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Meeting Transcript
April 20, 2006

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WELCOME

CHAIRMAN PELLEGRINO: Welcome to the 24th meeting of the President's Council. We're delighted to have you here, and I want to welcome members of the public as well, particularly Rachel Fink from Mount Holyoke and her students. Welcome. It's good to have you with us.
I want to recognize officially the presence of Dr. Dan Davis, the Council’s Executive Director and the Designated Federal Officer. His presence gives us a legal standing of some kind. I'm not sure, Dan, just how secure it is, but —

DR. DAVIS: Rather flimsy, I'm sure, but —

CHAIRMAN PELLEGRINO: Well, it's good to have you here. Thank you very much.

I also have the great pleasure this morning to introduce two new members of the Council. In keeping with our customary approach, we do not give long and lengthy biographical recitations, but Dr. Bloom, Floyd Bloom, to my right is from California, and he's Professor Emeritus in the Molecular Integrative Neuroscience Department of the Scripps Research Institute and Chairman of Neurome, Incorporated.

I also want to welcome Dr. Nicholas Eberstadt on my left, of the District of Columbia, who holds the Henry Wendt Chair in Political Economy at the American Enterprise Institute.

Both of these gentlemen have, as you would anticipate, impressive curricula. They've contributed to their fields. We're delighted to have them with us. Their full resumes you will find on the Council's Website, and I urge you to look at them and to acquaint yourself with some of their accomplishments.

This morning we will be picking up a new topic for the Council. This afternoon and tomorrow we will move to a continuation of the discussion we've been having on children and children's research. This morning's sessions will focus on the discussion of organ procurement and transplantation.

SESSION 1: ORGAN PROCUREMENT AND TRANSPLANTATION

And our first speaker will be Robert Veatch, whose name will be known, I know, to many of you, a colleague and friend of mine, and again, we will keep our introduction extremely brief. So brief that I will give you only his present title: Kennedy Institute of Ethics and Department of Philosophy at Georgetown, as well, who has had a long and very distinguished experience in the field of organ donation.

Dr. Veatch.

DR. VEATCH: Thank you very much.

It's my assigned task to introduce and provide an overview of some of the ethical issues in organ transplantation. The subject of organ transplantation ethics divides very nicely into two major categories: the ethics of the allocation of organs and the ethics of procurement.

The allocation issues are relatively well settled today, and I will say very little about them, spending most of my time on the procurement topic. Legally and morally in the United States, when it comes to allocation, there is a formal commitment to simultaneously consider the moral duty of maximizing benefit from the organ system and allocating organs fairly.

The UNOS Ethics Committee, in fact, has adopted a position of requiring that these be given equal consideration.

There's one new controversy that's worth mentioning before we turn to the subject of procurement. Increasingly, the Web has begun to play a role in allocation issues. There are a number of Websites. I provide here in this slide the front page of one of these Websites called matchingdonors.com. It is a device where people needing organs are allowed to register and make their case for a donation. This is an example of such a site. A picture is provided together with a rather attractive slogan, "I want my dad back."

You can see in the text — sorry — starting down here, "I am writing this on behalf of my very dear father. It has been over three years on dialysis for my dad now."

Further down in the text, "my children in the picture want their Papa back."

You can see in the text, "ironically I have worked as a transplant nurse for over ten years and have helped hundreds of people of all ages get their life saving kidney transplant."
The issue raised by this kind of a site is whether the private communication, a Wild West of the Web, makes organ procurement unseemly. I must say because my name is somehow associated with transplant, I was solicited by this Website wanting to know if I would like to advertise for patients for me to do transplants on patients on this site.

I indicated that since I'm not a surgeon I probably should not advertise for patients in the way they suggested. This, combined with the fees involved, raises questions about whether these Website are distorting the allocation process.

If you ask the question how does one obtain organs, through this Website, we're either getting altruistic, nondirected stranger donations that already would have occurred, and they're being diverted to the people who can make their best case, or what may turn out to be more likely, we're recruiting new donors who had not otherwise considered donating to strangers.

There are issues here of whether the fair allocation system is being circumvented. Notice that it was a transplant nurse who had the savvy, the knowledge of this site to make the pitch. It takes someone with knowledge of computers and Websites, as well as the funds to make this kind of appeal.

UNOS has said that it will not explicitly oppose this kind of recruitment. I think the question is whether the government ought to be concerned about the distortion of the allocation formula as a result of these devices.

The allocation formula is a very sophisticated, well worked out device that considers many complex factors, and this may end up short circuiting some of that allocation commitment.

Let me turn to organ procurement where, as I’ve said, I think most of the action will be with regard to the ethics of transplant. The story is rather well know. We have seen over the last ten or 15 years a nice, slow, steady increase in the number of donors that we have obtained annually.

We have, however, seen a dramatic rise in the listing of persons for organs, and it’s clear that the situation is getting worse and worse. The result is a steady increase in waiting time so that now the mean waiting time is up around 1,100 days.

The implications of all of this is that in the last decade, 59,000 Americans have died waiting on the waiting list for an organ transplant. At the same time, there are approximately 60,000 cases where there has been a potentially medically suitable donor that has been lost through failure to obtain the consent and obtain the organs in a timely fashion.

So that even at the rate of one organ per donor, we would have been able to provide transplants for those 59,000. Not all of them obviously would have survived with a transplant, but we're talking about a substantial number of people who are dying for lack of a organ.

To make the story more complicated, many people have no principled objection to having their organs procured following their death, but they’ve simply never made the commitment. It's a hard subject to think about, and many people don’t even write economic wills. This is not a high priority for many people.

So that we've got a situation where many lives are hanging in the balance, and yet there is no strong motivating force to get people to donate.

Furthermore, if someone dies and is a suitable donor, if that individual has not expressed a commitment to donation, there is a resistance among the family for making the commitment to donate the organ.

Realizing that the situation is getting progressively worse, there is increasing attention to what I think here in the Washington area it's appropriate to use the local jargon. So I will refer to it as the “nuclear option.” The nuclear option would be to abandon the donation model that our country has been committed to since the 1980s and go to something that is sometimes boldly called "organ conscription." That's the language that Aaron Spital, a well known physician in the field of transplant is using.

It's really just the old organ salvaging scheme in the late 1960s and early '70s. We talked about routine salvaging of organs. That is a policy where organs would be routinely procured unless someone registered an objection.

Now, there’s an empirical debate still about whether this would increase the organ supply. There’s some reason to fear that routine salvaging would produce a backlash and some people would refuse
to donate who otherwise might be willing to, but I think it’s plausible based on experience in other countries that a conscription model would, in fact, increase the supply.

The moral issue is whether we as a nation are ready morally to abandon the individualism that has characterized this country. There are basically two ways you can think about the relationship of the individual and the state, and some nations have chosen to view the individual as a source of organs unless an objection is registered.

In general, the Catholic countries of Southern Europe, the socialist Scandinavian countries, and some Asian countries have gone to a model that legally authorizes procurement without an explicit consent, usually with an opt out provision for those to register their objection if they strongly object.

The alternative is the donation model, which is adopted in the Anglo-Saxon countries of Germany, the Netherlands, Great Britain, the United States, Canada, where we would require some explicit donation.

Now, we should recognize that in the U.S. we’re not entirely committed to the priority of the individual. We have military conscription, and in an area closer to what we’re talking about, we have laws that authorize medical examiner autopsy without the consent of the deceased or the family.

So with good reason, we have considered a kind of conscription model, but we’re very hesitant to abandon the language of donation. I am struck by the fact that presumed consent is the euphemism that is often used for conscription. I’m open to moral discussion about conscription. I think countries that have adopted it are acting in good faith, and they’re not absolutely outlandish policies.

I’m militantly opposed to taking conscription and applying the euphemism that there is a presumed consent. The fact of the matter is empirically we know about half the population would not consent if asked. That’s true in countries around the world.

To claim you can presume consent when we have empirical evidence that a substantial number of people would not consent is at best a euphemism and at worse it’s a conscious effort to try to hold onto the consent in donation model when, in fact, there is no consent and no basis for assuming consent.

In fact, no country in the world actually has a presumed consent law, and if you’re going to talk about this in any further report, I would urge you to carefully distinguish between presuming consent and simply biting the bullet and saying we’re going to have a conscription policy.

Let me raise for you six less drastic options before we contemplate the nuclear option. I raise these because I think they are issues of current discussion or might force us to begin thinking about some future alternatives that have not yet hit the agenda.

I’ll say a word about required response, organ priority, market experiments, living donor exchanges, what I call the tainted organs problem, and finally, the most controversial, challenging the dead donor rule. Let me comment about each of these.

The first of the three that I list here potentially could double the number of organs. They are all models that would stimulate people to think about donation, and if they’re willing to donate, to actually make the commitment.

Realistically we could go from roughly 50 percent authorization rates for procurement, I suspect, up to about 75 percent by simply developing mechanisms to encourage people who are in principle willing to donate to make the commitment and do so without an undue inducement.

The last three options on this list could produce substantially more organs, somewhere between roughly a 200 percent and a 400 percent increase, and may even approach the number of organs that we need to stabilize the waiting list or even reduce it. The question is how far can we work our way down this list without ethical offense.

Let me say a word first about required response or mandated choice. We now have laws that require requests of families for potential donors. A hospital is legally obliged to make the request for a donation.

We’re also seen the beginning of the emergency of state level registries often related to Department of Motor Vehicles driver’s license applications. What is being discussed and I think is worthy of consideration is going one step further and actually requiring a response to the donation question, not requiring that people donate, but simply saying this is a critical life saving decision and morally
you are obliged to think about the problem to the point that you make a choice either in favor or
against donation. A wise strategy would present a third option so someone could say they don’t
know what their decision is, in which case we would default to familial decisions.

The Department of Motor Vehicles' mechanism is, I think, a particularly bad way of developing these
registries. There are 50 potential states so that it’s all decentralized. I do almost all of my driving in
the State of Virginia, but I’m not a legal resident of Virginia, and when I tried to register for the
Virginia registry, I was told they didn’t want my organs because I was not a legal resident of Virginia,
even though when I have my accident I will almost certainly end up in a Virginia hospital.

Furthermore, the interaction with the Department of Motor Vehicles is mercifully infrequent. It’s
only every five or seven years. So it doesn’t give you an opportunity to change your mind.

Most critically, from my experience, many of the employees of the Department of Motor Vehicle may
not be properly motivated to initiate a conversation about the ethics of organ procurement. So I
think that’s a bad idea.

I would prefer some national registry so that everybody is in the same database. My personal
preference would be to attach a donation question to the income tax return. It would reach every
adult or almost every adult in the country. The IRS is pretty good at rules of confidentiality. They
could download the responses, ship them to UNOS, and we’d have a national database that’s
renewed every year. So that would be my personal preference, but some national database seems
critical.

I think the Council ought to endorse a national registry.

Let me move on to item number two, organ priority. There are various strategies for rewarding
those who have donated by giving bonus points should those who have donated at some point need
an organ themselves.

We already have bonus points for those who are living donors of kidneys. So the legal issue have
been settled. This is not an undue inducement. It’s not valuable consideration that is prohibited by
law. I would like to see us explore ways of giving a small token, a bonus point or two for anyone who
has signed a donor cards and had that donor card for, say, two years. That would avoid people
signing the card just at the point they find out they need an organ for transplant.

I would also like to explore, although it raises some complex technical issues, whether we could give
bonus points to family members who donate their loved one's organs after the loved one is
deceased. I think the Council ought to endorse in principle the notion of bonus points and explore
ways that the model can be expanded.

The third possibility is to begin experiments in market mechanisms. We’ve got this terrible problem
of a lot of people who in principle are willing to donate, but they just have never made the donation
decision. They haven’t taken the time to think about it.

There are market mechanisms that have been on the table for many years. They have never been
taken terribly seriously until recently. As those two curves between donation and listing get further
and further apart, there are more serious proposals.

Now, there have always been those on the libertarian side who have thought markets are perfectly
legitimate. They’re a reasonable way of increasing the supply of organs. The resistance has always
come from those who I would describe as being on the left who are concerned that any market, any
payment for any step in the process, whether it’s donation or actually providing the organ, will
discriminate against the poor.

The concern for the poor is that offering financial incentives would be coercive. I’m pretty sure that
coercion is not the right term. Coercion is, if you talk to philosophers, a term for forcible removal of
options.

What we have here is the complex problem of the ethics of irresistible offers. Offering large financial
incentives to provide organs might turn out to be irresistible in some cases, particularly for the poor.

Now, the ethical problem for the Council to deliberate on is whether an irresistible offer is always
immoral. It’s pretty clear to me that it’s not always immoral. I consider the invitation to be with you
this morning an irresistible offer. It seemed like a wonderful opportunity, and quite frankly, I
couldn’t turn it down, and yet I don’t consider any of you immoral for having made the offer to me.
The real problem with irresistible offers is exploitation. Exploitation involves a rather complicated set of issues, and the Council may want to spend some time deliberating on exactly what constitutes unethical exploitation.

The exploiter needs to be able to offer some other options in order to exploit the one to whom an offer is made, but if a kidney or a heart surgeon offers a heart transplant to a patient telling the patient the alternative is death, that would strike me as for many people an irresistible offer, and yet a morally legitimate offer precisely because the surgeon has no alternative to offer to that individual.

The problem with financial incentives, if they come from the government, is that the government does have an alternative. It could have adopted a decent minimum wage or compensation so that no one is so deprived of the basic necessities that they find such an offer irresistible.

In 1983, I testified in Congress saying I opposed markets at the time because of the irresistible offer problem. I said if in 20 years or so we have not developed ways of responding to the basic needs of the poorest of our citizens we should revisit this question.

True to my word, I did revisit it 20 years later, and I’ve come reluctantly to the conclusion that it’s time that we begin experimenting with very limited market mechanisms to encourage people to get over the resistance of thinking about this question.

Now, I’ve covered the three topics that I think are relatively noncontroversial and worthy of the Council’s attention. Let me turn to three more in the time that remains that I think are more complex questions and maybe questions you have not thought about.

There are many people needing a kidney who have a willing living donor. Some of those willing living donors turn out to be incompatible with their planned recipient. So they are unable to make a living donation, and the recipient has to go on the waiting list and wait five years for an organ.

Some of these incompatibilities are A-B-O blood incompatibilities. Some of them are positive antigen cross-matches. There may be other reasons such as size.

If there is a blood group O potential family donor with a blood group O recipient, the blood group is not a problem. There may still be a positive cross-match. We could conclude that that’s an incompatibility and this recipient has to go on the cadaver waiting list.

But as an alternative, we could have this O donor donate to the cadaver donor pool and in the process move the recipient up to get the next negative cross-match blood group O deceased donor.

This turns out to be ethically relatively noncontroversial. It is a policy we’ve adopted here in the Washington area and in a number of other jurisdictions. So the idea of living donor-cadaver exchanges is something that is very much on the agenda today.

Let’s move to the next problem, however. There may be a family member willing to donate who is an A or a B or an AB blood type and their recipient is an O. That is an incompatible donation, and we could, following the model I just described, have this AB or A or B donor donate to the cadaver pool and in exchange for that, the next O blood group patient who donates to the cadaver pool — sorry — would then have that organ go to this original recipient who is O.

This presents an interesting ethical problem. This kind of an exchange has the effect of taking this person off the cadaver list and producing one more living donor transplant. So the effect is an overall shortening of the waiting list. That’s a very nice thing.

The problem is every organ that comes into the list is non-O, and every organ that comes out of the list is an O organ. O candidates are among those who have the longest waiting times as we stand today. So it presents a classical Rawlsian fairness problem. Utilitarians would generally accept the harm to the Os on the list — they have to wait longer — in order to get the overall benefit of an overall shortening of the list.

Justice advocates, however, have adopted the view that this particular kind of an exchange is ethically unfair even though it is utility maximizing because it discriminates against Os on the waiting list who are unable to bring a familial donor and make such an exchange.

Now, having confronted this, there has been discussion in the literature in the last year or so about ways to get around this injustice. One possibility would be to get the consent of the Os on the waiting list to wait a little longer for the good of the overall community.

Lainie Ross, a physician at the University of Chicago, and I have both pursued this question, and she
actually was part of a group that did an empirical study that founded 59 percent of the people on the waiting list would have been willing to wait a bit longer, but 59 percent is really not sufficient to justify the injustice to those who are already waiting the longest and would have to wait even longer.

The justification, if there is one, requires going back to our national commitment to balance utility and justice and explicitly make a commitment that we will have a slightly unjust allocation system in order to increase the number of donations.

I, as a way of proposing a temporary compromise, have urged the Washington Regional Transplant Consortium to cap the extra wait time for the Os on the list at 30 days predicted extra wait time.

But another alternative is to reduce the wait time for the O blood group by following a couple of strategies. One of them is to further some experiments in incompatible direct living donor exchange. There are groups, including at Johns Hopkins and in Japan, that are ignoring this block and are doing this exchange with some technological ways of attempting to protect the recipient from the blood incompatibility.

I doubt that that’s going to develop until we develop more technology to overcome that incompatibility. The strategy that I think is interesting is something I call a voluntary paired donation. It was the subject of my editorial in the January American Journal of Transplant. We have many cases, by my calculation 1,300 cases a year in the United States, of an O donor family member who’s willing to donate with a non-O recipient.

Now, this is a straightforward compatible donation, and they take place every day in the United States. We never hear about them because this is blood compatible and presents no problem.

However, looking at it from a systems point of view, you could describe this as the squandering of the O organ. We’re putting an O organ, a valuable resource, into someone who doesn’t need an O organ. We could find another pair, the pair I talked about earlier, of a non-O donor with an O recipient and pair these two people up.

This second group, the second pair, is not compatible, but what we could do is get this O donor to voluntarily give his organ to this O recipient in exchange for which the non-O family donor would give to this organ and that produces one extra living donation per paired exchange. If there is a potential of 1,300 of these in the United States, that’s 1,300 people a year of O blood type who could be removed from the cadaveric wait list. The result would be two compatible transplants rather than one.

Now, people like Frank Delmonico will claim who as an O blood type donor would go through this when they could just give the organ to their spouse or their loved one. My suggestion is that there are advantages all around, and that rational people when they think about it will see the wisdom of this not only in terms of contributing to the community. That’s obvious.

