobile outside here. The American system says the banker, the stockbroker, the investment banker get more money than the waiter, the busboy, the firemen, the cop, the soldier because of economic loss of livelihood.

So you have to reach out and decide criteria, if you decide at all that compensation is appropriate. There are these fundamental questions as to who qualifies for what injuries. Do you pay if the research that goes awry does not cause any lasting damage at all? It is temporary. It is compensation for loss of integrity, but not compensation for any long-term medical injuries. The mere fact that I was a research victim entitles me to X, even if I am up and about next week. Is that so, and if so, under what circumstances? And finally, what are the procedures that you want to establish for fact-finding and determination? This is a point raised by the chair at the opening.

Do you want the court system to be the determinant of who gets what? Do you want a special panel created by federal law that would, as with vaccines—there are other examples, you know, on the books. I can think of three or four examples of long-standing law, federal law—uranium miners are another one. As you know, uranium miners who came down with thyroid and other leukemia and other conditions during the 50s from mining uranium have a special procedure they go through to be compensated in lieu of tort in the courts. I am totally agnostic on that, other than to say that this committee, there's plenty of precedent—plenty—if this committee decides that we ought to create a bioethical alternative dispute resolution system rather than throw your lot in rolling the dice in the courtroom. The courtroom is of course the conventional way, the traditional way, the time honored way, and the usual way.

My final point is that almost always, policymakers opt for the tort system. In the last 25 years, I have carved out this niche when I'm called on to help compensate, as with 9/11, Virginia Tech, BP, the Indiana State Fair, the Pavilion, the wind that blew down the Pavilion 6 months ago. But these examples are extremely rare where policymakers prospectively decide, let us not go through the traditional, conventional tort system. Let us come up with an out-of-the-box thinking and design a system that either gives one victim a voluntary choice—you can opt into this special program or at your choice can go into the tort system, or can be mandated. Do not forget in 50 states, you have no choice. If you are injured on the job, that's worker's compensation, and for over 100 years we have had worker's compensation. Employees can't go to the courts for work related injury. That is everywhere, in every state. That's one huge exception to the tort system, and it has been that way for over 100 years. So what I do is pretty rare, I must say, and in almost all cases policymakers opt to allow people to go to court. You pick your lawyer. We will pick our lawyer. Judge and jury, etc.

And finally, in all too many cases, insurance is not the answer because insurance results in an incredible amount of litigation itself. You will find in all too many cases the insured in an effort to receive compensation from its insurer, whether that be a private insurer or the public, will find that the insurer box claiming this was expected and intended. You deliberately engaged in this research. Why are you coming to us seeking us to compensate you when this wasn't an act of God. This wasn't some accident. It was planned, and here's all the documentation and the

paperwork. So if you're going to go the private insurance route, that is a whole other area making sure in a recommendation that private insurance is meaningful rather than just a source of new litigation, and there is my 10 minutes.

Amy Gutmann: Thank you very much. I will lead off with a question, and then I will recognize the members of the subgroup who have been working on this, and then we're going to just open it up. So let me just ask you a very specific question. As you know and you just recognized, a lot of what you've been working on of late is not what we have been looking at. It is not a post hoc. Something really unusual has happened and we need to devise something retrospectively, but we have really been called upon to say if there is something prospectively that could be done to improve the current system. So were we to recommend that the government look at requiring researchers and institutions to have compensation simply—let us just say simply for the medical industry to provide medical care for those injuries resulting from experiments and research. Would an inclusive system along—you know, an inclusive system devised along those lines of research related injury compensation, would it necessarily require preemption of the tort system?

Kenneth Feinberg: No. Necessarily?

Amy Gutmann: Right. Can you elaborate? Could it exist, be designed in a way that it exists alongside the tort system and people could resort to the tort system beyond what was provided in compensation?

Kenneth Feinberg: You could certainly do that. The Supreme Court and federal law in the last 20 years, the Supreme Court in particular has made very, very clear that absent specific provisions designed to we hereby preempt the state tort system, federal statues all the time don't preempt the tort system, so you could create a parallel or sequential system. Here is what you do with research related injuries. After you do that, if the victim is not satisfied, he or she may opt into the state tort system. You could do that.

