



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

TRANSCRIPT

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James Wagner: Good morning and commissioners, welcome back, guests, welcome to the second day of our what did we say this is, the seventh meeting?

Amy Gutmann: Yes.

James Wagner: Seventh meeting of the President's Commission on the Study of Bioethical Issues. We ended our last episode last evening with a presentation from Ken Feinberg beginning a conversation on compensation for research-related injury. And this morning we are going to continue that, getting more input from additional experts. And welcome you both, Dan and Karen. Thank you for being here.

Our first speaker this morning is Daniel Wikler. And Dr. Wikler is the Mary B. Saltonstall Professor of Population Ethics and Professor of Ethics and Population Health in the Department of Global Health and Population here at Harvard. He is also presently the co-Director of the Program on Ethical Issues and International Health Research and the School of Public Health and he serves as the—has served rather as the first staff ethicist for the World Health Organization and remains a consultant to several WHO programs.

Professor Wikler's published work addresses many issues in bioethics, including issues in reproduction, transplantation, end-of-life decision-making, in addition to population and international health, quite a list of credentials and we're eager to hear from you. Welcome this morning, Dan.

Daniel Wikler: Thank you very much. It's a great pleasure to be speaking to you. If I can reminisce just a for a second with a few seconds of my time, a few commissions ago, the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, I served as staff philosopher on that group. We had a substantial budget and we could hire the very best consultants. And one of the first ones we went to was a young professor named Amy Gutmann, who wrote an excellent paper for us, arguments for and against equality in access to healthcare, which influenced the commission. So we are off to a good start. So nice to see you in the similar context.

Amy Gutmann: Thank you. And thank you for not saying how long ago that was.

Daniel Wikler: It was only yesterday [inaudible].

Male: It seems like a long time.

Daniel Wikler: My memory is not so good as it used to be.

Second piece of reminiscence is, you're not the first Presidential Bioethics Commission to take up this subject. See? We spent years on this subject. We thought it was going to go away. And others had done so before us. But it's a perennial.

And I had—when I was there, I didn't want to contribute to this because I was more interested in other projects. But was dragged into it with disastrous results because a—I think this the only occasion in which the contributions of a scholar, a philosopher in particular, namely me, was actually the subject of a journal article in *Ethics*, one of the premier ethics journals in the field of academic ethics. And basically it's a very thoughtful examination of what philosophers are doing in a body like this. And the argument proceeds by using a spectacular

case of mission failure. It was the President's Commission report on compensation for research injuries. And the disastrous performance in question was mine. Now he was kind enough—the author was kind enough not to mention which philosopher, but anybody who knew anybody who was there would be able to figure out it was me. So I was tempted to read you all of his damning prose here, but I'll just make it available to you later on. Of course, it might undercut my authority here. But let me just say I've learned my lesson, so I hope that this time it will be better.

So there's a kind of a meta-question here of the role of the advice of philosophers, but let me just get into the subject matter because that's, of course, why we're here.

Taking an enormously complex question and distilling it into what are now seven minutes is a challenge, but so that means I'll oversimplify like crazy. But nevertheless, here's the way I would outline the arguments.

If you look through the literature on the subject, there are many ethical arguments that have been offered for compensating injured subjects—reciprocity, they did for us, now they're in need, we should do for them, the desirability of avoiding free-riding, others in society benefit from the sacrifices they made. Why should we saddle these people alone with the costs? Let's spread the costs by offering them insurance at least and compensating for injuries. And then something like solidarity, not quite charity—the needs of people who are injured while performing a public service are privileged among the universe of needs for the reasons that are obvious. This came up again with the people who attempted to rescue and help victims of 9/11. Some of them got injured in the course of it and there was a nasty debate over whether or not their injuries were going to be their problem alone or whether society would help them with expenses. And the argument in favor of helping was pretty powerful.

Now the strongest argument against requiring compensation, well, there are two. One of them is that it might cost something. And if it costs something, it comes out of research budgets. And the scale of scientific research is reduced. There are forgone benefits to humanity, to Americans, to the taxpayers. So that's a—we want to lighten the administrative or—and regulatory burden on research so that we can get as much research for the buck as we can. It's a public good. And so that's one issue. Of course, this is a question of how expensive that it would be.