It’s also obvious that this person gains because he gets a living organ rather than a cadaveric organ.

What may not be obvious is that this individual here can also gain. He can gain by getting a younger donor, a donor with better kidney function or a better HLA match. So it’s not just an appeal to the altruism of this pair. It may be in most of the cases of the 1,300 possible that we could arrange this scheme so that it is simultaneously in the interest of both of these recipients to be involved.

I think the Council should endorse UNOS development of this voluntary living donor matching program.

Let me move on to still another, the fifth of the schemes I wanted to mention to you, the scheme that falls under the general category of medically suitable expanded criteria. Some have suggested that there are many organs out there that are classified as medically unsuitable that, in fact, could be procured. Approximately three-fourths of all referrals to OPOs for potential donors are classified as medically unsuitable for one of two reasons. The donor is believed to have some infectious disease, some disease that might be transmitted or — and this is kind of embarrassing — it turns out the donor is not yet dead.

We get referrals for organ donation, and when our team goes in and looks at the donor, it turns out the donor isn’t brain dead, may be very close to being brain dead, but not brain dead. So in order to avoid embarrassing the physician who referred that patient, we use the euphemism of saying that donor is medically unsuitable. The reason he’s medically unsuitable is not that he’s unhealthy. It’s that he’s not dead yet, and we have a policy called the dead donor rule that we don’t take organs from donors who are not deceased.
For example, we get referrals of patients who have high risk lifestyles, IV drug users or gay lifestyle persons, and historically we rejected those donors right off the top on the grounds that even if they test negative for HIV, they may not have seroconverted and there is a risk of transmission.

Now, the risk is very small, but it’s real. We have begun asking the question of those on the waiting list: if such a potential donor became available, would you be willing to take that risk and get an organ now rather than waiting until your turn comes up for an organ without this risk?

Now, some people on the waiting list are near death. So, in effect, the choice being presented is would you rather die or receive an organ that tests negative, but poses some HIV risk?

Surgeons don’t like to think these thoughts because it runs some risk of putting HIV into a patient without HIV, but we are now coding the waiting list so that people who are willing to consider such organs would have an opportunity to do so.

To stretch your thinking, consider that we get an organ that tests positive from a deceased potential donor. We by policy have HIV positive persons on the wait list for transplant. Could we even take the next step of offering a known HIV positive organ to an HIV positive recipient, explaining that there’s a risk of transmitting maybe a different strain of the virus and so forth, but could we make that offer recognizing people would have the right to decline if they didn’t want it.

And if you followed that step in this progression, think of the case of an HIV negative person on the wait list in liver failure, Status I, has a week to live, isn’t getting an organ. Do we dare ask the question of whether that person would be willing to take the HIV positive organ, perfused as well as possible, but clearly not being able to establish that it’s HIV free, and put that intentionally into a near death HIV negative recipient?

I think the Council should endorse coding of the wait list so that we have an indication of which of these tainted organs persons are willing to accept.

It turns out to be a problem not just for kidney or not just for livers and hearts, but for kidneys as well. We’re increasingly realizing that kidney transplant is a lifesaving intervention. The deaths per thousand for patients on the wait list you can see is about 50 percent higher than for persons getting a transplant. So even for kidney this is a potentially lifesaving intervention.

I have one last suggestion. If this isn’t controversial enough to stimulate discussion among the Council, let me move to my sixth and final suggestion.

Many people, thousands of people each year, are medically unsuitable because the potential donor is not dead. Now, some of these people are candidates for a planned cardiac arrest. That is a decision to withdraw life support because the individual, even though he’s not dead, may be permanently comatose, and the person could become a donor after cardiac death. That’s being done here in Washington. Ten percent of our donors are donations after planned cardiac death.

The more controversial and interesting problem is whether we as a nation should consider donation without brain death or cardiac death, that is, people who are legally today alive. To use another language, can we make exceptions to the dead donor rule?

In particular, there is beginning to be active discussion about procuring organs from those who are permanently comatose or permanently vegetative, but not legally dead by whole brain criteria.

Now, it turns out that there are two different strategies one might use. One might keep the existing definition of death and legislate exceptions to the dead donor rule, saying that you can't procure an organ from somebody unless they're dead, unless they are permanently comatose or permanently vegetative, and of course have consented to the procurement in advance.

Only explicit donors would have their organs procured under this scheme. That’s one possibility. The other possibility is to further amend the definition of death to move to what’s called a higher brain definition that would call people dead in our nation who have not literally lost every function of the entire brain.

As far as I know, no commentators have today that are commenting on death today really literally believe in a whole brain definition of death. It means every last function, every reflex through the brain stem has to be gone before death is pronounced.

If you read the literature, even the defenders of the present law acknowledge that there have to be exceptions for what one person has called an insignificant nest of cells.
So we could shift to a new definition of death that would classify some of these permanently
comatose persons as dead. In fact, a large group of scholars now in rejecting a whole brain
definition has either said go back to a cardiac definition and then write in some exceptions to the
dead donor rule or, alternatively, go to a higher brain definition where some of these patients would
be legally classified as dead.

The literature among the specialists in the field suggests that this is a plausible option, but would the
people, the ordinary citizen, accept it? Laura Siminoff, Stewart Youngner, and their group at Case
Western Reserve has recently conducted a study looking at the opinions of ordinary citizens in the
State of Ohio. The results are really quite provocative.

They studied 1,351 citizens, ordinary people through polling mechanisms. These are top flight,
sophisticated, empirical scientists. They presented three scenarios, pretesting to make sure that the
ordinary citizen understood the scenario, one involving whole brain dead persons, people legally
dead today in Ohio and every other state in the Union; a second scenario involving a permanently
comatose patient who is not legally brain dead; and a third scenario involving a permanent
vegetative state patient like Karen Quinlan or Terri Schiavo, who obviously is not legally dead today.

In their study they asked: would you consider each of these three patients dead? For the whole
brain case, 1,164 said they're dead. That's 86 percent. That more or less squares with our knowledge
that 10 or 15 percent of the population now have not bought brain-oriented death pronouncement.

However, what they also found was 57 percent considered the person in permanent coma to be dead,
and 34 percent considered the vegetative state person dead. Well, so far that more or less reflects
public opinion about brain death, with almost everybody accepting whole brain and lesser
percentages accepting these other options.

They then asked the question: would you procure organs from these three cases? And as you can
see, almost everybody who thinks the person is dead ends up favoring organ procurement. There are
a handful of people here who think the patient is dead but wouldn't favor procurement for whatever
religious or philosophical reasons, and this holds true right across. They're almost identical
responses.

Now, here is where it gets interesting. They then went to those who said these patients were alive
and asked even though they're alive, would you procure organs, and you see that there is another
group of people, ordinary citizens who don't have the sophisticated linguistic analysis to sort this
out. They say these people are alive, but it's okay to procure their organs.

Now, if you were to add those two groups together, you get in the case of brain death 93 percent who
say it's okay to procure organs. In the case of permanent coma, you get one way or another 74
percent who would procure organs, and even in the case of permanent vegetative state, you get 55
percent who would procure organs.

I suggest that it's time to consider the enormous lifesaving potential of opening the question about
going to a higher brain definition of death or, alternatively, making exceptions to the dead donor
rule.

The majority of ordinary citizens seem already to be in favor at least in the Midwestern State of Ohio.

Let me quickly summarize and I'll be done. Six schemes that I mentioned, each of which leads me to
make a recommendation to you folks. I think the Council should endorse a national registry. I think
the Council should endorse bonus points for those who have donated; should endorse limited
market experiments to sort out whether, in fact, this would get people over the resistance to being
willing to donate.

And finally, continuing the summary, I believe the Council should endorse UNOS development of a
living donor matching program, such as the one I described, particularly the one with the high
payoff, the voluntary exchange from familial O donors.

I think the Council should endorse coding of the wait list for willingness to accept organs posing
some level of disease risk, and you can talk about how far down that line you want to go with donors
that have either malignancies or viral infectious diseases.

And finally, the Council should initiate a study of organ procurement from those who would be dead
by higher brain definition of death, but are not dead under the current legal definition.

With that, let me stop and I look forward to any questions or discussion that might result.
Thank you very much.

(Applause.)

**CHAIRMAN PELLEGRINO:** Thank you very much, Dr. Veatch, for a very direct, clear, highly provocative presentation of the possibilities and the ethical issues that go with it. The full range, I suspect, has been presented before us with specific recommendations.

I now open up the subject for discussion by the members of the Council.

**DR. FOSTER:** Mr. Chairman, I'll ask the first question.

Dr. Veatch, in reading your paper — and maybe this is for the next session, and maybe it's covered in one of the six things — but I had anticipated that you would also address the issue that you've thought about of direct cash payments for the donation of organs. Now, if you think that's going to come up in the next session I'll hold the question, but if it's to the next session, then I would hope you would also add your comments at that point.

**DR. VEATCH:** Yes, my understanding is it will come up in the next session.

I've tried to adopt a very cautious, middle of the road approach. Historically I resisted all market mechanisms because of the risk of injustice. I think we've waited long enough. There are too many people dying. I think it's time to begin limited experiments with cash payments.

These would be cash payments either for donation after death, where payment would go to the estate of $1,000 or so, an enormous money saving proposition. So the money is not an issue. The issue is the ethics of that.

I think we're ready for a limited experiment, perhaps in a single state like Pennsylvania that has shown an inclination.

I'm willing to discuss cash payments in the matchingdonor.com kind of model for living donation of kidneys. Iran has adopted that policy and completely removed their waiting list for kidneys.

Now, our nation may not consider Iran as the model that we want to follow, but it's interesting to see what the result was at least in that culture and in some of the other cultures that have gone to cash payment.

I'm nervous about it. I think the way to go is very limited experiments before we decide whether it really has discriminatory effects.

**DR. FOSTER:** Well, I'll probably wait until the next thing, but I myself am rather skeptical that either any of these six things alone or combined can really do anything about the curves that are going on. I mean, if you really want to be serious about having people waiting for five years for a kidney, which is what it is in Dallas, and so forth, if you really want to do something about it, and if you consider premature death, which is not going to happen with people who have money and so forth, but for the poor it is right now.

I work in a hospital that takes care of the poor. We cannot get a liver transplant or a kidney transplant for many of our people who are new immigrants and so forth and so on. That to me is a radical problem about fairness and justice and so forth.

I'm not very interested in some of the concerns of justice that others have brought out in a minor way. I'm worried about people who every day have no hope of getting a kidney. It seems to me that one ought to be more radical in terms of the solution.

There's a lot of money made in this business. In Baylor Hospital, which is the biggest private hospital in Dallas, the most lucrative thing in the hospital is transplantation. I mean, these are huge amounts of money, and we're arguing about you use $1,000. I would say, you know, why not — I'm just talking about dead, you know — just enhancing the likelihood that a family to get the burial cost, let's say. Maybe it costs $10,000 to bury somebody. I don't know. It's so tiny that that would likely do something about it.

Now, I will save the rest of it, but as a person who works every day facing this problem, I'm not a transplant surgeon, you know. I mean, it just kills me to have people just die right in front of me that we could save because we can't get an organ. And I don't think that even 1,300 changing Os and so forth is going to do anything about it. I think we have to do something radical about it.
But I'll wait will the next issue to comment on that.

**DR. VEATCH:** My suggestion was that the combination of these six schemes has the potential of substantially changing that waiting list, but one of the six items is experiments with markets.

One last point. I’m uncomfortable trying to dress up cash payments by giving them a rationale like paying burial costs. If you follow through the logic if you pay the burial cost, the estate that normally pays the burial cost is that much larger, and it really amounts to a cash payment to the beneficiary of the estate.

I would prefer to call it that straight out rather than — there is a wonderful euphemism in the literature called rewarded gifting. We will not pay you for your organ, but if you give us an organ, we will reward you with cash.

I think that comes powerfully close to a market mechanism, and I would prefer to just say we're paying people for their organs.

**DR. FOSTER:** Let me just clarify my thoughts are not — I read your paper about that. I’m not interested in hiding this for anything. I’m saying you have to pay UNOS for these things. You know, they cost; you know, different places of the country you pay for these organs. I simply say we’re paying like everything else we do in the country for something at what it’s worth and just call it that. I'm not going to try to put it into a euphemism. I didn't imply that at all.

I'm just straight up saying this is a matter of solving a problem with money, and it will save money in the long run, apart from the humanitarian thing. So I didn't want to get confused about trying to — I’m not an ethicist. So I'm not trying to hide my thoughts there.

**CHAIRMAN PELLEGRINO:** I have Dr. Meilaender and then Dr. Eberstadt.

**DR. MEILAENDER:** I want to try to ask a couple of questions that sort of move behind where you began, if I could because I almost feel as if I were entering the discussion too far along for me at least to think it through. Because there just seem to be some issues that need sorting out that are kind of presupposed here.

For instance, a couple of times along the way you used language about encouraging people to overcome resistance to organ donation, but I need to know something more about the nature of the resistance in order to know whether I want to encourage them to overcome it or whether encouraging them to overcome it would be corrupting them in some way.

I mean if it’s just selfishment, that’s one kind of resistance, but there may be other harder to articulate sorts of resistance, and so I’d like just to hear you reflect just a little bit on that.

A second thing. You started with the nuclear option, as you called it, of conscription and then moved to some less drastic possibilities, but how exactly did you rank those lexically because several of the less drastic possibilities seemed more nuclear than conscription to me. Challenging the dead donor rule, for instance.

So I mean, I just don’t understand quite how that went.

And then third, and maybe most hard to reflect on and yet important, way back there somewhere underlying where you started are just questions about sort of what is an organ and what is a body and how are they related to each other, and is there some reason why organs shouldn’t be for sale, for instance? I mean, not everything is for sale. How do I know?

I think public offices should not be for sale, and if we try to explain that, we have to think about what it is and so froth. How do I know whether an organ is the sort of thing that should be for sale unless I think about kind of what it is in relation to a body?

Those are three examples of questions that seem to me sort of that come before where you started us, and I’d like to hear you just — and I know we don’t have a lot of time — but just say a little bit about them if you would.

**DR. VEATCH:** Yes. In some ways my response to your third point is tied up with my response to your first, your questions about my reference to encouraging overcoming of resistance.

Let me make a distinction between resistance to thinking about the question of donation and resistance to donating. I have enormous respect for someone who has thought through these issues and has decided that it’s not appropriate to donate. I’m more uncomfortable with the psychology of
someone who says, "Well, this is an unpleasant thought about my distant future or my death, and it’s just not something I want to think about right now."

I am committed to the view that each of us owes to our fellow members of the moral community at least enough to think about this question. So when I talk about encouraging overcoming of resistance, my main focus is on about the 25 percent or so of potential medically suitable organs from people who in principle don’t object to having their organs procured, but have never gone on record.

Lots of those organs are lost today because people have not thought about the question. I believe that we’re at a point where using small incentives like bonus points or even small payments to think about that question is not only morally legitimate, but morally imperative today, as long as we’re going to stay in the donation model.

If we go to the conscription model, then the problem goes away. I’m sufficiently committed to the donation model, the priority of the decision of the individual, that I don’t want to take organs unless there is a gift of the organ.

But at the same time I think there is a moral obligation on members of the moral community to have thought about this problem and come to some conclusion. The incentives that I have suggested are designed at least in part not to buy the organs but to stimulate people to think about whether they’re willing to make the donation.

I suggested that conscription was the nuclear option in large part because I think it requires the most fundamental decision about the nature of the relation of the individual to the society, and going to conscription or routine salvaging or what’s euphemistically called presumed consent requires a reversal of our traditional affirmation of the priority of the individual.

All of the six items I mention are less drastic in that sense, and some that sound most drastic, like procuring of tainted organs and changing the definition of death, I think are defensible on their own regardless of the implications for organ procurement.

I think people should have a right to choose to be alive with a tainted organ rather than dead without one. I think people should be allowed to choose a certain range of definitions of death based on their religious and philosophical belief systems. I’ve held that for 30 years, well before anybody ever thought about this definition of death issue in the context of organ procurement.

CHAIRMAN PELLEGRINO: I have four members of the Council who wish to comment, and it constrains me to make the comment also that the time is limited. So if you can make it as concrete as possible it will be helpful.

I have Dr. Eberstadt and then Dr. Hurlbut, then Dr. Gomez-Lobo, and then Dr. McHugh.

DR. EBERSTADT: Professor Veatch, what I think will be a quick question about your own thinking on financial incentives and organ procurement, I read your very interesting paper, and if I understand it correctly, your own thinking has been moved towards reconsideration due in part or largely by your judgment about the condition of the poor in the United States and what you see as our government’s failure to deal with poverty in the U.S.

As it happens I’m doing a monograph right now on the poverty rate in the U.S., which I believe is an absolutely dreadful mismeasure of material poverty, and I try to make the case in this monograph that since 1983, when you testified before Congress, the material condition of the U.S. poor has actually dramatically increased in many different ways.

My monograph may or may not be convincing to any reader, but if we hypothesize that you were convinced by this set of arguments I made, would that be enough to make you reconsider your reconsideration of financial incentives?

DR. VEATCH: I’ve said all along that financial incentives per se are not the problem. The problem is developing financial incentives in a social context where some would be exploited because of their desperate poverty.

So if you tell me that you hypothesize this society where that dreadful level of poverty does not exist, where the exploitation would not occur because of that, then I’m much more open to financial payments than I otherwise would be.

I focus on this analysis. I assume libertarians have always been satisfied with market mechanisms.
The political problem with markets has been the resistance from the egalitarian left, and I’ve said I was part of that egalitarian left leaning portion of the population, but we’ve waited long enough with the number of lives that are at stake, and we ought to cautiously begin experimenting.

CHAIRMAN PELLEGRINO: Dr. Hurlbut.

DR. HURLBUT: Well, picking up on that theme from a different angle, reading your paper and especially in the phrase where you speak of the poor being allowed to market the one valuable commodity they possess, it struck me as raising some fundamental questions that maybe we get on the table first.

First of all, it did strike me that I teach in a university and many of my students feel very poor. So it raises an interesting question of who should be allowed to donate a kidney in the first place.