Amy Gutmann: So you could have limited compensation? For example, medical care, so people who volunteer and get injured could be provided with guaranteed medical care and still give them resort to the tort system if they—

Kenneth Feinberg: Absolutely. Yeah. Now if you do that, though, what you are saying by your question is you are entitled to a gift, free medical care. You waive no rights. You are not obligated to give up your right to sue. We are doing this because it is sound public policy, and after you get that medical care, if you want then to – or parallel - file a case in tort, that is your right.

Amy Gutmann: I gave the example, because if the compensation is limited to what research related injury requires by way of medical care, so people do not have to use their private insurance to cover it, then it is a very limited—it is a limited compensation, but it goes beyond what exists now.

Kenneth Feinberg: That is right. Now that is a very reasonable position. It is too reasonable. Because what you'll find, I suspect, is if there is research gone awry and you are offering medical

care without a check, no money, no cash transfer, I query whether that will pass political muster. It's one thing to say, "Look. We haven't done anything other than provide you with free medical care." You can say, "What do you mean you're not—why do I have to go to court for 6 years? You did wrong. Why are you not giving me more than free medical care?"

Amy Gutmann: You've loaded it of course, research gone awry. Good research can still produce—

Kenneth Feinberg: Tell that to the victim.

Amy Gutmann: I understand. That is why the tort system is there. I'm going to ask Nita and Dan and recognize Anita, and then I will open it up in the back more broadly.

Nita Farahany: Thank you. This was so incredibly helpful, and thank you for all of your incredible service as well. I have a couple of questions for you that your comments have raised. The first one is there are 2 different things that you mentioned, right? The retrospective versus the prospective types of system. So the retrospective one to the ones you have primarily worked on and their special considerations as to why those retrospective systems might make sense. I take it you haven't done as much work with things like the vaccine act or worker's compensation, although you are obviously quite familiar with them, and building on Amy's question about the preemption types of issues and thinking about the way these systems have worked, I have concerns about a system which says it is a gift, and you have torts at exactly the same time without waiving any rights. I think you're right, that is probably a political nonstarter, but I worry about the kind of incentives that creates a system like that, and so I'm trying to think what a prospective system could look like if there wasn't federal preemption at least at the level of saying, you know, as a last resort or you could ex-ante into contracts, where you choose one option versus another. What do you think of that kind of system, which is an additive system, and what do you think the implications would be for adopting a prospective system in this area?

Kenneth Feinberg: I think is a fabulous summary you just raised. First of all, almost always the system is post hoc. In other words, everything I do comes after the disaster because it takes the disaster to galvanize the public and generate the type of support for an alternative to the tort system. In so you have a disaster like 9/11, no one is thinking about compensating the victims of 9/11 using public taxpayer money. So in almost always takes the disaster to trigger the type of political support you need to generate a cutting-edge approach. But second, a prospective system you would do well to start with a few of them that are on the books, like uranium miners and vaccines, where, well, based on past history, we're going to set up a prospective system, worker's comp, a prospective system. If you are in unfortunate victim of a vaccine that didn't work and caused worse injury than the illness, we have a system in place prospectively.

One final point. When you think about prospective systems, you are on safest ground I think when you look at procedures. In other words, prospectively we are not saying you can't sue—or maybe there are limitations on the right to sue—but we are at least going to set up an administrative process, procedure, to deal with the injury rather than let you immediately go to court and sue for a pot of gold. That might help I think transition you in the areas you are concerned about.

Daniel Sulmasy: Maybe I can ask you to say a little bit more about strict liability as a sort of alternative. You sort of glossed over that, particularly in a case like research in which the risks are in fact totally unforeseeable, and in fact that is one of the reasons that justifies the research to begin with, and whether torts or strict liability or some sort of prospective compensation plan is best, where does strict liability fit within that?

Kenneth Feinberg: Strict liability is counterintuitive. It has been for half a century in the United States. Basically strict liability says that even though the researcher did everything reasonable to minimize the likelihood of damage, there is damage. And A, in order to compensate the victim, who has been damaged, through no fault of the researcher, and B, very important, in order to deter the researcher from maybe acting the same way again, however reasonable, we want to compensate. And I think there is probably—and I'm guessing on this, but I bet you there is not a court in the United States that doesn't recognize in certain situations strict liability. It is now a fundamental principle of tort law regardless of negligence. It is really dollars shifting, as between the researcher and the victim, let us help the victim.