But the main one I think is an attempt to puncture the central argument in favor of compensation in the following way—unavoidably we have to ask people at least on occasion to volunteer to be subjects in research that carries more than minimal risk, so either it's burdensome in the sense that it's painful or it takes up a lot of time or it might be stressful or—and/or there may be a risk of real injury.

We can't avoid doing this if we want to get the results that we hope for from biomedical research. And there's no question that biomedical research is an urgent and continuing public good, both to advance the frontiers of medicine, but also and I think this is not emphasized enough to check over what is currently being done, much of which is being done because it was done by the teachers of the present practitioners and handed down by the apprentice system and some of which we find out every year is actually harmful, still more is useless. And we won't know that until we—unless we keep up research. Maybe we should increase the pace of research. So to—in order to do the research, we often have to ask patients to accept a burden.

Now the argument against requiring compensation goes like this. If it's okay to ask them to shoulder that risk, then why can't we ask them to shoulder a somewhat greater risk, namely to do it without a safety net, to say okay, you agreed to make a contribution to the public good by

exposing yourself to risk or by enduring stress or discomfort. Would you please do a little extra for us by agreeing that if you get injured, it's your problem and not ours?

So the argument is that anyone who thinks it's okay to do the first, to ask them to accept the burden of being a research subject in more than minimal risk, by logic alone has to say that the second should also be permissible. And if you think the second is not permissible, then the first couldn't be permissible, in which case we couldn't have any research with more than minimal risk. So that's in a nutshell how the argument goes.

So when you put—that argument says no one can consistently say that it's okay to have research subjects with more than minimal risk and—but that we have to compensate them. We can't consistently say that you must require compensation if you're also saying that it's okay to ask people to accept this burden.

Now back then I sort of left it that way, but now I'm not going to do that, so my—I've matured a bit I hope. So let me just state briefly what my conclusion—I actually think there's a fallacy or a fault with step two of the con argument. And it's not a—pulling a rabbit out of a hat here. I think it's probably clear to everybody.

There's a big difference between asking someone to shoulder the risk or the discomfort of research when that is ineliminable. In many cases we call our committees committees for the protection of human subjects. Now I've always thought that was a strange title because if you really want to protect them, tell them don't sign up for this research. So that's easy. You don't need a committee. Just let some other sucker do it. So we don't do that, of course. We expose them to risk and we ask them to take on the risk. That's what these committees for the protection of human subjects do. So what's that word "protection" doing there? Clearly it's to get rid of eliminable risks. We tell them there's no way we can do this research unless you or somebody takes on this burden. But we promise you we've scrubbed this thing clean of every risk we can eliminate that isn't required by science. So they're not really protection of human subjects from all risk. It's protection of human subjects from eliminable risk.

Now we have to—there's just the nature of the beast. We need human subjects for the simple reason you can't try new therapies on lots of people that you haven't tested. So we have to have human subjects. And there's going to be an unavoidable, ineliminable burden that this places on some human beings. But we have to be very careful that we spread this risk fairly, that we don't just pick on people who can't say no, the worst case, of course, we all about in the—it was in the concentration camps when they took people who had been imprisoned for—who had never done anything wrong and then used them in horrible ways, spared everybody else. So we just can't do that. So fairness is a big consideration as the Belmont Report says and others have said. And fairness has to be squared with the fact that we are asking people to take on this burden.

But the—doing it without a safety net is not required. You can do the science and provide a safety net. There's no reason, there's no excuse for imposing that on subjects whereas there is a perfectly good excuse for imposing the burden of being a research subject, namely you can't do research without it.

And we know it's possible because it's done in some places in the United States and certainly abroad. I just last month was in Cairo as part of a WHO team working on upgrading the system of ethical review in the Middle Eastern region. And one of the participants, who was a well-informed head of her university's human subjects review apparatus, asked me some details about our system of automatic compensation for research injuries. And I said madam, you are misinformed. And she said no, no, no, she just heard about it the other day. And I said okay,

here's my computer. I've got a web connection. You show me the page where it says we've got this. And a little later we heard a little shriek. She just couldn't believe that the United States didn't have this. I mean, I was—and I'm from the United States. I was there to teach them the subject. So we're a little bit behind from that perspective.