You mentioned that driver’s license is the moment, and they do that in California, too, where you can indicate a willingness to donate. They give licenses at 16. Is that too young for somebody to decide?

Let me give you a series of questions, and you can answer them all at once. Is that too young to decide?

I noticed in the picture that you gave us in the beginning Jackie Stupani and Mary Christiansen. If I understood it right, the younger woman donated to the older woman; is that right, in this picture?

DR. VEATCH: I’m not sure which.

DR. HURLBUT: The online thing where the 64 year old grandmother —

DR. VEATCH: I’m not sure what the answer is to your question.

DR. HURLBUT: Okay. Well, here’s the series of little questions. What’s the average age of death awaiting donation?

What’s the average age of a donor?

And what’s the estimated increase in life span after a donation?

And do you have a feeling for whether or not there’s an age where somebody shouldn’t donate? In other words, there are risks associated with donation. Let’s not ignore that fact, and there are idealisms involved that may be disproportionate, too. There are very positive idealisms obviously also, but the question is: is there something in the way of even just getting down to the equation here without the deep, deep questions that Gil was raising? Is there something a little sort of troubling about the idea of young people donating for old people, for example?

That’s the kind of category of question I want to address.

DR. VEATCH: I think we need to make a distinction between donation after death and living donation. For living donation, surely the consent has to be limited to competent adults, and there needs to be psychological work-up of the donor to make sure they’re competent. A 16 year old would not normally qualify for living donation.

For donation after death, the driver’s license checkoff, I am not uncomfortable with someone as young as 16 making that choice. We could adopt a policy that you can’t become an organ donor until you’re 18 or 21. By definition, the risks to the donor are not medical and direct. If there’s a risk to the donor at all, it is psychological and spiritual.

I’m quite comfortable with a 16 year old becoming a donor on a driver’s license. That doesn’t trouble me.

With regard to living donation, I am very hesitant to impose limits on bonded donors. By bonded donors, I mean someone with a preexisting relationship with the recipient like a spouse. It makes me very uncomfortable to envision, say, a spouse who knows that he or she has the lifesaving potential for dealing with a medical problem of a loved one and to have some review committee in the transplant world review the case and decide the donation is not acceptable because it’s too risky. I find that very troublesome.

I’m a member of the Living Donor Task Force and strongly oppose such limits.

DR. HURLBUT: Do you have the statistics for the questions that I asked about the average age and
DR. VEATCH: Those numbers are available. I don’t have them off the top of my head.

I don’t see difficulty with donors of too old an age once they qualify to be recipients of a transplant, certainly not in terms of cadaveric donation, but even in terms of living donation. Frankly, it doesn’t trouble me. I would be interested in hearing arguments to the contrary.

CHAIRMAN PELLEGRINO: I have Dr. Gómez-Lobo, and let me give the list please because the time is, again, going and I need to warn you about that. Dr. McHugh, Dr. Kass, and then Dr. Lawler. So that everyone may have a chance to comment, brevity would be most helpful as well as virtuous.

(Laughter.)

DR. GÓMEZ-LOBO: I’ll try to follow the path of virtue myself.

Let me go to the point that mostly worries me as a member of a Bioethics Council, as someone who is expected to give advice on ethics, and I think the most troubling part for me is the role of the empirical study in ethical thinking.

I have in front of me, of course, the results of the empirical study of the Ohio citizens. Now, what is the value of that for the Bioethics Council? The fact that people are willing to procure organs from people who they think are alive. Now, one way of viewing that would be to say, now, there’s a very serious corruption here in ethical thinking, if that’s what they think.

Now, what’s the solution for that? I really admire your willingness to go the frankness road and not call, say, rewarded gifting or compensated gifting “gifting.” I totally agree that one should call that purchasing and selling of organs.

But here we seem to face the idea of changing the definition of death. I would call it the criteria of death just to accommodate this possibility. Now, I find that, frankly, unacceptable. I think that the criteria for death should be independent of that and that there should be a moral decision affirming that we should never ever procure organs from people who are alive.

DR. VEATCH: I would agree that it is never acceptable to change a definition of death just to get organs. Leon will remember, I’m sure, Hans Jonas suggesting if that’s our strategy, why not define all college students as dead. We’d get much better organs and solve some other problems along the way.

(Laughter.)

DR. VEATCH: We can’t change the definition of death for that purpose. I tried to make clear that my starting point was that the present definition of death is incoherent as it stands, and there must be a philosophical correction, one that has been accepted for at least 30 or 40 years by a large number of theorists, including one of the leading moral theologians of the Vatican that endorsed a higher brain definition.

Once we have decided that there is a more philosophically defensible definition of death, the question then becomes, well, why don’t we adopt it and save some lives as a fringe benefit.

Typically the answer is, well, it’s a political problem. It won’t sell to the ordinary person. The sole reason I presented the Ohio data was to attempt to speak to the objection that even though higher brain definition of death is philosophically defensible, the ordinary citizen won’t accept it.

The result seems to be that many ordinary citizens don’t exactly grasp the difference between what it means to be dead and what it means to be alive. I, frankly, think I could take the people who indicated in the survey that they were willing to procure organs from the living and convince them that, in fact, the reason they believe they could procure the organs was they believe the person was already dead in the sense of having lost standing as a full member of the moral community.

So I use the survey merely to offset the claim that the philosophically defensible proposal is not politically feasible.

CHAIRMAN PELLEGRINO: Dr. McHugh.

DR. MCHUGH: Thank you, Dr. Veatch, for your presentation.

But I also have the same sense that Gil Meilaender has, that there are a very large number of themes
underlying this that relate to issues of resistance and religious matters of meaning in this process because we don't sell certain kinds of things to one another and don't make exchanges at that level.

But I have fundamentally a more simple question to ask of you and of all the people like myself who are involved in hospital care where we see that the clamor for organs is far exceeding its supply. And most of these solutions that are proposed, even the solutions you propose, I don't think are going to solve that problem.

Dan and I have been looking at the kidney business since 1955-56, when the first transplants were made, and have seen the wonderful achievements and progress in science in relationship to this thing that has happened over 50 years. It began with us with identical twins and now has come to the place where we're at.

Now, I'm not sure that I want right now — of course, for individuals I want them, the individuals I know and I appreciate my patients and the like, I would like them to get organs when they can, but at the same time, these statistics of showing this demand, it just says that the science has got to get better, and the science of xenotransplant, you know, the trajectory from the beginning at the Brigham with those twins to now, well, where are we with xenotransplantation? And shouldn't this pressure be the kind of pressure that we want to be presented, to acknowledge, and say more investment needs to come into xenotransplant because that's going to be the solution?

**DR. VEATCH:** Let me simply say I'm supportive of experiments in xenotransplant and immunosuppression as well.

**CHAIRMAN PELLEGRINO:** Dr. Kass.

**DR. KASS:** Since time is short I'll simply just register that I don't think the current criteria of brain death or whole brain death are incoherent. I think they can be defended; that there are people writing in the literature. It is too bad. Perhaps this Council could take up that subject and defend the understanding of death as the death of the organism as a whole, but you know I think that we differ. I have just been silent on the subject.

I'm more interested in — and this will perhaps be taken up more in the next session — your thoughts on the buying and selling and the market. You say in the paper that there really is — this is on page 14 — "There has never been any serious moral problem with permitting financial incentives to nudge middle and upper class people to think about their willingness to consent to organ procurement."

In other words, the issue for you has to do solely with the pressure that this places on the poor. Is it really true that if there were no poor we would have no concerns about becoming a society in which organs are bought and sold?

If that's your concern, why don't you simply say, look, only those people who pay income tax above a certain sort can enter into the business of buying and selling.

And, on the other hand, if you are now willing to experiment with markets involving the poor, why aren't you in favor of letting them get out there in the market and buy and sell to the highest bidder so that they actually make something from this?

In other words, isn't there really something disquieting about entering into a society in which parts of the body are treated as alienable things, like automobiles and other disposable goods. If that's not a question for you, I don't see why you don't find some solution compatible with your worries about the poor, either to let them get full advantage of their organs or just keep them out of the market so that they won't be exploited.

**DR. VEATCH:** Let me simply say that, indeed, I've been troubled by just those questions for a very long time. I believe what I've endorsed is incentives for thinking about donation. I'm more comfortable with incentives for thinking about donation than I am about incentives to actually providing the organs, but over the years I've been moved by the very serious problem of the number of people whose life and death hangs in the balance.

**CHAIRMAN PELLEGRINO:** Dr. Lawler.

**DR. LAWLER:** I think after listening to Dan I'm all in favor of more aggressive methods to acquire the organs of people who are dead in the noncontroversial sense of dead, but going further than that seems to me to be a huge problem.

The question Bill asks, I think you answered it too easily. A husband giving an organ to a wife, this is
an act of love. A daughter giving a kidney to a father creeps me out beyond belief for reasons Bill was trying to call to your attention, I think.

And then the Website creeped me out beyond belief for this reason. If you have a market, then you have to have advertising, and advertising means scaring up kidneys by having commercials like, "What are you doing at home sitting selfishly around with two kidneys? You don’t really need them."

(Laughter.)

Dr. Lawler: You know, “what kind of person are you?” It’s not so much the monetary thing that does bother — it does bother me. I’m not for it, but that in idealistic young people, 18, 19, we don’t have the draft anymore and they’re not going to conscript my organs, but I could volunteer my organs.

This seems to me to be quite unreasonable demand to put on people, right? And so when you create a market, you then have to stimulate demand and it requires a certain kind of advertising. In a way, although I would be very concerned about exploiting the necessity that governs the poor, I might even be more concerned about exploiting the idealism which governs the rich and pampered.

Dr. Veatch: I think those are all valid concerns. Let me simply note that in terms of volunteering organs, that’s presently legal today and is being done. So all the questions about the validity of the donation from a young person are already on the agenda and OPOs and procurement personnel have to screen nondirected donors to eliminate those who for one reason or another are not making an adequately competent donation.

Adding money to that mix doesn’t change that issue, although it raises the deeper kinds of concerns that Dr. Kass was trying to raise.

Chairman Pellegrino: Thank you very much.

We have reached the end of this first session. Let me point out that we have two more speakers on the same subject coming on at 10:45, and therefore beseech the Council to be back promptly on time because I intend to start promptly on time because I know you’ll want to have questions for the other speakers as well.

Thank you.

(Whereupon, the foregoing matter went off the record at 10:32 a.m. and went back on the record at 10:47 a.m.)

Session 2: Organ Procurement and Transplantation

Chairman Pellegrino: I think we will proceed, and let me begin with the first speaker for the next session, Dr. Richard Epstein, who is Director of the Law and Economics Program at the University of Chicago Law School.

Dr. Epstein, could you?

Dr. Epstein: How long do you want me to talk? How long?

Chairman Pellegrino: Half hour.

Dr. Epstein: Whatever you say.

Chairman Pellegrino: Well, I'll make it clear when it's over.

Dr. Epstein: Somehow or other I don't believe that we're —

Chairman Pellegrino: Did you jump to that conclusion?

Dr. Epstein: No, I think what I did is I understand this is a system with strong property rights in time, and what I will try to do is to respect it.

I should say in one sense I think having listened to many presentations on this subject, I'm proud to be an outsider to the so-called transplant community. I think I was brought here and I think rightly so to express a very deep and abiding skepticism. Everything that UNOS does, my modest policy recommendation is that the organization be forthwith abolished and we try to find some more sensible way in which to deal with organs, but rather than talk about it at that modest level, let me see if I can figure out a general way from an approach which involves a mixture of law, economics,
and yes, even moral philosophy to explain what my views are and how one ought to think about this question.

I think the first thing that one ought to do in trying to deal with any normative question is to ask yourself a couple of very simple, descriptive questions, and those are the kinds of questions which ask you how do we explain what the current situation is.

And when we're dealing with the organ situation, there's only one fact that seems to stand out above all others, and that is the chronic and irreducible shortage of available organs, particularly kidneys.

We know what the death rates turn out to be. Everybody is an expert on that. The explanation is why does such a situation come to arise, and I think the simplest way to put the explanation is just take the most naïve version of supply and demand, abstract out from every one of the special ethical and moral considerations that are associated with kidneys, have a negative sloping demand curve and a positive sloping supply curve, and then create a situation in which you place artificial restrictions on the price, in this case trying to restrict it to zero.

And the prediction is whether you're dealing with widgets or with organs, there will be systematic and massive shortages that will take place under these circumstances. Quite simply, you get very low supply at zero price and you get an immensely high demand, and the function of a price system in this kind of a universe is to try and figure out how you increase the supply, on the one hand, and reduce the demand, on the other, so that you get yourself into some sort of an equilibrium.

And the way in which people have tried to deal with this in many cases is to ignore this sort of blinding reality and to figure out other kinds of devices in which you could tweak things here or there in an effort to try and boost up the supply without trying to change the price, that is, to work on other kinds of terms. These could either be moral suasion, which easily turns into coercion. You could have public campaigns. You could have other kinds of disguised transactions like barter, which in fact clearly violate the UNOS guidelines, but everybody tolerates them because nobody wants to see more unnecessary deaths that take place.

There is a very elaborate understanding of the way in which when you have regulated prices people try to circumvent the rules, and so the first thing I would urge upon you when you start to think about this particular question is do not get yourselves into the illusion that there is something so unique and distinctive about the questions of organs or body parts or any form of transplantation that the general rules of economics do not apply with respect to this particular situation.

And that, I think, is the descriptive reality. The question then is how do we start doing this from a normative framework, and here the way in which Dr. Veatch put the point last time in the earlier session was, I think, rather misguided, but I think it represents the dominant thinking on this subject, which is to postulate that there is some kind of necessary and inevitable tension between the principles of the maximization of utility, on the one hand, and principles of justice and fairness, on the other, so that what we have to do is to constantly figure out ways in which we square the difference or overcome this thing. We're always working in a world of two values. We never know how much to weight them, and in the end what we do is we produce a giant form of stasis in which it turns out that the shortages cannot be eliminated.

Why is it that I think that this is wrong? Well, I think the deepest mistake that is made in talking about transplant as a conceptual matter is the regrettable confusion with compensation, on the one hand, and coercion, on the other. These two are treated almost as though they are synonymous, whereas in every other state of the world what happens is generally speaking compensation is, in fact, regarded as a way to make social improvements, on the one hand, without having a class of systematic losers, on the other.

If, in fact, you decide that every time you make a system with a compensation component in it that you've engaged in coercive activity, you make it impossible to have situations in which you can address imbalances that are created by natural circumstances through the imposition of this particular kind of transfer mechanism.

So let me, in order to make this a little bit clearer, sort of give one the definition that sort of an economic Kantian, to use that kind of a person, would take in the way in which you're trying to think about social welfare.

There are, in general, two kinds of definitions of social welfare that economists and, to a large extent, lawyers use. Let me mention them both here.

The first of these is something known as Pareto. A pareto efficient solution is essentially one where
you cannot make any person better off without making some other person worse off. More importantly, in a world of Pareto thinking, what you're always trying to do is to create a set of situations in which you move all people from one state of the world to a superior state of the world, in which somebody is better off and nobody is worse off, and indeed, ideally for the most part you would actually like the gains to be pro rata across all individuals to the extent that you're using state coercion to achieve that result.

In many cases, the only way in which you can create Pareto improvements is to allow allocative changes to take place and then to give cash compensations to the losers to offset what's going on. Indeed, most people when they start to talk about Pareto improvements as a criterion of social welfare are somewhat uneasy about using it in practical circumstances because what happens is that the condition is so restrictive that if you create a world in which one person is left the tiniest bit worse off and everybody else is made largely better off, you're going to veto the transaction because you have not had a condition of universal improvement.

So what happens is in many cases economists who are worried about this resort to another definition involving not actual but hypothetical compensation, and that's called Calder-Hicks efficiency, and what this means is that you have a situation where you can move from one state of the world to another state of the world, where, in fact, the gains to the winners are so large that you're confident that if compensation could be made, the winners could pay it. The losers would be happy to receive it, and the winners would still be better off than they were before.

So that what you do is you have a large allocative gain measured by subjective satisfactions, and the possibility of transfer payments, which are not realized because of practical impediments which would allow you to get to some kind of a parity.

And what I would suggest to you is in thinking about this subject, the one thing that you have to beware of in this vaunted business of ethics is a definition of coercion which is so large that it swamps up all efforts to use compensation mechanism to allow for allocative improvements, on the one hand, and a fair distribution of gains, on the other.

Let me give you one illustration from what was said earlier today about how it is that you can mess this thing up if you're not careful. We heard about something known as an irresistible offer, and then we were told it's nice to get irresistible offers. They're called recruitments.

Why does it turn out that it is somehow or other a form of coercion in some cases and a form of benefits in the other? I have to say I don't get it, and let me explain to you why it is that when you put this in the context of wealth and poverty, what is often seen as a dangerous and insidious tendency is, in fact, nothing of the sort.

If, in fact, you accept, which is I think commonly the case, that there is diminishing margin of utility of wealth, that is, the richer you get, the less money counts for you, and you hold out a constant sum of money to a rich person and a poor person, the rational response will be if you're worried about your own utility, is that a poor person should be more willing to sell, ceteris paribus, than a rich person precisely because the money has a greater change in his life than it does with somebody else.

And so, therefore, what you are calling in effect a kind of coercive situation that one ought to deplore really should be understood as an effort of the state to clamp down on a set of opportunities which should, in fact, be encouraged. Unless you think that these individuals are incapable of making their own judgments, at which point you would not allow them to make donations anymore than you would allow them to make sales, what people are identifying as a problem is, in fact, a benefit, and the reason why they are making the mistake is it turns out that they get themselves into a terrible pickle under these circumstances because they assume that any kind of a transfer payment involved, not as an economist would think of it, as a way of equalizing gains, but rather turns out to be something insidious and to be blocked in itself.

And it's this fundamental moral framework which leads, I think, to the prohibitions that one sees under the UNOS setting and which creates such incredible dangers in the overall operation of the system.

Now, thus far I've been talking about exchanges and talking about this in a sense of trying to figure out how everybody can act in a self-interested fashion in order to improve their lot through a series of voluntary transactions.