John Arras: And in addition to the sort of counterintuitive nature of it, if the person who has been harmed in research wants to go to court out of the system, correct?

Kenneth Feinberg: Under strict liability, unless it is a vaccine or it is a uranium miner. I think there are probably 30 of them still alive. Yes, I think that is right.

Amy Gutmann: And that is what I was recognizing. I was saying something that's specific to health research, which is there is not a recognition of strict liability, so you wouldn't go to court and use the tort system unless you are claiming that there was some negligence in the case.

Kenneth Feinberg: Or unless you are claiming strict liability.

Amy Gutmann: Exactly. Unless you are claiming strict liability. You have a set of—you know there have been thousands—we now last year have over 50,000 human subject research, and it isn't the case that you typically would go to court. It is rare that you would go to court and claimed strict liability in the cases of these, so you would have to change the law to be stricter.

Kenneth Feinberg: I wondered about that. Is that because the law is a barrier to sue, or is that because in those cases, there is quick settlements with the insurance companies or with the researcher?

Amy Gutmann: That is a good question.

Kenneth Feinberg: I don't know the answer to that.

Amy Gutmann: I don't know. I know the answer in some instances, but not—I do not know if generally. Let me ask Anita.

Anita Allen: On the insurance question, we heard this morning from some industry people that there is insurance available, and I take it that that insurance is available even though you could

make an assumption, a risk type argument, the one you pointed out. But what I like about your point is that there may well be litigation probably over causation. Did this agent that you were given in the research really cause your injury? There could be litigation around that. You wouldn't avoid the court system just by having a system of insurance. On the question though of going to court in an alternative to a non-tort alternative, when I worry about is that it might just be always impossible to win. I'm going to put aside the case of negligence and assume we're having a non-negligent injury.

But think about the traditional categories where something akin to strict liability applies. Possession of wild animals, that is not a good analogy. Ultrahazardous activities, that might be a pretty good one. It's like blasting or something like that. But if you look in the product liability area, we have a huge doctrinal obstacle that does not match our content of research. For manufacturing defects, you've got to show that there is some product that was defective. For a design defect, you've got to show that the risk utility balance didn't work out in favor of doing it, and if you treat it like a warning or a labeling type context, then we are assuming the informed consent process fully warns the research subject that this might kill them. So I just think if we did rely upon the tort system at all, the research subjects would always lose, unless we had in a specific new theory of liability which our judges decided to adopt or were required to adopt by statute to say that there is now strict liability for research injuries, just like for blasting cases.

Kenneth Feinberg: I am not going to—it is a very excellent point you make, except I will bet you that your concern that the victim will not win is not shared by the hospitals and others engaged in the work. I think—and I defer to you on this—but I will bet that any would be defendant medical institution would be chilled, would shudder in horror at the notion that there would be a recommendation to make it easier for victims to bring lawsuits under a theory of strict liability.

Anita Allen: It could evolve, right? And if enough smart lawyers started to bring these cases, we might see a change in the law, but given existing tort doctrines, you have to admit that we do not have any precedent within contemporary strict liability rules for a person to recover under these facts. But it may be that one would evolve if we had enough—again, you know, scared companies and clever lawyers.

Amy Gutmann: In some sense, what we are concerned about or one of the things we are concerned about, given all of the recommendations that we have heard, is about having some guaranteed compensation. It's the opposite in the spectrum from 9/11 and horrendous harm, which can go and does go to the tort system. It does. The people who volunteer for experiments and their expectation of benefit is minimal, but they volunteer—these experiments are, not all of them, but by and large a lot of them are for the people good—and they get injured in some non-horrendous this way, and they have to pay out-of-pocket for their medical care. And the concern—and I'm speaking now, you know, from what you call policy or ethics is couldn't there be a requirement that institutions insure themselves so they can compensate people for those injuries by giving them medical care?

Kenneth Feinberg: Absolutely. Absolutely. Why not? If you can find the private insurer willing to do it and the insured wants to pay the premium, that is the way we take care of most risk in the United States. I must say the government doesn't stand behind situations like this. Your

question—implicit in your question is the government, the taxpayer, doesn't become the insurer of first resort.