So if we look at that weak link in the argument, I think we find the Achilles' heel of the opposition argument. In fact, we can sort of turn the whole thing back in this—onto the same logic that is used by the opponents of compensation, how can you say it's okay to ask people to shoulder the risk, but not okay to ask them to shoulder the risk of uncompensated injury. Okay, now we can use the same jujitsu thing back. If you think it's okay to ask subjects to shoulder the financial burden of paying for care and otherwise making themselves whole after being injured in research, why should we get rid of the eliminable risks in research? Why do we have human subjects committees that try to make sure that all of the risks and burdens that can be eliminated while allowing the science to go forward be blocked? Why not just ask them that, too, because after all, they can give informed consent to that, too? So we can save a lot of money, get rid of human subjects committees. All we have to have is an accurate summary of the burdens that be involved, even—and we won't distinguish between the ones—between burdens and risks that we can eliminate and those we can't. And then we go out and find subjects who will agree to the whole kit and caboodle, the ineliminable risks, the eliminable risks, and also the expense. And we can find them, no problem done according to this logic. And that's obviously wrong. And so if we follow that one back we see where it goes.

So I'll close with a brief analogy. It's my favorite analogy in this subject. The analogy is between serving as a research subject and serving as teaching material for the education of new doctors.

Logic tells us that every doctor who knows how to do a lumbar puncture once did it to a patient when they'd never done it to a human being before. And I hope I am never that patient. But someday in a teaching hospital a doctor may come up and if this doctor is an honorable doctor she'll say Ms. Smith here is learning to be a doctor, has never done the lumbar puncture. You need one. Can she practice on you? And, of course, she'll say I'll be right three and after three stabs I'll take over and I'll reduce the risks as much as I can consistent with the training mission. And when that happens, I think I have to say okay. I mean, I've benefited a lot from the healthcare system. What I shouldn't say is let some other sucker do it.

So, okay, suppose that the doctor approached me and said we want you to do all of that and also by the way if she really screws you up and you get terribly injured you're on your own—will you agree to that? If I did agree to that, it wouldn't make it right. I'd be performing this public service. And how outrageous to ask me in addition to doing my part that requires the sacrifice, to ask me to take on something else.

If we're in that mood and we—we're concerned about the cost of research, I have a modest proposal of a Swiftian sort. Ask them to do it without a safety net and say by the way, we're—we really kind of short on research funds, you know, and I hate just cutting back. Do you mind giving up some tissue we can sell? And you'll find the people that say oh, yeah, okay, maybe a kidney. I mean, then you've really got a good funding stream for research. And you can see where this would go. We don't do that. We know that it would be outrageous to do that.

So just to conclude in a sentence, three themes have been predominate in the literature since the Nuremberg doctors trial—the autonomy and informed consent side, the patient protection side or research subject protection side, and also the fairness of burden-sharing. I

think the latter two strongly support a system of compensation, not lavish, but one that does the job, and the first one isn't inconsistent with it.

Thank you.

James Wagner: Thank you. Well, we're going to do is hold question and comment till we get a chance to hear also from our second speaker, who is Karen Moe. And Dr. Moe is Director of Human Subjects Division and Assistant Vice Provost for Research at the University of Washington. In addition, she is a Research Associate Professor in the Department of Psychiatry and Behavioral Science. And prior to joining the Human Subjects Division, Dr. Moe ran an active federally-funded research program on sleep and the science of sleep in older people and she ran that for fifteen years it says here.

Welcome to this second day. It was good to have you with us yesterday as well. Karen, please.

Karen Moe: Great. Thank you. Dr. Gutmann and commission members and staff, I thank you on behalf of the University of Washington for this opportunity to talk to you about our research compensation program. I also appreciate your indulgence at allowing me to use a PowerPoint unlike any of the other speakers. I do have a lot of details I want to go through fairly quickly about our program because I understand that you're interested in them. So this will help me do that so that I can save some time at the end to go over a few of the ethical and logistical issues that we are currently facing in our program.