There is, however, another problem here which I think is extremely important, and one has to figure out how to model that as well. And quite simply the question is: what does one make of the idea of altruism when it comes to dealing with various kinds of human transactions?
And looking at this, there is a great tendency in the world, I think, to dichotomize the concept, and what I mean by that is we start to divide the world into people who are egotists, on the one hand, and who are altruists, on the other, and what we're constantly worried about is the mixes between these two classes of individuals.

It seems to me that that's a mistake in the way in which we want to think about the world. Generally it's much more accurate not to think about two pure ideal contrasting types. You're usually going to be safer to think about the situation where there is a continuism of egotism amongst individuals. There are some people who will be extraordinarily selfish. There will be some people who will be quite generous. There will be lots of people who will be in between.

And so then the question is once you understand that, how do you try to model altruism in a way that does not make it into a radically discontinuous state from the various sorts of egotistical behavior; and in dealing with this in the particular paper that I wrote especially for this occasion, what I did is I gave a very simple model. For those of you who want it on the papers, I think on page 11, and you can look at the graph to see the way in which one ought to think about it, and here's the way you look at it.

Generally speaking, in a world of egotism, what you will assume is that nobody will make any transaction which results in a net cost to him or to herself. Those things are essentially not going to be acceptable because the theory of rational choice on a radically individualistic model is unless the expected utility after a transaction nettable risk is positive, you don't enter into it.

But what I think, in effect, is that that is clearly wrong. Even if you look at the current lamentable state with the shortages in question, if you use the rational choice model, you would come up with the observation that in a world that exists without any financial compensation, the number of anticipated transactions is zero. You would be basically at the origin. Nothing would start to move.

And yet it is incontrovertible that there is at least some positive response. So how do you try and model that without giving up all of the sensible stuff about equilibrium theory that results when you're talking about the usual equation of supply and demand?

And the simple response, I think, to this, which actually I have not been able to find anywhere in the literature, although I'm not a full-time professional economist, is to simply take the supply curve and make sure that it intercepts the X axis at a positive point, and then in effect have it continue to go down so that the supply will diminish until at the point where the cost to the individual donor is so large that even the altruist will start to give up under the transaction.

At this point, what you can then do with respect to the situation is to figure out what the equilibrium conditions are going to be on price, on the one hand, on quantity, on the other, even if you now make no other deviation from the usual neoclassical solutions.

That is, what you say, in effect, is that when you're dealing with altruists, if you give them a little bit of compensation, there will be a few more altruists who will come in there, and it turns out that when you cross the X axis, it's not as though the world is a discontinuous place. What will happen is that the altruism will continue to show its effect because the supply curve will be systematically lower and to the right than will the curve be if you've got pure egotism.

Once you do that and you assume a constancy with respect to demand and you then look at the equilibrium in the two cases, the following observation takes place. Altruism continues to have desirable social consequences. We don't know its size or its extent because in equilibrium you will find that there will be a larger number of organs or, indeed, any other good that will be transferred, and they will be transferred at a positive price, which is lower than would take place if, in fact, you had the pure egotistical equilibrium involved.

So that what happens is if you look at this, there is no particular reason to think if you have altruism that somehow or other the use of a market mechanism is going to destroy the operation in hand.

And here let me point out, which I think is a very important constant confusion and error which takes place in this literature which states Richard Titmuss, in his arguments, associated with blood supply, and the usual argument in these circumstances that we cannot allow cash transfer payments to take place because what it will do is it will crowd out the altruists.

Now, what you want to do is to look at those two curves and understand what is meant and not meant when you start to deal with the problem of crowding out under these circumstances. And here the same situation is if you just look at the standard conventional curve in which it turns out
that the supply at zero is zero and watch that thing go up, every time you raise the price what you
will do is increase the consumer surplus for those people who would supply it at a lower price.

So, in other words, in an ordinary market the moment you raise the price to ten, what you do is you
eliminate all of those people who would have supplied the good at five, and you can argue that that's
some kind of a crowding out because it increases cost, but the central feature in figuring out the
social welfare consequences of this kind of rule is not the size of the transfer payment. It's the
question of the total consumer and producer surplus that is generated by the transaction.

In other words, if you're thinking about the money going back and forth between parties, the right
way to understand it is as follows. First you assume that the increased prices is a loss to the person
who pays it, and then you assume that it is a gain to the person who receives it.

As a general matter, the utility of money is as a first approximation about the same in both hands.
So you can't figure out that there's any gain or loss from the transfer.

On the other hand, what you do is you push yourself back into equilibrium, and then afterwards if
you look at the equilibrium situation and work out the gains to consumers and producers, it will be
higher if, in fact, the transfer payments are made than not.

And exactly the same argument applies when you're dealing with the other supply curve, which
crosses the X axis at a positive point. You raise the price. The equilibrium will be different by virtue
of the altruism, but there's no crowding out that's taking place. There is simply the payment of a
transfer which doesn't have social consequences plus or minus one way or another, in exchange for
which we get a vast increase in the total supply, which allows us to bring this particular market back
into equilibrium.

So I think that the clear lesson that one learns from all of this stuff is as follows. There is, in fact, no
particular reason to create any rules that are distinctive to altruists relative to people who are
egotists. The same method of voluntary exchange will work whether you're dealing with one class of
the population or with the other. It is an empirical question as to how much altruism there is, and
the way in which you can understand that by looking at the graph is to just ask yourself: are you
somebody who believes that everybody is selfish, at which point that gap is very narrow, or do you
think in the general benevolence of humankind that the gap is very large?

Frankly, my dear, for the purposes of social policy, I don't give a damn which way it comes out
because the same intellectual solution applies in both cases. You're going to get to equilibrium.

If you're asking me as a philosopher king which I'd rather have, generally speaking, I prefer a world
with a little bit of altruism because you will get a lower price and a large supply of organs, and on
balance, you will have some degree of reduction with respect to human suffering.

Now, when we take all of this stuff, let's just look in the framework of the current system at several of
the problems that we're having to deal with to see how it is that we ought to think about them. Mr.
Veatch earlier in the day started to talk about the question of how it is you start to deal with organ
swaps and those cases when voluntary donations create the risk of incompatible transfers.

And so what happens is that taking the most dramatic situation, I'm A, my spouse is B, somebody
else has got the reverse situation, and what we do is we want to flip them over to get two transactions
instead of having none.

I think the first thing that one has to understand is that if anybody is serious about those wretched
definitions of what counts as valuable considerations in the statute, this is an illegal transaction. You
go back to Roman law. Transformations in barter have always been regarded as exchanges. They've
always been treated as such under the law. The thought that this is not valuable consideration is
simply a joke to anybody who's serious about what those words mean.

You cannot get a competent lawyer who will look at this stuff who would not say it's anything other
than an outright evasion of the statute, for which I say amen and thank you because it's about time
that we started to find some ways to get around it.

The more difficult cases are, it turns out, where you have the O-A kinds of oppositions, where you get
one person who, in effect, will make an A donation in exchange for having a spouse receive an O
donation off the cadaver list.

And here what I want to say is, in effect, if you're thinking about this in terms of the general
economic theory, you've got to understand, first of all, what the gains and the losses were. Mr.
Veatch was wrong when he said, in effect, that this is systematically a loss with respect to everybody on the O list.

And the reason why that is incorrect is you cannot simply look at the fact that it pushes people down by virtue of somebody getting up. That is, indeed, a minus. But if you're doing the whole thing systematically, you also have to take into account that everybody regardless of their place on the list has a positive probability of procuring one of these matches, and the right comparison is to ask whether or not that chance minus the delay is better than stasis, and almost invariably if you’re going to increase output, it would be very hard to find a set of systematic losers when, in fact, the rules are perfectly general.

In addition, it seems to me that this model is wrong also if you take his view of the Rawlsian veils of ignorance, which is very easy to misapply and was done so in that case. And here I think that there are a couple ways in which you could start to look at this thing, and the simplest of them is this.

Let us suppose, in effect, you're playing risk analysis. Then the first thing you have to do is to say we're doing it before anybody knows whether they're an O or an A donee. You just don't know, or an A or an O donor.

And at that particular circumstances, if you go behind the veil, the big mistake that Rawls made with respect to his own theory is to assume that people behind the veil of ignorance would be extremely risk adverse and would only worry about the condition of the worst off.

In fact, virtually everyone behind the veil of ignorance, even if they had some degree of risk aversion, would certainly think much more in terms of social utility in an expected value sense rather than in terms of this extreme situation.

Indeed, I would argue that the version of Rawlsianism which says that you look only at the guy at the bottom of the list is a highly immoral kind of conception, because what you're saying is that one single individual gets to determine and dictate the social preference for thousands of individuals.

So that what you really want to do from behind the veil of ignorance is that you know if you're an A guy you live, whereas otherwise you die. If you're an O guy, it turns out you've got this complicated set of choices and you're not sure whether you're bad or worse off.

Nobody in their right mind under those circumstances would ever assume that if they didn't know whether they were O or A, that their anticipated social value would be better off by blocking these kinds of transactions.

And the second point, again, that one wants to make about all of this, if you have any moral ambiguity associated with the status on the O list, what you do is you handle that through the payment of direct compensation, and so you try to figure out what the utility loss is, and you give cash, even taxing the As to give it to the Os so as to make it into an ex post Pareto improvement.

Your last thing that you want to do under these circumstances is to result in this freezing, and so it goes right back to the basic intellectual mistake that I talked about at the beginning. If this group is going to endorse a definition of coercion that includes compensation, you are bound to have lots of people meet needless deaths because you will never be able to get yourself into an optimal form of equilibrium.

Now, the last point that I want to make — and I have about five minutes, right? I'm pretty precise on this — is to talk about how we think about directed donations in other situations. If you recall, when I started at the beginning of the session what I said was the moment you get yourself a major imbalance in supply and demand by putting a maximum zero price on anything, you're going to find all sorts of people who are going to engage in various efforts of circumvention.

And so don't think about organs. What I suggest you do is that you just look at the headline on USA Today, and it said that higher gas prices lead to lower demand. I mean, the people do respond to incentives one way or another. It's going to happen here.

And if you block the obvious thing, which is paying price, people are going to go to more costly ways in an effort to bridge for themselves in more egotistical ways that markets would otherwise have in an effort to get to the head, and that gets you to directed donations in one way or another.

And so what happens is people will start to advertise, and they will start to put themselves up on the Web as individuals, and they'll have their children, right, and all of these piteous and horrible things. And I say God bless them. They're doing exactly the right thing, and anyone who wants to
stop that is to my mind being quite monstrous from a moral point of view given the enormity of the  
harm that’s associated with this operation.

It turned out that Dr. Veatch said that this distorts the carefully allocated system that we have under  
UNOS, and my reaction is the quicker we blow it up the better we are going to be. There is nothing  
carefully wrought out about the UNOS situation. What they quickly discovered is taking into  
account subjective elements that mattered to everybody led to such a hopeless degree of  
disagreement amongst the various members of the committee that they didn’t want to talk about  
those things.

So what they do is they reduce themselves to a series of largely useless formal criteria which would  
allow them to avoid the moral ambiguity of collective choice.

The great advantage that you get from directed donations is you don’t have choices made by  
committees that are paralyzed by their fundamental moral disagreements. Every individual can look  
at every piece of subjective information they want and if it’s their kidney, they can decide who gets it  
and why.

In fact, one of the odd things about this entire discussion on morality is the very clear standard  
natural law tradition on giving was a theory of imperfect obligation, which says that people can —  
under a duty to give it’s not enforced by law, but they could pick whomever they want and for  
whatever reasons and give them whatever they want. Nobody else could ask the kind of question,  
and that’s exactly what’s going on with these directed donations.

What's the result going to be? Well, it turns out it's going to improve things in my mind fairly  
powerfully on the recipient's side. One of the things that you get with these wretched UNOS criteria  
is that you can’t take the subjective stuff into account. You wait until people are so long in the tooth  
and so injured that the useful lives that you get when people get to the top of the queue are much  
shorter than they would have been if you could have gotten people in the middle.

When people are making individual judgments with their own organ and they take this stuff  
seriously, what you’re going to do is substitute recipients which will have a longer life and a more  
useful life for people who have managed to endure to the top of the queue.

And if you then allow this thing to work, it will shorten the queues so even those people who remain  
on it will do somewhat better than before.

So it seems to me that what we really ought to do under these circumstances is to engage in a  
systematic effort to try and figure out how it is that we continue to use the Internet and similar  
devices to engage in a way in which we continue to expand the matching capability.

Or to put it in another way, what we have done, in effect, through the Internet is to figure out how it  
is that we reduce the cost of matching, which means, in effect, that we have a greater probability that  
the altruists will find themselves and to work in that direction.

And I'm going to be in favor of the situation with respect to anonymous donations, which become  
less anonymous when people got to know one another, and I think that perhaps the single most  
appalling, mindless, senseless, gratuitously cruel proposal that has been made is the one by Zink and  
her colleagues who said, "Well, we've got to ban all of this stuff because we want to force people back  
on the queue."

This poor woman does not know that it's not going to be a one-to-one ratio. In fact, probably if you  
knock out direct donations, 95 percent of the people will simply disappear at a guess.

And so what you're saying is that somebody's aesthetic view of a queue which has no particular  
moral validity, is so strong that you're willing to risk .95 lives every time you chase a donor away.

So let me, in effect, say and end in the following words. I think the organ debate has been utterly  
marred by a series of false forms of intellectual sophistication, ethical niceties, aesthetic  
reservations, moral intuitions. There are too many dead people out there.

I'm not quite sure whether you can solve it, but here is the last sort of example. I co-authored an  
article in which we were talking about this, which was rejected by JAMA. There were two referees'  
reports which showed the stupidity of that operation.

The first one says, you know, you start putting in all of these cash incentives. They're not going to  
make the slightest bit of difference. Elasticity turns out to be zero.
And the other referee’s report said, God, if you put in these cash incentives, everybody will jump to supply these all.

It’s what happens in this world. The problem about ethicists is either demand is perfectly elastic or perfectly inelastic. If you just think of things going up on a an angle, you will be so much more educated than beforehand, and the moment you do that, those graphs make sense and the referee's reports basically are the very strong recommendation for shutting down JAMA on all matters of social policy.

(Laughter.)

**DR. EPSTEIN:** The level of ignorance that is encapsulated in that operation is a public scandal, and frankly, my dear, I don't care.

Who wants to repeat this? It is a public disgrace that a journal of that eminence should be able to operate in that particular way.

Thank you.

(Applause.)

**CHAIRMAN PELLEGRINO:** Thank you very much, Professor Epstein. Very much grateful to you for observing the time limit as well as your provocative remarks.

Next we will hear from Dr. Delmonico. He is a Professor of Surgery at Harvard and someone who has to walk the walk and talk the talk every day, and we'll, therefore, hear from the bedside or I guess I would say the operating room bedside.

Dr. Delmonico.

**DR. DELMONICO:** Thank you, sir.

I think whatever slides that we're going to have, I think we'll have to just abandon all of that so that I can respond to what we've heard here this morning, and I'll be pleased to have those comments withheld until we're all finished.

I'm here to represent not just myself, but a number of organizations.

Can you hear that all right?

And those organizations would take umbrage and concern about what Mr. Epstein has just said. I'm the president of the United Network for Organ Sharing, and over the course of the last 20 years thousands and thousands of hours of volunteer effort by professional colleagues that Mr. Epstein associates with today and who are, in fact, leaders within that organization have given their time to make what can be an imperfect, but the best of what can be done at the moment in terms of organ distribution and allocation and public policy.

That public policy is not ignorant, and just because his paper from JAMA was rejected doesn’t make all of that work in disrepute. Mr. Epstein wants to serve those who could have a longer and more useful life. That's, in fact, what his comment was just now. I would suggest that he analyze the list.

The question about what is the average age of the person dying on the list is apt because it's not the young person dying on the list. We're talking about, as he put the main issue here, about kidneys. More than half of the list now is the older age population, and the sector of that list that is less than 50 years of age is, in fact, stable and could be resolved by the unprecedented increases of organ donors that we've had in the country since 2003.

That list is growing because of inadequate medical care, and it's not just solvable by buying organs, and the organizations that we're here today to represent, and I'm going to read their statements as we get to that, we'll make that amply clear.

And Mr. Epstein is going to have a big obligation. He's going to have to overturn the National Organ Transplant Act, and why I'm here as well is to say I wish him best wishes to do all of that, but we
have an expectation and we'll have a fight. We'll have a fight at Congress that has already been visited to say that that won't occur.

We're also here to ask of this august group not to overturn the NOTA, not to bring a regulated market of organ sales to this country and do so on behalf of international organizations and their testimony is before you this morning.

Now, we'll return to the regulated market in just a moment. I do wish to address some of the comments that Bob Veatch made. He would have us reconsider the definition of death. That is particularly disturbing to me as a transplant surgeon of 35 years, and mentioned that the current definition of brain death is incoherent and that a large group rejects the whole brain death definition.

I'm concerned about the representation of a large group because I know of no such large group, and I don't find the definition incoherent in this whole brain concept.

Whole brain means, for everyone in this room, not only the cerebrum, but the brain stem, and the brain stem controls our spontaneous respiration. What Professor Veatch was suggesting is that somebody could be dead and breathing spontaneously.

I don't think our society is going to accept that. They just plainly won't. Whether he's got maybe 1,000 individuals to speculate about this in Ohio or not, up to now the legal definition is such that if you're breathing spontaneously, you're still alive. There's something about breathing that is sort of indicative of life.

Now, let's just take that scenario of extending the whole brain death definition or making exceptions about that and then paying for organs. I would ask this Council to think about that scenario so that there's a 23 year old minority individual in the intensive care unit, and now the intensive care physician comes to the family and says there is an irreversible brain injury, but your family member, this 23 year old, is not brain dead. Any further treatment will be futile.

The current situation is that care can be withdrawn and it does occur, but think of where Professor Veatch was taking us. We're going to make an exception in this case. We're going to consider this an extended kind of death even though your family member is still breathing, and by the way we'll be pleased to pay you for this individual's organs.

Think of the skepticism of our society about the care of the individual to begin with. Now, just think about that.

I don't see that coming about as standard medical practice. I just don't, and I would hope that you would reject it.

Professor Veatch suggested the allocation problem is solved. It isn't, and what is the dilemma? The dilemma is the list that I talked to you about earlier and the expansion of that list from the older age population.