Amy Gutmann: Exactly, but the government—but implicit in my question is also that the government, as a condition of giving research dollars out to do these experiments, could anything from encourage to require those who do research to have the capacity to compensate at least with medical care for research related injuries.

Kenneth Feinberg: Absolutely. And I suppose—and you know this better than I. I have no idea. With a requirement or a recommendation by the government to that effect, would you run up against the argument that you are disincentivizing research because by making us shoulder that burden and that cost, which we find unnecessary, you are hampering cutting edge research.

Amy Gutmann: You would definitely run up against that argument, and the response could be that we can factor that into research grants the way we factor everything else into research grants.

James Wagner: And the government is again the insurer of choice.

Amy Gutmann: Well it is not the insurer. It is the—

James Wagner: It is the underwriter.

Kenneth Feinberg: The taxpayer.

Amy Gutmann: Yeah. It is the funder, at least part of it. John?

John Arras: Thank you very much. This is wonderful. Sometimes I look at my file cabinets, and they have labels like death, AIDS, euthanasia. I think I work in the most depressing field imaginable, but you have topped us all, I think today. So I feel much better about my choice of career.

Kenneth Feinberg: You should have put me on it the end of the day.

John Arras: Thank you. I appreciate it. The issue has come up several times about the meaning of consent in this kind of the situation. If somebody consents, well then the system can say, well, hey, you agreed to this—if my Latin serves me—*volenti non fit iniuria*. Right? If you—one year in law school. So if you agree there is no injury, so it seems to me that the appropriate stance on this is a policy stance which says that's an offer. You know, in other words offering somebody the possibility of engaging in research without any fall back for injuries or compensation, that is an offer that should just never been made, period. That I think that is how you solve the problem of consent. That is an offer that should not be made.

Amy Gutmann: Do you want a response?

Kenneth Feinberg: I have never been, I must say, just as a practicing lawyer, I have never been particularly impressed with these lengthy disclaimers that you sign in hospitals. There is always a risk or–

Amy Gutmann: As a lawyer, or as a would-be patient?

Kenneth Feinberg: No. Thank goodness, a lawyer. Because in the law you run into this problem of unconscionable waivers, after the fact. Oh I signed anything. I don't know what I was signing. I was so desperate for help, I would have signed away my first born on this. After the fact, it is always difficult on both sides. You get into a harangue over the conscionability of that type of waiver, the consent.

John Arras: I was looking for a legal theory.

Amy Gutmann: Yes. It is called consciability.

John Arras: There it is.

Christine Grady: Thank you. I want to add my thanks. It was very clear and very compelling. I wanted to ask you how you would answer the first question that you posed. You said should there be compensation at all? What do you think there should be? Do you think there should be compensation at all in the research environment?

Kenneth Feinberg: I am a lawyer by profession, so I think compensation is the great leveler, and yeah. I think if the victim is harmed through no fault of his or her and through no fault of the researcher, I think there has got to be—now what that compensation is, is a major, major policy choice of this committee. Yeah.

Amy Gutmann: You know it isn't a policy choice of ours. We are purely advisory, for better or for worse. Dan? Let me just ask before I recall on people. Are there questions? Okay. So Lonnie. I will get back to Dan.

Lonnie Ali: They are working on this. So let him.

Amy Gutmann: It is okay.

Lonnie Ali: Mine is a clarification, because it is an assumption that we are working under, and I just wanted to make sure I heard you correctly. Is there a possibility of a person who is injured through no fault of their own, no fault of the investigator, to be taking care of medically, their medical needs to be taken care of through their private insurance?

Kenneth Feinberg: Through the victim's private insurance?

Lonnie Ali: Correct.

Kenneth Feinberg: Yes. I think probably there is if you can afford that insurance.

Lonnie Ali: But I mean normally that's not something—you said that you entered into this. It is not some act of God. It was not an accident. You knew what you are doing. You sign this waiver.

Kenneth Feinberg: I see what you're saying. Can the victim's medical insurance cover treatment, risky treatment that that victim voluntarily entered into?

Lonnie Ali: Exactly.

Kenneth Feinberg: You know, that is a very good question.