So first of all, a little bit of context about our setting, we are a large public institution in Seattle, Washington. We have a very large academic healthcare system, which we call UW Medicine. We receive a lot of research funding, last year about \$1.5 billion, and we have a very large human subjects research program, about 6,000 active studies at any one time.

This is the latest purpose statement of the plan that we have for compensating for research injuries in subjects. And I'll just read it very quickly. The University of Washington respects and values the volunteer human subjects who participate in UW research and recognizes that subjects may assume some risk by participating in that research. The Human Subjects Assistance Program is a no-fault program developed to provide medical and other assistance to subjects who experience a research-related medical problem that is likely caused by university-conducted research. And I slightly emphasized a few of the key points that I'll be going over.

So as a reminder, I referred back to this same commission report and I'm not going to say how long ago either, but it was a while ago. And this was the first time that we publicly presented our compensation program. I've shown you the first page of an article that was one of the appendices. A couple of predecessors before me in my position, Diana McCann and the head of university's risk management program at the time prepared this report where the described the first iteration of our program.

Briefly, the history of our program is that for the first five years when we had the program and started it, we used a commercially insured workers' compensation model. So we bought commercial insurance from a commercial company. We paid premiums every year. And during that first five years, as you can see here, we paid seventeen claims for a total of \$16,000, but our premiums were over \$260,000. That led to the subsequent change the next year, which was we decided to stop getting that commercial insurance and to fold the program into our own self-insured general liability program that was managed by risk management.

This continues today. And it is funded by central administrative funds through the university. The program then started out and continues to be today this component, which is that we pay up to \$10,000 per subject to reimburse them for any out-of-pocket expenses for a research-related injury. That may be for medical care provided outside of our system. It may be for taxi fees to get to a medical appointment, whatever seems appropriate for dealing with a research-related injury.

Now over time we've developed another component. And this is the one that usually evokes gasps from other academic medical centers. We provide an unlimited write-off of charges for care that is received at UW Medicine. That includes individuals who are not already patients at UW Medicine as part of being in the research protocol.

Now right now, we do not have all components of our system participating in this for a variety of reasons, but it does include two hospitals, associated outpatient clinics, and a very large regional network of neighborhood clinics. And it includes the facilities, as well as our physician practice plan.

Now what is not included in our plan is first of all any research that funded and initiated by industry. So we do expect that those industry-initiated clinical trials will provide some sort of compensation for the treatment of research-related injury. And we negotiate that very hard when we come up with those contracts. We also do not cover research-related injury that occurs under a subcontract from the university to another institution. For example, if we're the prime recipient on a multisite clinical trial, we don't cover the injuries that occur at the other sites.

We don't cover any research that is not under the direct control and supervision of a UW researcher. And I'll talk a little bit more about what that means and the difficulties that that can create.

And this one sometimes surprises people—except for those considerations, the location of the research is otherwise irrelevant. In other words, we do provide coverage for injuries that occur in other countries or other areas outside of the Seattle region.

Now we've been revising our plan. We've been working on a revision for a couple of years. We are very close to implementing the revision and we are close enough that we all agreed that it was appropriate to share with you how we are revising the plan because I think it illustrates some of the important challenges and issues with having a plan like this.

And here's the reasons why we're revising the plan. One of the most important is that there have been significant changes in the regulatory environment for the provision of healthcare in this country. The CMS or Medicare system now provides coverage for some clinical research trials. In addition, in the last few years, CMS or Medicare has expanded their interpretation of what's called the Medicare Secondary Payer rule. That basically means that Medicare is always the last payer if there are other promises to pay for something. They have now made it clear that this extends to research and to coverage of research compensation for injuries. So if you promise to pay through some kind of compensation program, you can not first charge Medicare and then pick up the remainder. You are the primary payer and Medicare is secondary.

Another reason that we have been revising our program is that like many large institutions, we are expanding greatly, especially our healthcare components. And our researchers are very creative. They develop all sorts of interesting affiliations and partnerships so that now it has become very difficult to determine what exactly is a University of Washington research study. We talk about it instead of having a very discreet system, we talk about the University of Washington cloud because that's a much more appropriate and realistic way to explain it.