Now, the government is telling us, that is, the Division of Transplantation has brought before UNOS a prescription that we have to be contending with the net benefit of life achieved by a transplant. This utility factor now is very central in what our considerations are all about, and the life span of a kidney may far exceed what the life span of the individual that gets a kidney at 65 or 68 or 75 years of age.

So the allocation of kidneys now has to consider what net lifetime survival benefit might be realized by any given transplant.

The question that was raised about a young live person giving to an older age person is also apt because these ethical considerations when you're having donor and recipients before you are very much on one's mind as to what might be realized. How long will this older age individual live and what risk are we placing the younger person in giving such a kidney or part of their liver or a lobe of their lung?

So I would say to you that allocation isn't solved; that the net lifetime survival benefit is a priority before us; and we will have to consider that as we reckon with this expanding list of older age patients.

I want to make a comment about a solicitation. Professor Veatch said, well, this is a distortion of the allocation system. I don't think there was clear thinking there.
Solicitation for deceased donors, solicitation for deceased donors is fundamentally different than a solicitation that happens with matchingdonors.com for live donors. For deceased donors we, indeed, have an allocation system, and so if someone puts up a billboard in Texas as they did and overcomes what might be the most next medically urgent patient, that is a problem that I have with solicitation as from the UNOS system of allocation. And we can't allow that to occur.

And so last summer there were flyers, for example, in the New England area, New York area, from individuals soliciting for livers, and the conundrum we had was that this individual might be receiving a liver ahead of other individuals in the same intensive care unit who were of different gender, different ethnicity, and were ahead on the list. We had to sustain the list of allocation and not overcome that.

Solicitation for live donors is a different matter because it does not involve allocation. It becomes a directed donation, and there I can't regulate how relationships are formed. So the UNOS position on matchingdonors.com is a concern because of the finances that are entailed with it, but it is not something that UNOS is prepared to prohibit because I can't tell people how they may come to know of possibilities of live donors and regulate how they develop relationships.

The transplant centers bear an additional burden, however, of these donor recipient pairs that come along because they have to assess the motivation of the individual and the expectation of what will be derived as a result of their donation and what imposition that might be on the individual, the recipient's life thereafter.

And I hope soon to have a conference on this very topic to address those issues because there's an added burden of responsibility that comes along when these donor-recipient pairs come forward to a transplant center.

On the solicitation piece, however, the UNOS position is that we can be of help. We will not object or prohibit a solicitation, but at the same time, it isn't for UNOS or the government to say, "Uncle Sam wants you." This is, indeed, to be the vehicle of the solicitation because there are risks, and those risks have to be accepted in an altruistic way.

The risks of live donation for kidney are, yes, unusual, perhaps less than three percent of some kind of complication occurring, but as it pertains to other organs, the liver and the lung and now there are live donor pancreas and intestinal transplants. They carry a higher complication rate. The liver transplants, the death is one in 300. The complication rate is anywhere from 35 to 60 percent.

If you're going to pay for one organ, why is it that you wouldn't be paying for another?

Now, on a pair donation where Mr. Epstein feels that it is, indeed, valuable consideration, there are other attorneys in the country who don't think so. So it becomes a legal dispute, and the basis of that is to say that a paired donation remains a gift.

And it is a gift if it's done altruistically and simultaneously.

The valuable consideration clause was put in the 1984 National Organ Transplant Act principally to prohibit the sale of organs, and that is what has been sustained. Pair donations that are done with the acceptance of transplant centers, now many, New England and a variety of places, Baltimore, et cetera, they're done in the context that this is not a violation of the National Organ Transplant Act. No one has some notion that that's what is occurring here.

And the concept about valuable consideration is not taken that this kidney is anything else but a gift. I have some trouble with the way that Professor Veatch presented his proposal about voluntary paired donation because I think it's flawed by the premises of suggesting that one could have the better HLA match as an incentive to enter into the system that he proposes.

If you don't have an HLA identical match, any other HLA match today is not consequential to successful outcome, and so that, in fact, is what has propelled living unrelated donation in this country, about 30 percent of them. About 30 percent of them are indeed unrelated genetically, that is, they're either spouses or friends or anonymous.

I personally am very supportive of the paired donation system. I hope that UNOS will develop such a system, and there are these existing already as I mentioned in certain locations of the country. But I don't anticipate that the strategy that Professor Veatch proposed to you where an O donor having the knowledge of a recipient before them would enter into a system in which there is a lack of awareness about how the transplants would be occurring, et cetera, and that they would go into that system.
Just from a transplant surgeon perspective, the logistics of these paired donations are complicated. They're like a space shot, and when they're done, we even have to call the corresponding hospitals to know that the anesthesia is being administered simultaneously.

And the work-up, well, all right. Thank you, Mr. Epstein. I was very reserved in holding any remarks. So if you would be kind enough to do the same, sir.

It is, indeed, altruistic because they're giving simultaneously, but what I'm suggesting to you is it's complex, and it is not something to be taken, well, with an expectation that an O donor knowing the recipient will be readily available to come into such a system and have the expectation that they'll be happy to do so, I would suggest to you not.

Now, in my remaining time I wish to deal with what Mr. Epstein said: let's not have any illusion that economics don’t apply to body parts. Well, he’s just flat wrong. I don’t think it’s an illusion, and I’m going to suggest to him by the statements of the following organizations that he’ll have to contend with as Congress takes up this matter and as you do as well.

The United Network for Organ Sharing is opposed to a regulated market for organ sales, and the first, if I may bring to your attention of statements that is before you is from UNOS, and there is a series of them now before you as well.

And so that it is not Francis Delmonico per se who is before you, but all of these organizations knew of this presentation before this Commission and wanted to officially register its concern about any concept of a regulated market in this country and the impact that that would have on this country and transplantation practice and the practice of transplantation around the world.

So I would ask that you take these statements with some consequence because they've been derived for bringing to your attention the profound opposition of these organizations to a regulated market of organ sales.

So UNOS rejects it as a means of increasing the supply for organs for transplantation as not being ethically justifiable. It would diminish the respect of persons resulting from making body parts a commodity. That’s no illusion.

And the concern is captured in the ethical principle of respect for persons. There would be a diminished voluntariness of consent. This concern is expressed by the principle of autonomy. There would be a diminished emotional support for families. This concern is expressed by the principle of visits (phonetic).

Now, I want you to also know that we’re not opposed for removing financial disincentives from an individual to be an organ donor. So to the extent of a reimbursement of expenses, I don’t see that as a problem, and I think it is something that could be certainly considered as proper, and so it says so.

The American Society of Transplant Surgeons is opposed to a regulated market of organ sales. That’s not an illusion. That’s a reality that Congress and I would hope that this Commission would contend with. The surgeons are opposed to a regulated market of organ sales.

And Dr. Cosimi wrote to me to bring to your attention this opposition, and it was restated recently. "The ASTS believes that living and deceased organ donation represent altruistic acts. The ASTS has consistently been strongly opposed to the buying, selling, and brokering of organs for transplantation in agreement with the NOTA, which makes it illegal to exchange organs for valuable consideration. The ASTS reaffirms that position."

The next is a statement from the National Catholic Bioethics Center and Jon Haas. "Pope John Paul has stated acts of selfless love are most solemn celebrations of the gospel of life and a particularly praiseworthy example of such love is the donation of organs performed in an ethically acceptable manner with a view to offering a chance of health and even life itself to the sick who sometimes have no other hope.

"The National Catholic Bioethics Center strongly opposes any regulated market of organ sales. Such a scheme would harm the charitable nature of organ donation and substitute in its place a market for buying and selling of human body parts. It is not a matter of just economics. We can't equate widgets with organs just from an economic perspective.

"The human body is not a commodity, but a gift which God has given us limited stewardship." Now, I’m quoting this. "Furthermore, to turn the body and its organs into commodities places at great risk those who are poor and vulnerable by making them susceptible to the allure of monetary gain from a
surgical procedure which in no way benefits them medically."

If we had a regulated market in this country, what would be to stop immigrants from wanting to come to this country to sell their organs? How would that be justified?

And what impact would that have on the rest of the world in which illegal black market practices are occurring? The World Health Organization is very concerned about that, and they have a statement as well here. I've been with them in Manila and Karachi and South Africa. One of the slides that I would have put up, but I can show you if you would just refer to page 1, it talks about kidney trafficking.

A woman in Brooklyn who goes to South Africa and the vendor comes from Brazil and it is brokered by an individual from the Middle East.

A regulated market in this country would set that kind of practice into acceptability.

The National Kidney Foundation opposes a regulated market for organ sales, and the statement is there before you. Congress has appropriately refused to revise, nor to initiate demonstration projects for payment of organs. Many Americans are not inclined to be organ donors because of their distrust of health care system, including the concern that the care of a potential donor might be compromised if their donor status were know. Financial incentives would intensify this mistrust.

Think about altering the definition of death and saying, "Well, no, we'll pay you for some organs." What of that mistrust of the medical system? And the National Kidney Foundation calls attention to that.

My good friend Dan Brock at the Harvard Medical School, Department of Ethics, there's a statement there before you as well, and he concludes by saying that if a system would unavoidably lead to a serious exploitation of such donors either here or abroad, that would be a strong reason against implementing a regulated market.

The Transplantation Society internationally is opposed to a regulated market of organ sales. An endorsement — now, I'm reading verbatim, and the statement is there before you sent by Katherine Wood to me just a few weeks ago, again, in preparation for this presentation, to bring all of these testimonies to this Commission's attention about its opposition to such a regulated market.

"An endorsement of such a plan by the President's Council on Bioethics would send a profound and troubling message to the United States Congress and the transplant community worldwide. As you are aware, the transplant community is now confronted by transplantation tourism that has an international dimension. The transplant tourist often obtains a kidney in countries in which poor individuals are exploited for their body parts."

And parenthetically, there is a picture very well depicting what this is all about. If you go to the second slide set, you'll see a picture of vendors in Karachi and the other one, that from the Philippines.

"It is the exploitation of the poor that makes the practice unethical. Regulating the practice by a government program does not make the practice ethical. If the United States were to adopt a regulated market by the United States government, many challenging issues would emerge. Could the U.S. government justify limiting the sale of such kidneys by its citizenry? Would not such a regulated market for the sale of organs drive individuals from other countries to come to the United States to sell his or her kidney?

"The Transplantation Society urges the President's Council on Bioethics to affirm an unequivocal opposition of transplant tourism and a regulated market of organ sales."

With that I'll conclude, and I thank you for your attention and that I might be here. Thank you very much.

(Applause.)

CHAIRMAN PELLEGRINO: Thank you very much, Dr. Delmonico, and thank both of the speakers for being very respectful of the time of the council.

You have now an opportunity to ask questions of either of the speakers, and I might ask that you direct your questions to a specific speaker if possible.

Dr. Foster, I have you first on the list.
DR. FOSTER: Thank you.

Dr. Delmonico, it seems to me that it's a curious thing from you and all of the societies that you just quoted, that you simply want to stay in the status quo. That is to say, why is there no concern for the fact that the poor cannot get transplants?

There are other things I don't even want to talk about. In Dallas, let's say with a kidney it takes five years, and you go 20 miles across the way to Fort Worth. The UNOS system gives you a kidney. You can get a kidney, you know, in two years, or you can go to Jacksonville, Florida, and you can do things.

But I'm very concerned about your unconcern for the poor, that they cannot get transplantation done. Why is that?

I mean I've got people dying right now in Parkland Hospital that nobody will transplant because they don't have any insurance or money. Why? Why do you want to keep a system intact that doesn't work?

I mean, it works for the people who have money or have insurance, but it doesn't work, and it seems to me all I heard you say is that this is a good and wonderful system that we should not in any way change.

DR. DELMONICO: Dr. Foster, may I respond to that?

DR. FOSTER: Sure. That's really what I want. What I want to know is why today in the United States — at least I don't know how it is in Boston, and so forth — but certainly in Dallas —

DR. DELMONICO: I'm very familiar with what's happening in Dallas, Dr. Foster.

DR. FOSTER: Well, please. I mean, I'd just like to hear why we want to stay with a system, and my transplant surgeons don't feel like you have cited. I don't know.

DR. DELMONICO: I know them very well. I know (Dr. Goran B. G.) Klintmalm at Baylor very well. I haven't suggested that all of these organizations are opposed to regulated market, that that justifies the system as it currently exists. There are disparities about access to the list that are unequivocally there, and I don't accept that at all.

So I don't want you to make a conclusion, Dr. Foster, that opposition to regulated market is to say that the system as it currently exists as to the disparities in getting on the list or the disparities once on the list about transplant is to be solved by a regulated market or that the regulated market is then a conclusion that an opposition to that is a sanction of the current system.

It isn't. So I'm concerned just as you are about the poor that might be in any location of this country and their insurance issues that don't get them to the list or that they're identified as having renal failure, don't get them through the system that enables them to have the proper medical care that someone else might have.

Those inequities do exist. The opposition that you just heard from all these organizations is not about that at all, and UNOS is very much concerned about these disparities. That's why the meld system was introduced. That's why the changes in lung allocation were introduced. That's why we are trying to change the allocation system of kidneys in this country.

So please, if I can say to you, the opposition about a regulated market is not justifying or saying that the current system is perfect or that what we want to stay with.

DR. EPSTEIN: Can I answer?

DR. FOSTER: Well, let me just say one. I would presume as a transplant surgeon that you would like to have enough organs, whether it's young or old or poor or so, that there would be an opportunity for this treatment which has been wonderful to be available, but you still haven't answered the question to me, how you want to solve that.

You say, well, we're concerned about that. Where does this concern go? I mean it doesn't help me for you to say that you're concerned about it. What I want to know is what are we going to do about it. Are we going to — I mean, what's your answer to this?

DR. DELMONICO: My answer is that it doesn't resolve by a regulated market, number one.
Number two, okay, so what positively? We can increase deceased donation as we're doing. We can increase live donation as has occurred. We can do the types of paired donations, et cetera, but I think what you're as well going to have to wrestle with is that the reason why the list is expanding as it is because of poor preventive medical care, and it, in fact, is the case, and it's the poor person that doesn't get that care that is becoming a major aspect of that list.

So I would ask you, sir, what are you going to do about heading it off at the pass, as it were, instead of just coming down to the very end of it and say, "Well, un-huh, now we need organs."

Why is it that you wouldn't be considering better preventive medical care as a component of obviating the need for the organ to begin with?

**CHAIRMAN PELLEGRINO:** I want to point out I have —

**DR. FOSTER:** I can answer that, and I spent my life as a diabetologist, and if you want to read some of the stuff, you know, that's know. I mean, New York City, somebody facetiously said that uncontrolled diabetes is causing more deaths than 9/11 or anything else. So I mean, I don't want to get into that.

But if we've got a curable form of diabetes right now, but obesity is not curable, I mean, practically. It sounds like we're getting in an argument. I don't want to do that, but I also don't want to give the answer that we can do better preventive medicine is the problem. I mean, that's not going to get more organs to transplant if we live longer and solve those problems.

**DR. EPSTEIN:** We have spent how much on Medicare and Medicaid? Most of what we do by way of incremental expenditure is badly managed. More money in that direction may have some good, but that doesn't mean that you don't move on every front simultaneously.

And Dr. Delmonico's proposal is to the extent that he maintains the ban on regulated markets a proposal to rearrange deck chairs on the Titanic. The shortage is ignored, and the only viable method to stop it is shut off.

lements from black markets and overseas exactly what one says with every other commodity. You make something into a black market commodity, and you get shady operators and corrupt transactions. You bring it above board and much of that coercion and intrigue disappears.

So what you're seeing is an artifact of restrictions. It's just why the slum lords of New York are miserable and skuzzy, because of rent control, and in Chicago it's just not an issue because you've got the market clearing prices.

Nobody says a widget is the same as an organ. What you're saying is the same forces of supply and demand work, but the individual transactions in market will obviously take place in different ways, just the way all other commodities are sold in different ways.

You don't sell jewelry in the same fashion that you sell pears, even though both of them are widgets. So it's just a complete misconception.

And the other point is all of the recitations, I have never read a more pathetic document than what Mr. Graham submitted to you as justifications for endless numbers of lives. I urge everybody to read it and ask whether or not they could think of 1,000 counter-examples.

If this is the best you can do, it's politics and muscle. It is ethically barren.

**CHAIRMAN PELLEGRINO:** Dr. Delmonico, a brief reply because we have seven members of the Council who wish to comment.

**DR. DELMONICO:** Well, I'll only say this. It isn't me speaking here. It's all of these organizations, and you'll have to reckon with it.

**DR. EPSTEIN:** Well, no. If you want to play tough guy, you're winning.

**CHAIRMAN PELLEGRINO:** I would ask that each person ask a question and you will have the opportunity to respond, and then we'll try to keep the debate down for the moment. I want to get the Council members in. The meeting is for their information first.

The next question I have is from Dr. Meilaender.
DR. MEILAENDER: Professor Epstein, I would like to think about ethics a little bit with you if we could. You said a couple of things right at the very start of your presentation. You said there’s only one fact, sort of the chronic and irreducible shortage of organs, and you said, and then it has been sort of involved in the ongoing conversation — I don’t have the exact quote — but something like there’s nothing so unusual about organs that the laws of economics don’t apply.

And I am so benighted as to doubt that in a way and would just like to think about it a little bit with you, and one way of thinking about the world is that — and I mean, I think there was a time when lots of people thought this way — is that there are human beings and there are resources, and you have to think about how to distribute resources to human beings. And we can get into ethical arguments about what the best way to do that is.

Another way is to think about human beings or at least parts of human beings as themselves resources to be distributed, but that’s a fundamental shift. That’s a different way of thinking about the world, and it raises all sorts of troubling questions about where exactly we locate the person whose body is a resource now to be distributed.

And if we’re going to make that shift and think about the person as a collection of resources that are commodities to be distributed, we might want to worry about those things.

So what it seems to me we need, I mean, there is a starting point presupposed in what you said, and the starting point is that it’s better to think about the world in such a way that human beings or at least the parts of them become resources that some other human being kind of floating around above the body distributes. And I don’t find that a terribly persuasive way myself to think about human beings, but I’d just like to hear what you would say about that.