Lonnie Ali: Plus it is experimental.

Kenneth Feinberg: I guess Lloyd's of London or somebody will sell that insurance, but implicit in your question is it is not easy to get, I guess.

Lonnie Ali: No. I do not think the victim would be going out trying to get it prior to entering into such a study. Something that would already be existing, I would think.

Barbara Atkinson: I think I know the answer to it. The answer is that your insurance will pay for routine medical care but not something above and beyond. I am pretty sure that if you have ordinary medicare, at least, that is what it pays for, the routine medical care that you expect, but not if you have some extra complication from the injury. That is the difference. But what I interpreted the pharmaceutical people to say this morning was that they buy insurance that would be over and above what that is. That is at least one option.

Kenneth Feinberg: It is a very good question. I'm not sure the answer.

Amy Gutmann: Steve?

Stephen Hauser: I thought about, as one of the non-attorneys on the panel, I'd like to ask a particularly perhaps naïve question as part of a potential policy for compensation or at least for the medical care component. How would a system be developed that would determine cause and effect? Causality?

Kenneth Feinberg: You would have to have an administrative fact-finding in which outside—we're talking about a non-legal, and not nonjudicial approach—where based on the procedures that are established, let us say there is a single arbitrator, and the victim, the researcher would, I suppose, as the vaccines and uranium miners to name 2, or workers comp I guess submit findings of fact, conclusions reached in a way that is adversarial, but it is less adversarial than the tort system, and the arbitrator might take a day hearing by each side or their representatives to make the case, and there would be ruling. In 9/11, we required the submission of documentation, a claim form, a standard claim form. Attached to that claim form was the documentation of the particular claim. We then had a staff in 9/11 that examined the submission and reached a conclusion. Now we didn't have an adversarial, because there is nobody on the other side. It was just the claimant making the submission. The terrorists were dead, and there was nobody

challenging them, but we still had to—there has to be an infrastructure to examine the validity of the claims, including causation.

Nita Farahany: I want to ask an unfair question of you, I suppose.

Kenneth Feinberg: I've been doing a lot of them for years.

Nita Farahany: Yes. But to build Christine's question, you answered that you think compensation should be provided, but as a lawyer of course you recognize that the devil is in the details. Right? And you also said that the tort system is the honored and reasonable way that we do things in this country. So given your experience of all the compensation systems that you have worked with, and the incentives that each of the different models create, how would you design the system? Would you do a compensation fund? Which you change the tort rules to allow strict liability that would be a product liability base? And I recognize this is unfair and that we are addressing this issue, but I think your experience would be invaluable to us in thinking about options.

Kenneth Feinberg: First of all, understand that these programs I get involved in are exceedingly rare. The tort system almost always trumps anything else. And these programs I get involved in should be exceedingly rare, because telling people—certain people, bad things happen to good people every day in this country. They do not have a 9/11 fund. They do not have a BP fund. The idea that philosophically you're going to carve for very special treatment, just these people, where everybody else goes through a different system, I do not think that is sound public policy. I haven't said that. If this commission concludes that there ought to be a non-tort alternative, how you design it, the experts are around this table. I am not sure, other than to point in the direction of some sort of efficient streamlined system that can reach resolution in months, not years, provide clear delineation of procedures, does not require any showing of fault. That is a nonstarter in an administrative system.

You do not want to require that there need be any evidence of wrongdoing or liability or negligence or—that is the antithesis of an administrative system. There is a cap on what people can receive though in an administrative system. There is no punitive damages. There is no pot of gold. The trade-off is strict liability, no showing of fault, but as the chair points out for example, medical care only or maybe cash, but limited, compensatory, lost earnings or something like that, so that simplified fact-finding, one person, no jury, a procedure that is sort of straightforward. You might look at the vaccine and the uranium miners or worker's comp as an example of how it might work because those fundamental building blocks would be the same for something like this, I think. And then the big policy question that the chair raised at the back end, after you have received this compensation, in whatever form, can the victim opt then to head to the tort system?

Nita Farahany: And your opinion?

Kenneth Feinberg: That—I would have to know more about the circumstances. You are not going to get me on that one. I would have to know more about the system and the nature of the injuries, the nature of the injuries.