Unfortunately for a plan like this, you can't operate very well with a cloud. So one of the things that we've been doing in our revision work is trying to develop more crisp boundaries around our compensation program.

And that's the third bullet. We've been trying to clarify the roles, responsibilities, and procedures along the lines of what Ken Feinberg was talking about last night, who did a wonderful job at describing some of the issues related with this kind of program.

We haven't had some of the roles and responsibilities as crisply defined as we would like. And so we're working on that. And we're also dealing with a few specific liability and risk management issues.

So the revised program we are—it consists of the following key changes. First of all, we are retaining the \$10,000 out-of-pocket expense component of the program. We do ask our risk manager every once in a while to raise that amount because \$10,000 really doesn't buy very much in today's healthcare climate. She has resisted that, but she does have the flexibility to go beyond that whenever she thinks it's appropriate and she does.

We are still going to write off the healthcare charges, but we are coming up with a couple of new twists on this, some of which have created some real ethical conundrums and discussions for us. One of them, the third bullet down there, is that we are imposing a cap of a quarter of a million dollars. Previously it was an unlimited write-off.

These write-offs are absorbed directly by the bottom line of our academic medical institution. It is a self-insured program that comes directly out of their day-to-day operating costs. That's how we fund this. And they do not feel that they can any longer accept unlimited liability in this situation.

The other issue, which frankly some of us are still a bit uncomfortable with is that we are looking for ways to treat like subjects alike and possibly to treat unlike subjects in a slightly different way. That's sort of a general statement of what our other change is, which is we're dividing the medical problems that might occur into those that are anticipated or known to be likely, for example, with a specific drug, and those that are unexpected or unanticipated. We're also going to be requiring that they be reported within one year and that other issues might—that might occur would go to the tort system. And we are also broadening the definition of a medical problem.

Now this is just a brief description of the various components at the university that are involved in the program. I'm going to skip over that in the interest of time and talk a little bit about the challenges of this program.

So first of all, I already mentioned the changes in the regulatory environment and the importance of the MSP rule in terms of how it impacts us. Basically what we are doing because of the risk of billing people inappropriately under Medicare when they have had a research injury and we've provided compensation, we are absorbing costs that we might otherwise be able to charge to Medicare because of the billing issues and the risk of a false claim.

And if you know anything about the history of the University of Washington, you know that about six or seven years ago we had an unprecedented fine in the history of this country for billing claims with Medicare. That's made us a little bit nervous. And so we are very cautious about how we bill for research-related care. Nonetheless, we think it's very important.

The financing, obviously there are financing challenges here. Our healthcare system, like most, operates on a very thin margin. They are willing to assume this on behalf of the university for now, but we do have concerns about that.

We have the crispness at the boundaries—how do we determine when something is a UW research program and when it is not and do we determine when the medical problem is related to the research or not? We have a fairly low bar for that. Our criteria is that the problem needs to be more likely than not related to the research program. So there's no need to prove fault or negligence. It's a pretty low bar. And then we are concerned about the research burden. It does require some additional reporting on top of our researchers. And, of course they have a significant amount of burden already.

One of the last things I'd like to point out is that one of the things that's key to our program working, actually there's two things. One is that we do have a university that is very committed to its research program and that believes that this program, the compensation program, accomplishes three things. One is that it addresses the ethical issues that we have about protecting our subjects. The second is that we think it's the best way to deal with our financial liability. Our experience back in the seventies showed us that having our own program was actually cheaper than having commercial insurance. The third is that we believe this is a great way to facilitate our research mission, not only research in general as a public good, but because it's so important to the University of Washington and to the State of Washington. We can tell our subjects in our community we are trustworthy. We have this program. We will take care of you if something happens and do what we can to make it right.

Another reason that this works, and this will be my last remark, is that we do have a somewhat unusual structure at our university with respect to our academic medical system. The same individual is both the CEO of our academic healthcare system and the dean of our School of Medicine. So he is obviously very committed to this program and wants to have it continue in order to further both the teaching and the research mission, so much so that this actually is one of the only six standing orders from our Board of Regents.

Thank you.

James Wagner: Karen, thank you very much. And I believe our chair has the opening question.