And I’d just like to see if you think more my way, then you’d never say that the only fact is that there’s a chronic and irreducible shortage. That might be one fact, but there would be some other facts about how to think about human beings that would be important.

How would you take that up?

DR. EPSTEIN: Look. I mean, there is a very long tradition which starts to argue that the life of a human being shall not be treated as a commodity. My favorite example of that is Section 6 of the Clayton Act in which they announced that provision, and the net effect of that was to organize labor cartels and agricultural cartels.

That is, lots of times when people start using the theories that commodification is terrible, they don’t mean that they can’t sell it. It means that they can monopolize it.

And so you have to be aware of the fact that there’s a lot of abuse that is associated with that section, and then even in its proper sense, virtually every serious economist when they talk about resources divides them into two halves, human, on the one hand, and natural, on the other. And —

DR. MEILAENDER: But you wanted to talk ethics.

DR. EPSTEIN: I am talking — yeah, I’ll talk ethics.

DR. MEILAENDER: For the moment I don’t care what every serious economist says.

DR. EPSTEIN: Because I mean what happens is these are resources, the human beings, and in fact, an ethicist is committed to treating them as resources when they’re willing to allow a donation to take place. That is a transfer of resources from one individual.

It may well be something which is done without consideration in the technical sense of the word, but it is certainly a transfer, and the justification for it is that the gain to the recipient translates into overall social welfare.

The problem about ethics is it is basically an empty set unless it can transform itself into some kind of a social welfare function. To give you an illustration, the Kantian proposition that every individual shall always be treated as an end and never be treated as a means, right? If you take it —

DR. MEILAENDER: That’s not the proposition.

DR. EPSTEIN: Well, that’s —

DR. MEILAENDER: It’s that every individual shall be treated not as a means only
DR. EPSTEIN: Not as a means only. Okay, but I mean, if they're not, then if they can be treated as a means partially, it has got to be in the service of some end. And what the purpose of ethics is to figure out how you allocate these resources in which to get the greatest maximum of good for all people inside the system.

Given scarcity, that translates back into an economic problem, and if you start looking at the Kantian propositions, it begins the prohibition against exchange because of the fear of exploitation, and that becomes so utterly restrictive because you can't have labor contracts at that point for so-called ethical reasons.

Well, once you allow voluntary exchange of labor, then you are always worried about the specter of whether it's slavery, and you're going to ban those.

I mean, one of the things that was wrong with Dr. Veatch's presentation is he somehow assumed that the organ problem was worse because we don't have a strong minimum wage law. But I can't think of a single ethical argument in favor of a minimum wage law, and I wonder what would it be.

CHAIRMAN PELLEGRINO: May I intervene for a moment? We do have a limited time, and I realize the problems between you are difficult to resolve in a brief time, and I understand you. We have a question of civility and courtesy for the rest of the members of the Council.

This is no reflection on anybody's involvement in the discussion. I understand that, but I would like to call on Peter Lawler and we might come back if there's time to pick up your discussion.

Peter.

DR. LAWLER: I first want to congratulate both presenters for very effective and illuminating presentations.

I'm against the trafficking in live organs and even somewhat creeped out, as I said before, by the donation of live vital organs, and so I guess I generally agree with Dr. Delmonico, but I also as usual am very moved by Dr. Foster.

And so let me give you the two hardest questions I would have. Number one, given that there should be no market in live organs, what do you think about the market he suggested in dead organs or some payment for dead organs?

And number two, this transplant tourism thing from the point of view of justice. Now, let's say the U.N. can't stop it, which is likely since they can't stop anything.

(Laughter.)

DR. LAWLER: Then prosperous Americans will avail themselves with increasing frequency with transplant tourism. It will be shady, but not that shady, and they'll generally get good results, and so the only people who don't have access to live organs unjustly procured will be people who can't afford to engage in transplant tourism.

And I don't think we'll ever be tough enough to say to the transplant tourist, "If you come back here we're not giving you any medical treatment because your kidney was unjustly acquired."

So from the Rawlsian, left wing justice point of view, aren't we entering into a very unjust phase insofar as kidneys will be available to everyone except people who can't afford to engage in transplant tourism?

CHAIRMAN PELLEGRINO: Dr. Delmonico, Dr. Epstein.

DR. DELMONICO: Transplant tourism, the WHO is going to do something about it. The South African situation was shut down, and the physicians there were arrested. I think that's the fact. Whether you agree with it or not, the premise was that the U.N. can't stop it, sir.

Americans are going to China currently and buying organs from executed prisoners. Six thousand or so organs last year were derived from executed prisoners in China. The President of China is in town here today. The Vice Minister of China within the last ten days said that they will have a legal ban on transplant tourism.

The WHO plans to go to the variety of markets that exist, black market that exists, and try at least within the legal framework to exercise what is the illegality and make that practice stop. I have no illusions about that. However, the fact that the poor might not be able to avail themselves of
transplant tourism in my view is not a reason to sustain transplant tourism. The fundamental problem is the transplant tourist situation, and that’s what we have to address to try and prohibit.

No marketing for dead organs. If you finance marketing for dead organs, how can you then justifiably say we won’t finance marketing for live organs? I don’t know how to reconcile it.

Where there is no risk and you finance marketing for dead organs, why wouldn’t we then want to finance marketing for live organs? And the problem is we don’t wish to commodify life organs just as another economic tool. That’s the fundamental difference.

You either accept that or you don’t, and once you say then that you’re going to provide that kind of a market, why would we stop at a kidney? Why can’t we sell a lobe of the lung? Why can’t we sell a part of the liver? And why is it then that the same justifications that are applied apply to other kinds of social behaviors that are not accepted, for example, prostitution?

CHAIRMAN PELLEGRINO: Professor Epstein.

DR. EPSTEIN: Globalization is an effort at circumvention. World trade is, in general, a good thing. The problem with the circumvention in these cases is that if you’re starting to take organs off of dead people, these are not voluntary markets when they’re sold by the Chinese government.

And what one wants to do is to open up legitimate sources of supply so that these perversions don’t take place, and let me be very clear. I did not agree with Dr. Veatch when he wants to kill people off prematurely in order to increase the supply of organs. I think it’s a market of desperation and sadness that people actually think you’re going to have to sell diseased organs under these circumstances or give them away.

I would rather sell a healthy organ than give away a terrible organ. So I think what you’re doing is you’re looking at the cure and treating it as part of the disease, which only in the organ transplant community is compensation coercion.

And if you keep with that equivalence you will basically think that coercion has to be avoided, and it’s worth paying the price of 20 deaths a day to avoid it.

I think it’s crazy. I mean, to somebody who is in the outside looking at this community I can’t even understand it, and just to go back to the ethical point, I do not know of a coherent nonconsequentialist ethics in a identical form. This is the answer to the earlier question, which essentially is sustainable, and that’s why in the end you can’t do ethics unless you know some economics.

DR. DELMONICO: Dr. Foster, I just want to say this. I have the same sense of the problem of the death on the list. Trust me. I can only want to assure you in a personal way that I do. I’m just unable to solve it by regulated market. I can’t go there.

CHAIRMAN PELLEGRINO: Professor Eberstadt.

DR. EBERSTADT: I have two questions for you, Dr. Delmonico, and one question for you, Professor Epstein.

DR. EPSTEIN: I’ll wait my turn.

DR. EBERSTADT: Okay. Dr. Delmonico, you’ve associated yourself with the ASTS statement here. The first one says that payments would exploit the most vulnerable members of our society.

Well, I note the phraseology “most vulnerable” is an ordinal rather than a cardinal ranking of people. There would presumably be a most vulnerable member of the Forbes 400 list. Is there any level of general affluence and education at which the concerns about the most vulnerable member of society would abate or reduce?

Secondly, the statement here talks about arbitrarily assigning a market value to body parts. With enough technological innovation, I can imagine, and already science fiction writes have imagined, the notion of manufactured body parts and body replacements.

What if, obviously a hypothetical, science fiction-like future world; what if Microsoft were able to manufacture body parts and the richest man in the world, Bill Gates, were to sell them? Would the reservations about the sales of human-like bioparts still obtain that you mention here?

Professor Epstein, you’ve made the economic argument about the benefits of a national market for
exchange of organs. Would you extend that argument to an international sale, international commerce in body parts?

DR. DELMONICO: In the regulated market in Iran, it's the poor person that sells himself, and when Bob said that, well, they've cleared out the list, we have no idea about the list. I actually know the data, the prevalence about renal failure in Iran, we never know who might have gotten to the list.

The vulnerable is that it's the poor person. It's the expectation that it will be the poor person that wants to sell the kidney and/or other organs because of their need to do so to generate those funds.

I don't have an expectation that it will be other than a poor person because that's what the experience has been internationally.

The arbitrary market piece, when the Pennsylvania folks had the $300, you know, that they were going to assign for funeral expenses, et cetera, you could imagine that every state might take up such legislation. The problem of all of that was, and we wrestled with this in the American Society of Transplant Surgeons. What money would you assign in Pennsylvania or in Texas?

Once you start seeing that we're going to provide some funding for this, where is it that you declare Uncle Joe in Texas is worth 5,000, but you may not be able to get that in Pennsylvania?

And by every state it becomes somewhat arbitrary as to what those monies might be. Within those legislatures, I don't believe that we would be able to make a consistent determination of that monetary amount, and it becomes arbitrarily applied. What is the value of Uncle Joe in Texas for his liver, and does that differ because Uncle Joe is 65 or 25?

That's, in fact, what goes on in these market situations. There's a difference in gender and in ethnicity and by age as to what the market brings for those organs.

DR. EPSTEIN: As well there should be. I find it remarkable. The problem of valuation and multiple prices exist in any market which is regulated. If you want to find out how to do it, you just simply remove all of the state mandates for stipulated sums, and you will get an equilibrium because you'll eliminate the arbitrage.

So what you're talking about is the value problem that comes under regulation, not the value problem that comes under markets. The question is how do you determine values in markets. Remember what Hobbes says. It's the appetite of the contracting parties that do it. There is not a single commodity or non-commodity that works in any difference.

Even in such delicate barter relationship as marriage, it is ultimately subjective and joint, and all we can do is observe the manifestations of consent and infer from that mutual gain.

And what we can also observe is when there is no compensation possible, we will get chronic shortages, and all of the talk and all of the "trust me's" in the world will not change that simple brute fact.

CHAIRMAN PELLEGRINO: Dr. Kass.

DR. KASS: I have two questions, one to lean on each of you from the side of the other having listened to the presentation.

Professor Epstein starts preoccupied with the fact that people are dying because of shortages, and that's the only fact that is relevant at least for this argument to start with.

But Dr. Delmonico in the written paper and also here is concerned about the deformations of medical practice if the vendor relation enters, referring to just a sentence or two in the article, repeatedly speaking about the indignity of the commodification or trading of body parts, quite apart from the question of the coercion of the poor, which is a separate matter.

And he raises the question of whether or not this push for an ever more expensive and ever more morally challenging technical solution isn't in a way the wrong system error, that there's another system error having to do with prevention of the disease.

I want to know from Professor Epstein whether any of these concerns matter and, in particular, the question of whether or not there really is something different about the human body and its parts such that there really is a loss when you begin to trade it around, and that's made even worse when you begin to trade it around for money.
On the other side, to Dr. Delmonico, Professor Epstein’s one brute fact that he harps on at least in our present situation, and Dr. Foster has underlined it, demands some kind of response. Let’s say for the sake of the argument that all of these little partial solutions of Robert Veatch amount to nothing and don’t give us the additional organs that you need.

Are you in a way prepared to say for the time being those concerns for the change in medical practice, those concerns for human dignity and its violation are sufficient so that I’m willing to say as a transplant surgeon it’s a sad necessity in the situation. These people are going to die.

Let’s assume that he’s right, that the only way really to produce the kind of equilibrium of supply and demand is through markets, and that we face that fact. Are we then prepared to say that’s just tough?

**DR. EPSTEIN:** Well, I’ll answer my question first. I always think dignitary stuff is nice, but it’s the kind of thing which you could handle in 1,000 subsidiary ways after you open up the set of markets.

You know, you watch funeral homes, right? They’re markets. They manage to work for exchange, and yet it’s strange. In a funeral parlor nobody treats the dead body as though it’s a piece of meat to be thrown down by a hook, right? Because it turns out the conditions and the demands and the empathetic situations of the suppliers and the buyers in these markets require a different kind of delicacy and tact.

My own view is that if you allowed this thing to come up, the way you will handle the dignity thing is by the development of customs and trade and exchange and cooperation and by a selection of people who will be part of that particular community who have the greatest level of empathy.

So I think all sorts of forms of selection in there will do it, but to say that the diminished respect for organs resulting from making body parts a commodity, if that is a cost, and I don’t think it is particular, it’s trivial compared to the value of a life.

What would you monetize it at, $1,000 and a life at six million? I mean, maybe you’re right that there’s something there, but it’s a cost, and it’s certainly not a cost that gets near enough to amount to the prohibition.

You yourself said, and I think it’s right, if you really thought this (made the poor more vulnerable), put a minimum taxable figure of $5,000 or $50,000 in income before you can sell.

My view about that is I would rather not see the restriction in there because now you’re telling the poor there are fewer opportunities than anybody else, abut I’d certainly rather have that than the total thing.

I mean, make it very clear. On a day-to-day basis, anything that loosens this up I will accept, including all of these so-called altruistic bartered exchange that are done simultaneously because, of course, there are sales, on the one hand, between parties, and there are voluntary gifts within the family, and they’re both.

**CHAIRMAN PELLEGRINO:** Dr. Kass?

**DR. KASS:** I will pose a question and let him not answer.

**CHAIRMAN PELLEGRINO:** Okay.

**DR. KASS:** For all of us, what about the Will Gaylin? It was Jonas actually who thought about it first. These lives could be saved, but only really by perfusing corpses and letting them be farms for these parts, by consent with payment, with or without payment.

Do we want to live in a society in which that is the way in which these lives are saved or are those minuscule considerations compared to these lives?

I think there’s something in your economistic account here that just is left out, that’s missing, that’s of great importance.

**CHAIRMAN PELLEGRINO:** Dr. Delmonico.

**DR. DELMONICO:** Well, you go ahead.

**DR. EPSTEIN:** Oh, sure. I mean, Leon, the point is you could always invent a case such that you would allow for voluntary consent that nobody would want to do. The real question is, all right,
open up this possibility and see if it's a ghoulish as you say. How many people take advantage of it?

And the answer is you won't find many people taking advantage of it if you could find other forms of exchange that have a higher level of tolerance both for themselves and for others.

There has got to be a selection effect within markets. Just because you make exchanges legal doesn't mean that anyone is going to want to do each and every one of them, and there is a second social filter. The argument here about norms and respect comes in in the way in which markets operate. They're very heavily norm defined, and so forth, and I'm not being economistic and saying that everybody has to be a brute rational choice guy.

I'm saying if you open up exchange, all of these subjective and very important elements can be brought into the occasion as they are right now in delicate human arrangements with psychiatric care, with sexual dysfunction, with funeral arrangements. They do not look to me in exactly the same way as you an A&P, and so as long as we see that these voluntary differentiations take place, I don't think the argument from dignity gets you within 1,000 miles of a ban.

DR. DELMONICO: It's because I don't run an A&P. It's because I don't want to place a monetary value on life that we take this opposition, and it's not me. It's all of these organizations that I just brought before you. And that becomes really the profound difference.

Dr. Foster, I can't do it. I cannot come to myself personally as a surgeon-physician, and I respect the fact that you are as well and that you care about the patients as well, and I do respect that.

But what I can't do, nor can these organizations; I can't be a part of placing some payment, monetary value on somebody's life to say that's what it's worth in some economic terms, and it goes to the core of what this is all about, and it's that difference that separates us.

CHAIRMAN PELLEGRINO: Do you want a point?

DR. FOSTER: I think that, yes, you're answering Leon's question. You say, yes, it's sad that all of these people have to die without organs, but the price is too high. So your answer to him is yes, our societies believe that the cost is too high and that the cost of their lives is not high enough to overcome it.

DR. DELMONICO: Well, it's not a matter of cost that it's too high because if we had an accurate source of organs I'd be the first one on it around the clock to get it done.

DR. EPSTEIN: Well, Dr. Delmonico, there's a big difference between saying I can't do it and no one else in the world can do it because I have these strong instincts. What you're doing is you're coercing other people through these organizations, and if the vote is 99 to one, then 99 surgeons don't do it and the other guy does it. You have to explain not to your aesthetic preference for staying out of the purchase market; you have to explain why you're going to stop other people from doing it. I have —

DR. DELMONICO: It's not me who's stopping anything. It's —

DR. EPSTEIN: What do you mean it's not you? You and your organizations are making transactions illegal because you don't like them.

CHAIRMAN PELLEGRINO: Especially, DR. EPSTEIN, as a lawyer I'm sure you're familiar with the role of the judge.

(Laughter.)

CHAIRMAN PELLEGRINO: I must ask for a little more restraint in the responses and a little more brevity. We have five more members of the Council who wish to comment, and so I'm going to take the Chairman's prerogative and extend the time of discussion. I don't mean in any way to restrain anyone's comment, but they can be made with more brevity and perhaps more on the point.

Thank you.

Now I would like to call on Dr. George.

PROF. GEORGE: Thank you, Dr. Pellegrino.

I do have a question for both presenters, but before asking that question, I'd like to ask Professor Epstein just to clarify the sense in which he's using a particular term, and it was the term "consequentialism" in response to Professor Meilaender.
I certainly agree with you that someone who wants to do ethics seriously, at least in quite a wide domain, has to know some economics, and indeed, a good deal of economics.

And I also agree with you that someone who believes that, as I do and you do, has got to reject a purely deontological approach to ethics.

But then you said any coherent sensible ethics will, therefore, have to be consequential. Now, maybe there's a sense in which that's right, and if so, I want to give you an opportunity to clarify the record on that.

When folks like Professor Meilaender and Professor Gomez-Lobo and someone like me hears the term “consequentialism,” of course, we think of Elizabeth Anscombe's definition of it when she introduced the term into ethics, which essentially boils down to the view that in situations of morally significant choice, one ought to choose that option which promises overall and in the long run to conduce to the net best proportion of benefit to harm, and there's your master principle of ethics.