James Wagner: A complete block is worker's comp. A complete block to the tort system with worker's comp.

Kenneth Feinberg: That is worker's comp. 50 states. A complete block. Employee cannot sue her employer.

James Wagner: Is that also true of the vaccine?

Kenneth Feinberg: I think so. I think at the end of the day the panel decides you cannot opt into the court system, and the reason that legislation was enacted 40 years ago is because the manufacturers of polio vaccines and other vaccines threatens to take the vaccines off of the market because they said it wasn't cost-effective to have to litigate these cases in the tort system. It was over deterrence. The court system over deterred, and therefore Congress stepped in.

Daniel Sulmasy: One common counterargument against this system of compensation scheme that you are probably familiar with and can maybe give us some help with is the fear that once we have create these sorts of systems, they are just riddled with fraud and abuse, that people make bad claims and we wind up having huge cost escalations. In your experience, is that really a big problem, or is it something that is simply exaggerated in political discourse?

Kenneth Feinberg: I think it is exaggerated, although I will say in the BP funds, we had about 14,000 fraudulent cases, but that is out of 1 million filed. So the problem with the BP fund is by announcing there is \$20 billion, which is what BP announced, you know build it and they will come. I've received claims from 50 states, 38 foreign countries. So far. So far. So fraud is an issue. This seems to be sort of a self-selected minimum. You guys know better than I do. I do not see this as resulting in a veritable flood of claims.

Anita Allen: Thank you, and I want everybody to know that in my field, Kenneth Feinberg is a rock star. He is just terrific.

Kenneth Feinberg: I am not asking you what your field is.

Anita Allen: Law. So we have been thinking about distinguishing between medical benefits, compensation, and reparations. And maybe reparations would be preserved for unethical research, the extremely rare unethical research. And I'm wondering if you think that triad of distinctions make sense, and when it comes to say something beyond medical benefits that we call compensation, that might include—and you mentioned a couple of these as being within the realm of possibility: lost earnings. What about pain and suffering? Pain-and-suffering cap or uncapped? What about loss of consortium? What about wrongful death paid to families? And then one of my favorites, what about if there are germ line sort of consequences, so DES daughter and granddaughter type issues, where, you know, 20 years later, the research subject's children discover they've got some kind of cancer they can be causally related to the research? Do we compensate those as well?

Kenneth Feinberg: I would stay away from those. Those are all legal, judicial concepts. Pain and suffering, loss of consortium. You are getting into the tort arena. Now if you want an option to go to tort, that is fine. But you see—

Anita Allen: But you mentioned in the 9/11 compensation plan, you did use tort-like notions to compensate the victims of 9/11.

Kenneth Feinberg: Two answers to that. First, Congress required it. Congress said in the statute that when I compensate victims of 9/11, you will consider not only economic loss, work life, the banker versus the cop, but pain and suffering, so you know we did? In an administrative system, we came up with very objective pain and suffering. Everybody who died, 2983 people, gets \$250,000 for pain and suffering plus \$100,000 for each remaining spouse and dependent. That's it. Streamlined. No individual subjective delay ridden calibration of pain and suffering. We had to do it because the statute required it, but we just made it administrative. We said, "We do not want to know the facts." If you died, and you have a spouse, that's 250,000 and 100,000. If you had 2 kids, 250, 100,000, 100,000, 100,000. That is it. And that is how we dealt with that. Very rare in administrative schemes do you consider tort principles like pain-and-suffering and loss of consortium.

Anita Allen: You would recommend to us, tentatively, because I know you said this is a new area for you, but you tentatively recommend we stick to medical benefits for the immediate research subjects, not worry about pain and suffering, not worry about families, not worry about long-term consequences for next generations, keep it to medical benefits and hopefully insurance will cover that.

Kenneth Feinberg: Or you could say—this is a policy choice—medical benefits, one. Economic loss, Two: The banker who is bed ridden has more lost future income than the cop who was bed ridden. Three: if you want to have pain and suffering, go ahead. But like the 9/11 fund, have an objective mathematical formula without having an absent jury determine he suffered more than she suffered. You can do it, but if you're going to do it, I would urge in an administrative system that is very streamlined and ministerial without requiring any subjective fact finding.