Amy Gutmann: I just want to start by thanking both of you for—we've had just incredibly clear and thoughtful presentations on this subject and both of your presentations have been phenomenal in that regard.

So I have a question for Dan and a question for Karen if I may. And I'll make them very brief. So for Dan, there are many different—going from your recommendation and the philosophical, the moral underpinnings of it to what's possible to institute, you've thought about this and looked at it and we asked—I asked the same question to Ken Feinberg, so I'll ask it to you as well.

Is it possible and desirable or possible or desirable—if it's not possible, it's not desirable—to have some system for providing treatment for injuries, compensation, that doesn't preempt the tort system? In other words, that's compatible with also the, you know, using the tort system when you want to, when you think it's appropriate? So that's my question to you.

My question to Karen is given all of the challenges that you have because once you have such a system you have to deal with all of the details and as people like to say the devil is in the details or God is in the details, either one, is there—those two statements are compatible, my question to you is if you didn't have a system now, would you create one? And would it be like the one you have now?

Daniel Wikler: I'm going to duck your question because I'm not really qualified to say. I'm not a lawyer. I'm not Ken Feinberg. And so ask them. But I'll use my moment here to add to your burden.

Amy Gutmann: Could I just rephrase it so you don't have to be a lawyer?

Daniel Wikler: Sure. Okay.

Amy Gutmann: Would you think it's—I'll just do the desirable part—desirable to have people who are guaranteed compensation for injuries regardless of fault also able to use the—to sue, to go to court and sue for, you know, negligent injuries?

Daniel Wikler: Again, there—I think there are too many things I'd need to know that I absolutely don't know.

Amy Gutmann: Okay.

Daniel Wikler: So I don't want to hazard a guess. But I will—there's one thing that you said raised a question in my mind on this subject.

Amy Gutmann: Okay.

Daniel Wikler: Let me just voice it. It's entirely understandable that you want to cap the free care provision of your wonderful plan. But—and you say having a plan—and I completely agree with you. Having a plan allows the university to say to its potential subjects this is a public service that we're doing and you're a part of the team and we're there for you. But having the cap, of course, says we're with you unless you really get hurt. And then we're not.

Now, again, this is not to say that the university is heartless. It's, you know, there are constraints. But when you put the cap on, what—who bears the burden of an injury that is just fantastically expensive to treat? And that sounds like a lot of money, a quarter of a million dollars, but we all know there are patient [inaudible] cost a lot more per case, not that many, but some. These rarely are the result of research injuries, but when they happen, in those cases, are you saying well, in that case, you're on your own? Well, in that case, you would hope that they would have the tort system to turn to because what are they going to do otherwise?

Amy Gutmann: They can sue. You can sue.

James Wagner: Well, Karen that—three quick questions for you.

[Crosstalk]

Amy Gutmann: —answer the question of whether she would put the same system in if you were doing it now because it's a—you did it decades ago—not you personally, but University of Washington did it decades ago. So would you do—what it—it's the sort of question what have you learned that would lead you to do anything differently than what you have now?

Karen Moe: Gosh, that's several questions. I'll do my best. I actually was thinking about that this morning, would we redo this if we had—if we didn't have one. I'm not sure we would. We still would have the same desire to do it. I think the commitment to this program is institution-wide. It's not just driven the IRB office or the Vice Provost for Research or the Dean of Medicine. So I would like to think that we would do it again.

We have learned a lot from our revision process in the last four years. We've been spending a lot of time basically constructing the program from the ground up again and we have decided to keep almost all of the same characteristics, but just to basically clarify many of the administrative procedures and provide this cap.

Amy Gutmann: Good. That's [inaudible].

Karen Moe: Yes, so I would like to add that the tort system—and this is an issue that Ken Feinberg brought up yesterday, too, is in addition to this, so we do not require people to say that they will not sue us if we provide them with compensation. If you look at old materials that describe our program, in fact, they do say that you have to give up your right to a lawsuit if you accept this compensation. But we, in fact, dropped that many, many years ago. So we think of it as a sequential process and that if they were to go beyond the \$250,000 cap or they required care that we weren't able to provide in our healthcare system like long-term nursing care, they could go to the tort system. And also our risk managers in our healthcare system have some flexibility to go beyond that cap.