Now, I think you can believe all of the things that I said that I share with you in believing, rejecting a purely deontological ethics thinking that economics is something we really have to understand to do ethics right today, and across a wide domain without embracing consequentialism in that sense. All you have to believe is that consequences do matter.

But, of course, that's going to be true for lots of people who reject consequentialism in the sense that Anscombe meant the term in the sense that she rejected it in favor of saying an Aristotelian approach that does take consequences seriously, but doesn't embrace any such master principle of ethics that would involve aggregating goods, commensurating them and making decisions in the way that I described.

**DR. EPSTEIN:** And that's why the economics is important. The Anscombe definition of consequential is — talks about a family. It ignores the distributional and separation is concerned. If you go back to the Pareto definitions or the Calder-Hicks definitions, each of them in effect treat each individual's occupying unique space and the utility function so that the gains to one can simply not be taken into account, ignoring the losses to another. There is either a question of explicit compensation required or, in effect, a hypothetical compensation so that this is not sort of an aggregate blob utilitarian thought, which often I think leads to immense troubles, utility monsters and so forth.

For example, you get one person who says, "I care so much. Trust me," that the harm to everybody else doesn’t matter because I have this over large psyche.

The distributional constraints in a Pareto system, I think, answer the Anscombe situation, and every Kantian proposition is consistent with a preference for Pareto over Calder-Hicks efficiency.

**PROF. GEORGE:** Well, the point that I'm pressing is that the options aren't the kind of utilitarianism you describe and reject, on the one hand, or Kantianism, on the other hand. But I wonder if the alternative that you've proposed is the only possible alternative.

I mean, how would you view, for example, a straightforward contemporary Aristotelianism?

**DR. EPSTEIN:** The same problem that you always have with all of these things. There's too much essentialism in it and ideas that there's sort of abstract categories into which people fall from which they cannot go out, too much of a fixed definition of what has to go in or not into the individual subjective utility functions. I would leave that thing completely unbounded. So I would not sort of limit it to certain kinds of taste as opposed to other forms of taste though that you have.

But even if you want to stay within this Aristotelian framework, the hard problem for political ethics is the question of when we use state coercion to justify the limitation of choice of other individuals, and the Aristotelian position has always been very hard because it's essential to say that certain transactions which have mutual gain for the parties can be trumped because of some kind of philosophical objection.

I regard that class of cases as empty, and since I do that is why the "trust me, I wouldn't do this kind of surgery" is fine for Dr. Delmonico not to take those patients, but it's not fine for him to tell Dr. Foster he can't find another physician to do a paid transplant.

And the fundamental point is the difference between coercion and voluntary participation, and the Aristotelian theory is very weak on policing and working that distinction.
PROF. GEORGE: But you take that view, obviously, based on a set of philosophical assumptions that you make which themselves can’t be justified in economic terms, for example.

DR. EPSTEIN: No, I don’t think that’s right at all. What I do is I assume that each individual is autonomous. I assume that they have well ordered preference functions one way or another. I don’t do it from economics. I get that thing justified from knowing if they are bid or trying to —

PROF. GEORGE: Those are straightforwardly philosophical assumptions.

DR. EPSTEIN: Well, and you try to learn them by learning as much as you can about both the moral — not the moral — the emotional and cognitive basis of human behavior, and I actually don’t do it —

PROF. GEORGE: Well, you —

DR. EPSTEIN: — you don’t do it from the economics. What you do is you derive the economics from the socio-biology, and at that point I think the fundamentalism question that you answer as to where people come is not economic postulates.

In fact, what is very persuasive in the normative discourse, as you well know, is that it turns out that people who have the pure rational choice model are the one set of people who can’t trade because they don’t have any empathy.

PROF. GEORGE: So your understanding of this thing is that you don’t have a philosophical view competing with a philosophical view. You’ve got a philosophical view competing with a socio-biological account which has no philosophical presuppositions in need of defense?

DR. EPSTEIN: Well, it’s an effort to try and solve the condition of what the definition of naturalism is, how it is that we take these people as given. The old philosophical inquiry is take human beings as they are and put institutions as they ought to be, and this is an effort to find out what they are in order to create the institutions.

And the normative criteria is a consequentialist one with a distributional constraint, and I think once you play that framework in there, the only way you get after voluntary exchanges is to prove negative externalities or defects in the transaction, and I think these are both feeble efforts to work into those two categories, and frankly, my dear, they don’t amount to very much.

So it’s not as though this is anything you want to do by way of contract or individual choice comes out of it. This is a real set of normative constraints on human behavior.

PROF. GEORGE: Well, I got my answer to that one. If I could very quickly, Dr. Pellegrino, can I ask the question I had for both or is there not time?

CHAIRMAN PELLEGRINO: Very quickly, very quickly. This is a fundamental discussion obviously that we aren’t going to settle this afternoon.

PROF. GEORGE: It’s not clear to me how much of the dispute between our two presenters is a matter of differences about economics and how much is a matter of differences about ethics.

And so I’d be very happy if very quickly, for example, perhaps Dr. Delmonico could say where you think your disagreement with Professor Epstein is on economics or at the end of the day is there not a disagreement about economics? It’s really about values. It’s about ethics.

DR. DELMONICO: It’s about values and his wanting to place a market value on life. I’m not prepared to do that, and that’s just from a personal view, but neither are these organizations, and neither was the Congress in 1984.

DR. EPSTEIN: The politic Congress has no normative layer. I think we both agreed on that. The interesting question is you cannot justify a system of voluntary donations unless you have some conception that the gain to the recipient is larger than the loss to the donor.

So you have to be in the valuation game in any world in which there are any transactions. Whether it has to be a market price system, who knows?

The reason why he likes to barter — I’m going to psychoanalyze him — is that you don’t have any cash exchanged in the transaction. So you could have a mutual gain without having a valuation question, and in fact, that is a very powerful insight, particularly in many cases when valuation is difficult to do.
If you could trade commensurables, right, you can have mutual gain without doing the valuation question. Whereas markets always require you to get enough information to set prices.

I'm all in favor of that. I just think it's a joke to call this thing altruistic when you do them simultaneously because of the distrust that takes place between the pairs. There's altruism within the families and there's bargains across families, and I don't care what lawyer he gets, I could get him disbarred if he wrote that kind of an opinion.

CHAIRMAN PELLEGRINO: Dr. Bloom.

DR. BLOOM: You can attribute my remark to the fact that I don't yet understand how the Council does its business and makes it recommendations, but it strikes me that the interchange between Dr. Delmonico and Dr. Foster strikes at the heart of the larger problem that as long as we deal only with the supply side of this issue all of the heroic and intellectual statements that we've heard are not going to solve our problem.

But we can't ignore the fact that we don't know how to do preventive medicine in that way, and to me that's the bigger moral imperative that we have to engage in order to deal with this as a sub-problem of that problem.

CHAIRMAN PELLEGRINO: Thank you very much.

I also have Dr. McHugh.

DR. McHUGH: No, I pass. Having heard various things, I'm not going to comment.

CHAIRMAN PELLEGRINO: All right. We have the end of our time, the extended time. We have had a request for the Council members to stay for a few moments before hastening off to lunch for a photograph. Our visitors wish to take a group photograph. I hope you are willing to do so. It won't take very long, will it?

Thank you.

(Whereupon, at 12:28 p.m., the meeting was recessed for lunch, to reconvene at 2:00 p.m.)

SESSION 3: CHILDREN AND CLINICAL RESEARCH

CHAIRMAN PELLEGRINO: In keeping with our attempt to stay within the program time, I think we'll begin this afternoon session. We'll be moving from the organ transplantation (discussion) of this morning into a different topic, namely, the area of children's ethics, which the Council has been addressing for several of its meetings.

In this particular meeting we'll be emphasizing research in children and the specific problems that go with it. Our first session will be regarding children and clinical research, and our speaker will be someone who has worked in the field of research and research ethics from its beginnings literally. Dr. Robert Levine, Professor of Internal Medicine at Yale University, also a colleague and a friend. Bob.

DR. LEVINE: Thank you for your very laudable, brief introduction. That says who I am, and that's enough.

I'm going to talk about clinical research in children soon, but first I'm going to talk about component analysis and the justification of the risks of research.

Ed Pellegrino, when he called me to come here, asked me to talk about some of the stuff I've done criticizing the Declaration of Helsinki, and the central feature of that criticism that has a bearing on what you're here to do today is the idea of component analysis. This replaces the false distinction between therapeutic and nontherapeutic research.

I want to say right now that every document that relies on a distinction between therapeutic and nontherapeutic research contains errors. When we point these errors out to those who wrote the documents, they are generally embarrassed. It's particularly troubling when they're not embarrassed.

Incidentally, this component analysis is relevant to research involving children. The National Commission adopted component analysis in the course of its debates on research involving children. That's why their earlier reports, research involving pregnant women and the fetus and
research involving prisoners, had a number of errors. The fetus regulations were only corrected about seven or eight years ago, and the prisoner regulations are not corrected yet, although SACHRP is reviewing them.

Now, the next slide I will present is the slide I prepared for presentation to the World Medical Association Ethics Committee on the occasion of accepting their assignment to propose a revision or to chair the committee to propose a revision to the Declaration of Helsinki.

I said the document was illogical, relying on this distinction; that it was out of touch with contemporary ethical thinking, such as thinking on placebo controls; and that finally, the document was widely disregarded and had lost much of its authority because people were violating it as a matter of routine.

Let's take a look at two articles from the Declaration of Helsinki as of 1996. All of the things labeled with the Roman numeral two are under their rubric of clinical research or therapeutic research. Number three is the nontherapeutic research.

(Article) 2.6: "The doctor can combine medical research with professional care only to the extent that research is justified by its potential therapeutic value for the patient."

Article 3.2, "Subjects should be volunteers, either healthy persons or patients for whom the experimental design is not related to the patient's illness."

Let's take these two statements and apply them literally. What is forbidden by Article 2.6? All research in the field of pathogenesis, all research in pathophysiology. Since you can't justify these categories of research by therapeutic benefit, then you must do this research either on normal volunteers or on patients whose illness is unrelated to the protocol.

If I wanted to pursue some of Dr. Bloom's work and study catecholamines and the pathophysiology of depression, it would be okay as long as I studied it in people with arthritis, but I'd not be allowed to study patients with depression. That's what I mean by embarrassing. It rules out most epidemiology.

What about therapeutic research? Therapeutic research is an incoherent concept. All research has some components that are not intended to be therapeutic. Research by its very definition is the pursuit of generalizable knowledge, not individual specific knowledge as we get when we're doing a diagnostic evaluation of a patient.

Therapeutic research gives us what I call the fallacy of the package deal. What happens is that people look at a proposal to do research, and if they find something therapeutic in it, they justify the entire protocol according to the standards for therapeutic research.

Nontherapeutic components are justified as therapeutic. I've surveyed the literature of randomized clinical trials, and let me show you some things that were justified as therapeutic research. Repeated coronary angiograms in patients who in the practice of medicine would have one or none.

Repeated endoscopies in patients who in the routine practice of medicine, patients with peptic ulcer, usually would have none, but these were repeated once every week in order to satisfy an FDA requirement that you really show shrinking of the lesion. This was the evaluation of the H2 receptor antagonist.

Liver biopsies done on the place by group for no reason other than to maintain a double blind. Placebos administered into the coronary arteries, that (were part of) the National Heart, Lung and Blood Institute's TIMMI protocol evaluating various clot dissolving agents in the treatment of people with myocardial infarction.

Now, component analysis is different. In component analysis we don't evaluate the entire protocol as therapeutic or nontherapeutic. We evaluate individual interventions or procedures. Here is the language taken from the regulations on research involving children:

"Interventions or procedures that do or do not hold out the prospect of direct benefit for the individual subject."

Beneficial procedures are justified as they are in medical practice. The risk is justified by the anticipated benefit to the individual subject. It's required that the relationship of anticipated benefit to risk be at least as favorable as that of any available alternatives.

I've already mentioned what we do with beneficial procedures. The only limit is the anticipation of
personal benefit. In nonbeneficial procedures, however, we have prescribed limits, thresholds, what sort of justification does it take to expose child subjects to increasing levels of risk?

For example, if there is a minor increase over minimal risk, the procedure that presents this minor increase must be reasonably commensurate with those in the actual or expected situation of the child. The anticipated knowledge must be of vital importance to understanding the subject’s disorder or condition.

I don’t know how many of you have read the case study for tomorrow, but this will afford you an opportunity to figure out what it means when it says “subject’s disorder or condition.” Just what is a disorder or a condition?

The subtitles in Subpart D are enormously confusing. A little bit of history. When the National Commission finished its report on research involving children, it turned it over to what was then called the Department of Health, Education, and Welfare. The regulation writers produced a set of proposed regulations based upon this report.

The National Commission said, "No, you’ve got it all wrong," and made them go back and develop a new proposal, and then the National Commission went out of office. So the new proposal came out faithful to the National Commission’s report, but the subtitles were written after the National Commission went out of business, and so the subtitles restore therapeutic research.

Research involving greater than minimal risk but presenting the prospect of direct benefit, and then the text says "interventions or procedures that do or do not hold out the prospect of direct benefit.”

Unfortunately, too many people working in the field of research ethics or an IRB administration seem to have only read the subtitles. They haven’t gone to the finer print that is actually the regulatory standard.

Now I’m going to shift to a more explicit discussion of research involving children. I’m going to talk about some general considerations that are problematic in designing and reviewing research involving subjects, including children, and then I’ll offer some considerations that are specific to children.

General considerations. Ever since the Office of the Inspector General asserted that IRBs are overly burdened to the extent that they can’t get their work done, this has been a topic of conversation that’s near the front of all conversation on research review. I agree that they’re overly burdened. That’s beside the IRBs are required to do things that don’t need doing. They’re required to do periodic, usually annual, review at convened meetings.

You can’t imagine the number of adverse event reports that come across the desk of the IRB Administrator. There is no reason in the world for a convened meeting to review all of these things. This is something that should be done by the Data and Safety Monitoring Board, which has the advantage of reviewing all of the data and it also knows the denominators for the data, where all the IRB gets is a lot of disconnected reports that probably belong in the numerator.

Review of — I beg your pardon. I just discussed the second bullet. The first bullet, periodic review at a convened meeting. This is also a meaningless exercise. Usually at the first anniversary of a protocol the research has not even begun yet. You’re still waiting for the study section or the Council to decide whether you’re going to get your money.

But even after it has begun, there’s usually nothing that requires the attention of every member of the committee, and finally, documentation that all regulatory requirements were considered. If you review the list of observations that OPRR first and now OHRP came up with in those universities where it closed down the research operation until they got their IRB system straightened out, these are the three things that are most frequently mentioned.

What do I mean by documentation that regulatory requirements are considered? The way this plays out in real life is that you have to say if research involves children, we have made a determination that the risks are not minimal. They’re a minor increase above minimal risk. We have made a determination, and you have to essentially repeat each of the regulations as you say, "Yes, we did that. Yes, we did that.”

By analogy, it’s like every time you stop for a red light writing a report saying, "I did not go through the red light," the behavior should be sufficient without all of this documentation.

What I have come up with is a proposal for modified expedited review. I would have each of these
categories of activity carried out by an experienced member of the IRB not to approve or disapprove, but to see whether or not this crosses the threshold of requiring attention of the entire IRB at a convened meeting.

This person would not necessarily have the authority to say this is okay or this is not okay, but rather to say this should be reviewed by the full meeting.

We don't have much empirical information on this, but we have sort of an informal empirical study. Norman Fost, who has been involved in this business almost as long as I have at the University of Wisconsin in Madison, took 3,000 consecutive protocols that required periodic reapproval. He reviewed them according to the old method, that is, having expedited review with one expert member looking at the protocol and deciding what, if anything, ought to be changed before they issued reapproval.

He then took these 3,000 consecutive protocols and turned them over to the fully convened IRB. The number of cases in which the convened IRB made substantive further revisions was zero. That's what I mean by doing things that don't need to be done.

considerations. Two, "waiver requirement for consent, assent and permission." This that's represented in the regulations says that the could not be practically carried out without such a waiver. We need some authoritative statement on what "practically" means. Some policy and some policy enforcers have seemed to believe that means with waiver of the requirement for assent or permission it would be impossible. Medical record review is customarily done without individual consent, assent or permission. Nobody seems to have their rights violated by this or interests, if you can keep things adequately confidential.

It's not impossible to get informed consent to review medical records, but imagine going out, having the investigator go out and contact sometimes 1,000 or more patients to get consent for looking at the medical records.

The standard minimal risk is the trigger of many regulatory requirements, particularly the trigger for waiving or altering some of the requirements of the regulations. We use this standard to waive the requirement for parental permission, and we use this standard to justify risk in terms of anticipated benefits.

Minimal risk: What does it say in the definition of minimal risk? It says two things. One is that the risks are like those in everyday life, and it says the risks are comparable to the risks of a routine medical or psychological examination.

Now let's see how these are applied to children. Many IRBs around the country say that if a child is going to be exposed to sexually explicit language, this is greater than minimal risk. I think that people who are experienced in talking with children know that they generally already know about language that would shock the investigators. I would say this sort of thing should rarely be considered more than minimal risk, given all of the additional things that the investigator would have to do.

What about the risks of the routine medical examination? The routine medical examination, as most of you know, consists of a deep probing into one's family history, a deep probing into one's social history, looking for all sorts of behaviors that might have a bearing on one's health or on making the diagnosis.

It's my belief that as we interpret whether or not the procedures in a given research protocol go beyond the threshold of minimal risk, we should keep in mind what goes on in a routine medical examination. The OHRP not too long ago reached a determination that if you asked the subject to give sensitive information about their relatives, you not only had to get consent from the subject, but also from the relatives.

This is what I call regulatory excess. The problem is not in the regulations. The problem is in how those who are responsible for implementing the regulations interpret them.

The assent form, you know, the purpose of consent is to empower the prospective subject. You give them information, and they develop the capacity to protect their own interest through consenting or withholding consent.

The purpose of documentation, by contrast, is to protect the investigator and the institution. If the subject comes back a year later and says, "You did not get informed consent from me, you didn't tell me I had a right to refuse," now you can pull a document out of your desk and say, "I not only gave
you that information, but I’ve got a signed receipt for it."

