

Panel Discussion

Audience:

This is a question about paying for risk. I'm going to pose a hypothetical situation: I set up a little hobby in which I go out into the streets of Manhattan, find competent adults, and offer them amounts of money to undertake various risks. I pay them a little bit if it's a small risk and I pay them a lot if it's a big risk. Would you curtail this activity in any way. If so, why? And if not, why not?

Dr. Rebecca Pentz:

That is an interesting question, because we actually do pay people for risk in all kinds of activities. The question is, why do we pay for risk-taking in the wage world and not in the research world? My first response is that I'm concerned that we not offer risky research to subjects in a way that would make them do things that they wouldn't normally do. For some reason, they don't understand that research is a risky enterprise and so they sign up for risky research.

Dr. Lance Stell:

One difference that occurred to me between taking risks in the wage world and in the research world is that there are a number of occupations that pay people a pretty good wage to take risks, but I think the assignment of risk in these areas is a very different kind of thing. In a job situation you can develop skills and ability with experience, so that over time the level of risk can lessen. It seems to me that in the area of medical research the subject of the research has no control. The risk is in the drugs, and there is nothing they can do to change the odds in their favor.

Audience:

Is it appropriate simply to pay people to undertake risk?

Dr. Pentz:

No it is not. It's different if you are paying them to undertake risk that also has collateral benefit to the party.

Dr. Stell:

The issues are: What risky things do we allow people to do? Do we allow them to do them and

then offer them money? And, at what point does the money become too good? I don't think there is going to be a "one size fits all" answer, or a theory to explain why it is not acceptable to provide financial incentives for medically related risks, while it is okay to pay people to be stuntmen or to go down into mines where the risks can be much, much greater. I think it is a very complicated issue.

Dr. Daniel Moros:

To go even further, let's look at some of the paternalism that we practice in permitting people to assume risk. For example, we take ninth graders and praise them to the world for being good at football or being terrific wrestlers, with tremendous risk to their bodies. We could criticize the whole educational environment for the establishment of high school football. Perhaps I am blind to a value in these activities that a tremendous number of people see. I know that at one time in my life I would have outlawed high school football. I'm not sure if I would have been right to do so. It is very difficult to come to grips with the issue of what is acceptable risk and at what age.

Dr. Pentz:

Risk, as I understand it, is the probability of harm. There are two parts to it, the magnitude of the harm and the probability. Would you say that it is risky for someone to undertake an activity with a very, very small probability of death? Is that a big risk or a little risk? If we can't say what is risky, then we don't know what we are talking about.

Dr. Stell:

One particular problem with risk—and there is a lot of literature on this—is that individuals in general are very bad at assessing their own risk. A good example would be that even post-9/11, it is much, much safer to fly than it would be to drive from New York to Chicago. But most individuals aren't able to understand that, or to make that kind of informed decision very effectively. So I am generally sympathetic on the point of autonomy, but I think that we have to be careful that the risk is presented in a way that is understandable.

Dr. Moros:

In failing to honor autonomy, the IRB has failed on the consent side just as badly as it has failed on its overstatement of what constitutes improper inducement. The IRB does not inform the research subject of the Committee's risk assessment. I don't see how IRB members, in good conscience, can not tell potential subjects about the risks that concern them. The nonsense surrounding informed consents is incredible. The IRB risk analysis should be provided as part of the informed consent.

Audience:

The scandal is that except in research programs sponsored by academic medicine, subjects who accept risk associated with a research project would ordinarily be insured by the sponsoring organization. In the case of a bad outcome, they might receive some sort of compensation, maybe 1–2 million dollars, or more, or at least their estate would. But research institutions and egg donor institutions are playing fast and loose with people by permitting them to engage in risks. It doesn't matter how much money is offered. The sum is usually trivial compared to losing the ability to have children. And who should assess risk? Not the IRB, whose members are from our group, but insurance companies whose business it is to assess risks. They will tell you realistically the cost of the risks in running the research. I put this forth because in this discussion we keep assuming that if you inform individuals of the risk, then unless there are very strong issues of altruism, the individual will refuse to participate.

Dr. Bonnie Steinbock:

I want to remind everyone that there is a relevant distinction between magnitude and probability of risk. One could say, as a potential egg donor—yes, there is a chance that I will lose my future fertility, and that is a very big harm but a very, very small risk. If I were thirty years younger I would not be an egg donor and I would do everything in my power to prevent my daughter from becoming an egg donor. But it is not for me to say that somebody couldn't rationally understand what the risks are and agree to be a donor. Also, I don't think that the money is most manipulative here. The manipulation involves not telling donors everything they should take into account and trying to hide things from them. For example, we talked to one egg donor who said that her second cycle was cancelled and she wasn't sure why. The program had re-

trieved 40 eggs and she thought this meant that she was superfertile. After she left the room, the doctor said that she had been hyper-stimulated and that she hadn't been told, because they wanted her to come back in the future. He added, "Donors are very easy to manipulate."