Amy Gutmann: Thanks. So you answered both questions, thank you very much.

Barbara Atkinson: And how often does that happen?

Karen Moe: How often—

Barbara Atkinson: Do they sue? I mean, is it—

Karen Moe: Not very often.

Barbara Atkinson: [Inaudible].

Karen Moe: I think we've had about one in the last couple of years. This system is very effective. And I don't know how much of it is the people who administer it and our institution's reputation in the community. But what we believe is that when you treat the subjects with respect and you respond to them very quickly that it does a great deal to alleviate any concerns and anxieties that they have. And so—

Amy Gutmann: There's good actual data on that.

James Wagner: Nelson?

Nelson Lee Michael: I have two quick questions for Dr. Moe and they are linked so the first question is who's the bill-payer for this system? Does it come from your indirects, does it come

from your endowments, operating costs, and therefore do you have increase fees to researchers as a consequence of this? And then reflecting on that situation that's unique to the University of Washington, do you think the system that you just described is generalizable to institutions that have a smaller research base and they have less flexibility?

Karen Moe: Great questions. So the way in which program is funded, there are two sources of funding. The \$10,000 out-of-pocket fee or part of it is funded by general administrative funds, just general university funds, which come from the State of Washington, our general operating fund.

The write-off of the healthcare charges is funded directly by the academic healthcare system. So they absorb it as part of their charity care mission. We write off some incredible amount of charity care every year. I think it's about \$240 million a year. And this is absorbed into that on a day-to-day general operating basis. So we do not charge fees. We do not charge anything to research grants. It's not coming out of our indirect costs. It's coming directly out of the academic healthcare system.

Nelson Lee Michael: And generalizable to other perhaps smaller research—

Karen Moe: You know, that's a very good question as well. I think one of the challenges is that first of all the other institution would have to have an academic healthcare system that would be capable and willing of absorbing these extra costs. The increasing challenges that we're facing with regard to billing because of Medicare and because private insurers tend to follow Medicare is making it really difficult for us to continue this. We're going to do it, but it is very difficult in terms of the administrative burden.

James Wagner: We have time for one more. Well, maybe we'll do these two, last two, Steve and Anita.

Stephen Hauser: Maybe two quick questions if I might. First a question, do you have current data on the costs of the program for the 6,000? And second, you mentioned that you carefully negotiated with industry-sponsored trials. And perhaps you could just expand upon that landscape currently?

Karen Moe: Right. So our current charges are that in the last five years we've written off about \$250,000 worth of healthcare costs. That's total over five years. Most of that is from one incident that happened last year and somebody had a cardiac problem and they were in intensive care for two weeks. The \$10,000 out-of-pocket component, we pay about \$8,000 a year on average, so very low cost.

And I'm sorry, what was the other question?

Stephen Hauser: The other had to do with industry-sponsored clinical trials and the negotiation process.

Karen Moe: Right. So our stance used to be that we would not do any industry-sponsored trials unless the industry, the company was willing to pay for injuries to all subjects. We've relaxed that just a little bit and so we now negotiate in terms of the specific requirements and limitations

that might be placed on that and depending upon how valuable we think the clinical trial is to the University of Washington and its patient populations. So, for example, some small startup companies may not be able to provide the kind of insurance that would allow them to provide total coverage. And so we negotiate with them with some limitations about say emergency care or certain other kinds of restrictions.

James Wagner: Anita?

Anita Allen: You described your University of Washington system and the tort system as sequential. And I'm wondering in those very rare cases that you described where you do have a patient who does opt to go to the tort system, I imagine somebody who got the \$250,000 but needed \$250,000 more to cover their actual losses, is your school's attitude or approach biased towards quickly settling those kinds of tort claims? Or do you think it's important to go and fight those claims in order to avoid establishing through the court system a rule of law, which says that there is strict liability for research injuries?

Karen Moe: I think our general—I'm speaking on behalf of the risk management and attorney general's office and I'm not the expert on that, but it appears to me from my vantage point that our perspective is to settle those issues out of court very quickly in part because of concerns about the cost of the litigation that it—we think it's more financially effective to settle them quickly.