Raju Kucherlapati: One premise in thinking about this type of compensation is that the current system is not efficient or is not working. Do you subscribe to that?

Kenneth Feinberg: No. It is not very efficient. It works.

Amy Gutmann: It is inefficient, but it is working.

Kenneth Feinberg: The tort system I think it's criticized much too much. There are some examples of mass litigation, like asbestos or DES or Dalcon Shield, where the tort system tends to over deter inefficient, unfair, takes too long, haphazard results. I think two things about the tort system. One, it works pretty good. And two, very important, even if you do not think it works pretty good, it is so ingrained in the fabric and history of the country, it is not going to change. So you are tilting at windmills if you think that there ought to be a 9/11—that 9/11 or BP also be a precedent for changing. 9/11 or BP is a precedent for nothing in my opinion.

Amy Gutmann: And none of us, just so you know, none of us on this commission in our wildest imagination brought up that as something that would be relevant to this. It is more, as you can tell from the questions, that very few people who were injured who just want medical care and, as you said, possibly compensation for lost wages. Very few people are going to go to the tort system for that.

Kenneth Feinberg: That is interesting. I have found that to be the case.

Amy Gutmann: Yeah. In a medical experiment, they will go to the tort system for more and all the other things, or if they suspect negligence.

Kenneth Feinberg: I found in Virginia Tech, which wasn't tied to the tort system, by giving victims compensation without any condition, virtually all of them decided voluntarily not to then go to the tort system. Only two people sued. I was surprised by that.

Amy Gutmann: Yeah. That is a longer discussion about what you see prevents people from going to the tort system if they are dealt with in what they think is a basically fair way. So I actually think to an earlier comment you made about how to pay for, this might actually prevent such larger costs from occurring in this, in giving people more a sense of just fairness at a pretty low cost level. That is just based on experience of how it's worked in going to the tort system, but I am here to read a question. I have one contractual obligation to Mr. Feinberg, which is to end this at 6 o'clock sharp. So there is a question from Sara Hernesal. Sara, would you please stand up? It is a series of questions, actually, and I will just read them. How would compensation for injuries related to research work in a population already compromised? How would compensation for injuries related to research work in a population already compromised by illness? How would a patient or participant prove his or her injury was related to the investigational agent, and not their underlying condition, and what process would assist the participant improving their injury?

Kenneth Feinberg: That is the question that Dr. Hauser asked. First, it happens all the time that the fact finder, whether it be the arbitrator or a jury, was the injury caused by the research, or was there a pre-existing injury that really all the research simply accelerated what was already there? That and the second question all relate to causation. The question that was posed by Dr. Hauser, how do you demonstrate eligibility for compensation when there is conflicting evidence as to whether it was the researcher and the research that caused the injury or a pre-existing condition or what have you? It happens all the time with tobacco. With asbestos, for example, did asbestos inhalation cause your disease, or the fact that you smoked two packs a day before you even started dealing with asbestos cause the lung cancer? That is the causal question, a very important question, and whether it is an arbitrator, one arbitrator, three, a panel of three, a researcher chooses one. The victim chooses another arbitrator. The two of them choose the third share of the arbitration panel. You come up with a mini process to get answers to the questions of causation and damage.

Amy Gutmann: It is been a sheer pleasure to have the opportunity to hear from you and hear your answers to our questions. I am true to my word and I will just invite you if you have any concluding comments you would like to make to us, to offer them now.

Kenneth Feinberg: The only comment I would make is this. I think before I accepted this invitation, I did a little research. The lawyer that I am. I think the work that this committee is doing is so incredibly interesting and important. I wish you all well. I will tell the chair, when it comes to this subject of compensation, I cannot say I know a whole lot about all the other issues on your agenda. I've looked at the two days. I mean, fabulous agenda, and when it comes to the compensation, if the committee or subcommittee wants to get back to me, if there is anyway I can help in reviewing a proposal or alternatives, I would be honored. This is such an important committee. I would be honored to provide whatever input I can. That is up to you. But I am honored that I was invited, and I thoroughly enjoyed the opportunity.

Amy Gutmann: And I'm sure we will take you up on your offer. For now, thank you very much.

Kenneth Feinberg: Thank you very much.

Amy Gutmann: Ladies and gentlemen, we stand adjourned for the day.