Audience:

In terms of money, the most common problem today, particularly in academic settings, is simply the conflict of interest of being bribed. Pharmaceutical companies, medical instrument companies and others ask for expert advice, for which one is actually paid. However, those who have been paid are also the same people who sit on bodies which approve or disapprove a particular product. They are also the ones who are seen on television or might be in the newspapers promoting a product. Over the years I have been unable to persuade the medical journals to ensure that every published article, letter or editorial state whether the author has or doesn't have a conflict of interest. Readers should know if authors were taken out to dinner, sent off to Japan, etc., by somebody who influenced their opinion about what they are writing.

Dr. Lewis Burrows:

I think that whether something counts as a bribe depends on whether money is taken in exchange for the betrayal of trust. In Japan, for example, medical directors can accept up to \$2,300 for their referrals, and that is not regarded as a betrayal of trust. Is this a betrayal of trust or not? I think we would quickly conclude that they are taking bribes, but that is not the way they see it. Are they wrong?

Audience:

When people have a financial interest in a center they give as much as 60% more referrals. Has anybody done an empirical study in Japan? If they get money for the referrals, do they give more referrals? If they do, I think it is a betrayal of trust even if they don't agree.

Dr. Burrows:

I don't know the answer to that, because for one thing the Japanese physicians don't talk about it. It is regarded as dishonorable to talk about. Earlier, there was a question about how successfully American physicians have disciplined their own. Disciplining can be done in private or in public. When sanctions are distributed privately, the public doesn't perceive that medicine disciplines its own.

Audience:

Going back to the question of whether it is morally permissible to donate eggs, I am trying to find an equation. We don't allow people to sell themselves into slavery even for a good cause. If I was willing to sell myself or dig anthrax out of the ground for the good of the world and a price, why would those transactions be out of bounds?

Dr. Stell:

Mill's reason for why we don't let people sell themselves into slavery is appropriate here. When you sell yourself into slavery you are giving up all of your freedom to make future choices. Mill thought that violates the principal of liberty. We don't allow you to use your liberty to destroy your liberty. I think that selling yourself into slavery is really different. It's even different from the freedom to kill yourself, where you are destroying your freedom. The dead are not going to be making any choices. If you sell yourself into slavery, you give somebody else control over your choices.

Dr. Moros:

To use Mill for the issue of slavery is one thing, but Mill was extremely opposed to paternalistic intervention.

Dr. Stell:

He would prevent people from going across an unsafe bridge. His argument was that you would be interfering with their choice but not with their best interest. Considering their best interest, they wouldn't want to cross an unsafe bridge.

Audience:

That would be equivalent to prohibiting women from selling eggs without being told everything.

Dr. Steinbock:

But what you can do is tell them. What I think should be done, particularly in terms of surrogacy, is that the surrogate should have a lawyer who is representing her interests, so that she is both being informed and having someone protect her. What happens now with surrogacy to some extent, but even more commonly with egg donation, is that young women think they are being taken care of by the lovely people at the clinic who are being so nice to them. They don't understand the conflict of interest. The interest is all about wanting to get as many eggs as pos-

sible for the people who are to receive them. What you have to do is change the institutional structure to assure that people are protected. Focusing on money keeps us from looking at other things which are much more significant.

Audience:

Even when you sell a car there are certain standardized disclosures that have to be made. You are describing a situation where the most rudimentary standard disclosures are not being made. But, does that mean the procedure shouldn't be done?

Audience:

In living liver donor transplantation, I believe there have been one or two deaths, which amounts to a 1% or lower risk of death. As a surgeon, do you think that is too much of a risk of death to allow anybody to undertake voluntarily or for money?

Dr. Burrows:

For the time being, I asked for a moratorium, despite the fact that it might upset my colleagues in the transplant field. Not only because there is a risk of death, but because there is also risk for major complications, prolonged hospitalization, and lots of side effects. Only centers with the requisite proficiency should do the operation. I asked for a moratorium because I think that even a 1% risk of death is too high. There is only one place in the country that is doing living donor pancreas transplants, and that's in Minnesota. The exact figure hasn't been disclosed, but it involves a 10–15% chance of the donor eventually developing diabetes. I think that is an unnecessary risk, and I would put a moratorium on that for sure. Liver donation is truly a life-saving operation. The recipients who get the livers would die within a year or sooner without them. But again, I think the procedure should be in the hands of the most competent transplant people before we extend it, as we have with kidney transplant.

Audience:

So what you are pointing to here is another distinction that people don't usually want to make. People like treating all of these professionals as being equally professional, and you are recognizing huge differences. We don't like making distinctions about money and we don't like making distinctions about expertise, but they are all relevant.