Why then do we need assent forms? Why is so much energy put into developing assent forms? The child is not going to come back and litigate. I believe the main purpose of the assent form should be to give the child the sense of participation. Just like the parents sign a form, let the child also sign a form, but don’t get so preoccupied with developing the sorts of assent forms that serve as perfect analogues for the consent form.

Final slide. Research involving adolescents. I knew that I’d be getting to the end of my time allotment now. So what I simply said is in recommending policy for the future, one should pay attention to the guidance of the Adolescent Treatment Network’s Ethics Panel. This is a panel established within the National Institute of Child Health and Development.

It recognizes the emerging autonomy of adolescents. Adolescence is just one example of how we, as a society, have painted ourselves in the regulatory corners. We develop rules that described how you could involve children in research, and then some years later we discovered that adolescents with HIV infection would have to go through enormous hassles in order to comply with these rules when what you really wanted to do is give these adolescents the treatment of choice, which often included a drug on investigational status.

We’ve done the same thing through ourselves with prisoners. I could give you examples in many other categories, but today’s assignment is children.

Now, I wanted to stop here or I proposed to stop here, but I told your leader, Ed Pellegrino, that in case anyone was not familiar with the Adolescent Treatment Network’s recommendations, I have a few extra slides I can show you. I said I would ask if the group was interested. He said, "Don’t ask. Do it.”

(Laughter.)

DR. LEVINE: So what I’m going to try to do now — oh, my God, what have I done? Help.

As you can see, this is a talk that I really designed to give in Singapore a few years ago, but here it is.

Self-authorization by adolescents to serve as research subjects. The default position in the Code of Federal Regulations is that adolescent’s assent requires parental or guardian permission unless either the minor is emancipated or the IRB finds that permission is not a reasonable requirement, for example, in studies of abused or neglected children.

This is an inadequate position, and without getting into all of the reasoning, I’ll now end. There must be an appropriate mechanism to protect subjects to substitute for the protection usually afforded by permission, and this is the passage in the regulations that the adolescent treatment network picks up on. The waiver may not be incompatible with any laws.

Now, under what circumstances is permission not reasonable? First, the one that’s mentioned in the Code of Federal Regulations says that the children are neglected or abused, but the National Commission mentions some other circumstances in which it would not be a reasonable requirement.

Research on diseases or conditions for which adolescents may obtain treatment without parental permission, and that’s quite a number of disorders, many of which are the target of ongoing research.

Minimal risk research involving mature minors and children who are designated by their parents as in need of supervision.

Parents are legally or functionally incompetent.

The waivers that are permitted by Subpart A, and that is the general regulations for all people who are research subjects, and the regulations on children explicitly reference Subpart A to say here are the standards for satisfying the regulatory justification for waiving the requirement for consent: no more than minimal risk. The waiver or the alteration will not adversely affect the rights or welfare of the subject. The research could not practically be carried out without the waiver. I’ve already commented on that one, and whenever appropriate, there would be debriefing or dehoaxing or the sorts of things that are characteristic of research in psychology when you are not given full information at the outset.

I’ve already said something about minimal risk. So I’m not going to repeat it here. Even in Singapore I talked about the medical examination, probing the most sensitive details.
Now, here are the recommendations of the Adolescent Treatment Network. First, Category 1 research consists of anonymous surveys and other research in which there is no risk whatever. They say you need not consult the parents in this type of research.

Category 2 is research with any risk of physical, psychological, or social injury.

And Category 3 is research involving investigational new drugs or other FDA regulated test articles.

In Category 2, in which there is some risk but no test article, they want to encourage and assist the minor to obtain parental involvement. If I may digress for a moment, much of the discussion until the Adolescent Treatment Network got in on this had a tendency to alienate children from their parents. You would come to the child and say, "We don't have to get your parents' permission. You can authorize this on your own."

And what ATN is saying: no, encourage them. A lot of them would be well served to discuss their issues with their parents, but don’t insist.

B, the upper limit for risk of nonbeneficial procedures is minimal unless greater risk is justified according to the standards in the Code of Federal Regulations. And I mentioned those, the procedures commensurate. There’s a minor increase above minimal risk, things of this sort.

Category 2 continued. They would like to see in any project that carries out research presenting risk to children or adolescents develop a structure through which they can get consultation with the community. They would like to have a community board that would be overseeing this research to provide advice, criticism, and let them know what is and what is not acceptable.

If I went to them and said, "It's okay to use obscene language in a consent form," in some communities they would say, "Yes, we know the kids know this," and in some they would say no.

Here’s a crucial point. The minor is already obtaining health care services either independently or with parental permission, and the research is being conducted in conjunction with such health care services. There are many adolescents who have the go-ahead from their parents to get medical care at a certain institution without reporting on each and every component of that medical care. This is what the Adolescent Treatment Network is talking about.

Now, thirdly, research involving investigational new drugs. A, just like before, "encourage and assist minor to obtain parental involvement. Upper limit of nonbeneficial procedures is minimal. Community consultation and continuing involvement. The minor" — this is just like Category 2. Here’s where we began to see a difference.

There should be an advisor or an advocate appointed for each individual patient subject. This is very important. One obstacle to having many adolescents get involved in trials of new treatments or diagnostic procedures is that they simply don’t want to tell their parents, "I need treatment for drug abuse. I need treatment for HIV infection."

Many of the researchers say if we insisted upon parental permission or guardian permission, this would devastate our chances to do research in this population, and so I think this is a pretty good set of recommendations. I was part of the — I still am part of the Adolescent Treatment Network. So what I’m really doing is hawking my own product to some extent, but I hope you will also find it reasonable and perhaps take some action on it.

I apologize for the fact that you don’t have it in your handouts, but it’s in the President's Council's computer, and you can make handouts as you see fit.

Thank you very much for your attention.

(Applause.)

DR. LEVINE: I would like to respond to your comments or questions, and I'll even sit down if somebody would shield that projector.

CHAIRMAN PELLEGRINO: Thank you very much.

Dr. Levine’s presentation is open to commentary and questions. Any member of the counsel who would like to being the discussion?

DR. LEVINE: It’s unprecedented that I could talk for 30 minutes and not create some confusion.
CHAIRMAN PELLEGRINO: Or to be so convincing. I don’t see any body language that indicates an urge. Maybe it’s the luncheon period.

Thank you very much.

Well, Robby George and Dr. Bloom.

DR. BLOOM: Bob, you talked about unnecessary documentation for the research protocols. Does the same apply to the HIPAA regulations in terms of child research?

DR. LEVINE: You have to follow HIPAA regulations when you’re doing research on children as well as adults. The HIPAA regulations are, I would say, in a majority of protocols, not an undue burden for the individual researcher and not an undue burden for the IRB. They are burdensome in other respects, and I wish something could be done to tend to that.

Now, what has happened though is that there has been some what I consider inappropriate use of HIPAA regulations or HIPAA type requirements. I will give you a recent example that I was consulted on.

There’s a group of epidemiologists who want to do research in the State of Connecticut looking into certain patterns of distribution and risk exposure for various types of cancer. We have in the State of Connecticut a state authorized tumor registry. That means information goes into the tumor registry on every patient who has cancer, and this is done without consultation with the patient. It just goes there. It’s automatic.

And the state regulations say that researchers, bona fide researchers — they have to present some bona fides — will have access to this. However, in the HIPAA era some of the IRBs in Connecticut, indeed, a majority of the IRBs in Connecticut have said, “You can’t look at that information without the authorization of the patient’s personal physician.” That is bringing the whole program to a halt.

The problem is not necessary with the laws of the regulations. The problem is the way they’re interpreted. Now, the thing that precipitated their consulting me is that they got information out of a record of a woman with breast cancer. There was a follow-up study which showed that she had the genes that would predict a high likelihood of developing additional breast cancers in her and her family.

They wanted to contact this woman, and the IRB said no, not without the permission of the private doctor. The private doctor did not give permission, and wouldn’t you know it? Four or five years later she developed another breast cancer.

So this is not the main reason to authorize access, but it’s just one of the aspects of unintended adverse consequences of interpreting these regulations.

Thank you for your question. It would not have been better if I had planted it.

CHAIRMAN PELLEGRINO: Dr. George.

PROF. GEORGE: Thank you, Dr. Levine, for your presentation.

I wonder if you could clarify for us... a concept that I thought appeared in one of your slides, and that was the concept, if I have it right, of emerging adolescent autonomy. Have I captured the proper phrasing?

DR. LEVINE: I think you quoted it exactly.

PROF. GEORGE: Now, is that a concept that concerns an individual adolescent and like all adolescents an emerging control both in terms of ability and in terms of permission of family and larger society about decision making or is that a social concept? Is it a concept about the way in which there has been a shift toward permitting adolescents to have more freedom?

And then once that is clarified, do you regard it as a purely descriptive concept or is it a concept for the purposes that you had in mind that has some normative content, that it should guide policy decisions one way or another when it comes to research involving adolescent children?

DR. LEVINE: The answer to your last either/or question is I intend both, but let me go back a little bit. We already have a national policy which recognizes the emerging autonomy of all people under the age of 21. We recognize that there is no autonomy in the infant.
The National Commission's recommendations said that you have to get assent, but in the age range before assent becomes meaningful, children can register what the National Commission called a deliberate objection.

A four year old, for example, not every four year old, but an individual with cognitive development of the typical four year old can’t really understand the abstractions that go into giving assent, but they can be told, "We want to draw your blood, and you know, all these other times that we draw your blood you have to do it because it's for your own good, but this one is not for your good. It's for the good of other people.”

And a four year old can say, "Well, if I don't have to do it, I’m not going to do it." That is not assent, but that’s what the commission called a deliberate objection. It didn’t appear in the regulations, but most IRBs respect this.

Now, what we have from the people who study the development, child development, is we’ve got some milestones. At about the typical cognitive development of a typical age six or seven, we first begin to see the capacity to engage in some of the sort of thinking that goes into giving consent or assent.

The six or seven year old can easily comprehend, "You don't have to do this." They can easily comprehend, "If you do this, it will hurt." But they're not going to be able to respond to other regulatory requirements like, "In case you get injury, there will be no compensation or disability." So six or seven was one milestone.

The next milestone that was offered was about the age of 11 when they could begin to engage in certain sorts of abstract reasoning that would embrace such things as altruism and so on, and by the time they’re 14, probably, if my memory serves — I learned this long enough ago that I do remember it — at about the age of 14 they’re able to go through the processes, the components of consent as good as any adult, as well as any adult.

Between 14 and perhaps 18, 21, even though they can go through all of these maneuvers, what they lack is judgment. They don’t have a mature judgment. Even though they can go through all of these maneuvers, many 16 to 19 year olds have not yet grasped the idea that they, too, might not be immortal, you know.

So, yes, we already have policy that recognizes all of this stuff, and we spin off concepts like mature minors. There's another category called emancipated minors. I think these sorts of things should be brought up as we’re considering what sort of assent we’re going to require in any particular protocol.

I think also that there are some protocols where you might say, "We're not going to give you a general rule here. We want you to interview each child to see whether or not this particular child is capable of independent decision making."

And in the case of the ATN, the Adolescent Treatment Network, in certain types of work, particularly the evaluation of FDA regulated test articles, they want to make sure that you’ve got an individual counselor for each child that gets involved in this, and the main target of that is to help supplement the immature capacity for judgment.

It may or may not interest you to know that when the federal government first issued its proposed regulations for research involving children, it took no position on when children could assent. So it asked the public in the public comment period to help them. They asked either seven or 11 or case-by-case determination by the IRB, and the case-by-case determination is the way it finally came out.

That may be more than you were asking.

PROF. GEORGE: No, I have more to ask.

DR. LEVINE: Oh, okay.

PROF. GEORGE: Actually it's very helpful. I just want to follow up so that I can learn more about it.

So far as the concept is descriptive and within obvious limits, are the milestones strongly socially conditioned? In other words, if we studied different cultures would we find the milestones at about the same place as at six and 11 and possibly then 18 to 21?

And then secondly, within our own culture or generally if there isn’t strong cultural conditioning, are there significant milestone differences between the sexes?
DR. LEVINE: Oh, my. First, let me say you've just taken me beyond the bounds of my competence, but I'm going to answer anyway.

What you'll find is that social perception varies around the world. In my work in developing international documents, I have found that the age of consent, the lowest age of consent I've seen specified in national legislation is 12 and the highest is 21. So to the extent that the regulations or the law of a society or of a country reflects social attitudes, there is quite a bit of variation around the world.

I think also the concept of autonomy doesn't work very well in many parts of the world. So it's really — I mean, I can capture it in one epigrammatic statement. At one of our meetings to develop the SIOMS guidelines, there was a Francophone physician from Central Africa who said, "You know, in your part of the world you've got a saying, 'I think. Therefore I am,' which I thought was really French. He said, "In my part of the world the saying is, 'We are. Therefore, I am.'"

The idea of self-determination in many parts of the world is considered antisocial behavior. Even in Europe, even in like Norway the expression is anyone who tries to rise above the crowd, we hammer them down like a nail.

PROF. GEORGE: I'm certainly not surprised that there would be differences in regulation in different cultures, and it seems reasonable to assume those would reflect different perceptions of ability, but I guess what I was really interested in was the deeper question — and you just might not know the answer to it, but if you do I'd be curious to know what the answer is — whether there are actual differences from culture to culture as to the age at which certain capacities truly do manifest themselves.

So, for example, would the capacity for abstract conceptual thinking be about the same everywhere or might it be different, you know, in Tibet than in Norway or in Albania?

DR. LEVINE: I don't know. I can tell you though you asked also about gender differences. Based upon my totally vicarious experience of research in child development, contrasting, for example, the account of child development of Kohlberg, say, with Gilligan, whether or not people are capable of abstract reasoning at any particular developmental level depends entirely on how do you study them. What do you ask them to do, right?

So I think somebody who follows the Kohlberg model, as so many people who did follow the Kohlberg and his predecessors' model, said that females are, in general, a case of arrested development. All right? That's because they hadn't internalized all of these abstract principles.

And if you read the work of his student, Carol Gilligan, you get a very different vision. You know, so with that lurking in the background, I just don't know how to answer your question.

PROF. GEORGE: A final question that's not related.

DR. LEVINE: Okay.

PROF. GEORGE: And perhaps I was misinterpreting a different slide, but was there in one of the slides a category of anonymous surveys or anonymous questionnaires which were —

DR. LEVINE: Yes, that was the ATN's Category 1.

PROF. GEORGE: And these are regarded as having no risk?

DR. LEVINE: No risk.

PROF. GEORGE: And why would that be? It seems to me it wouldn't be — I can imagine plenty that wouldn't have a list, but I can't imagine saying, you know, in a kind of universal way that there would necessarily not be risk. Certainly some surveys I wouldn't want my daughter to be filling out.

DR. LEVINE: Let me say that one of the badly abused words in our university environment is "anonymous." Many people think it's anonymous if you don't put the patient's or the subject's name in the same place that you put the data, but when ATN talks about anonymous, they mean really anonymous. There is no way to reestablish the link between any personal identifier and the individual subject.

Now, they are talking about utterly anonymous research like going into the medical record room and taking out demographic or other data with no personal identifiers attached, and you have a data set.
Use of that data set would conform to their Category 1. There is no way to link any information to any individual human.

By the same token, if you ring up the clinical laboratory in a hospital and say, "I want all of your leftover specimens of blood," you would send a lot of blood. If they asked you to do electrolytes and stuff like that on it, any that you haven't used, give to me. I'm doing research, but I don't want any identifiers of any sort or even you might say, "Give me only the blood from those who had high blood sugars." This is still anonymous.

This is what they're talking about. Now at the time you're interacting with the subject, at this time the things that are going — I mean you can't be anonymous when you're actually interviewing somebody. So you might then say that there's some aspect of this interview that would rise — that could be considered a risk of injury of some sort, social injury, physical, whatever. Then it would come out of Category 1 and move into Category 2.

**PROF. GEORGE:** I was concerned about matters that would go beyond anonymity. It seems to me reasonable for parents to think there are some questions they don't want their children to be asked about or confronted with, some matters they don't want their children to thinking about. It could be for moral reasons. It could be for religious reasons. It could be because they think that the reflection on that could lead them to behaviors that are dangerous for them and so forth, just the asking and reflecting on the question.

So it seems to me that the content of the questionnaire itself no matter how comprehensive the anonymity could create what could reasonably be interpreted by parents as the risk of harm. Is that not so?

**DR. LEVINE:** Sure, and it's precisely for that reason that the ATN wants you to have community consultation and community advisory boards, to help you out with that sort of —

**PROF. GEORGE:** So there would be an evaluation in the ideal circumstance, an evaluation by some community board of the appropriateness even of an anonymous questionnaire —

**DR. LEVINE:** Yes.

**PROF. GEORGE:** — because there would be a recognition that even an anonymous questionnaire could create risk.

**DR. LEVINE:** Exactly.

**PROF. GEORGE:** Okay.

**DR. LEVINE:** And you know, the regulations say the community representation in evaluating proposals to do research may be limited to one member of the IRB who has no connection with the institution, apart from membership on the IRB.

But what ATN and the whole AIDS treatment program, AIDS clinical trial group, what many of these programs are doing even for survey research is going far beyond that and saying we don't want just one member who could be outvoted or outnumbered. We want a whole community advisory group.

**PROF. GEORGE:** Sure, and that would mean that, for example, the idea of parents' rights when it came to questionnaires for children could be a matter that would have to be deliberated about.

**DR. LEVINE:** It could be, yes.

**CHAIRMAN PELLEGRINO:** Dr. Meilaender.

**DR. MEILAENDER:** Yes, Dr. Levine. Two questions. One I think is just sort of very focused, and the other, much broader.

The narrower one. I think there's a sort of puzzle that folks who aren't regularly involved in this have when they think about this whole set of regulations, and I have to admit it puzzles me sometimes, too. On the one hand, it looks as if you've got a very developed, clear set of regulations that tell you what to do, but then, on the other hand, you get a concept like minor increase over minimal risk, and it's very hard to know what that means actually or why we should share a notion of what it means.

And so I would just welcome anything you had to say about clarifying a concept like that. That's the narrow question.
The larger one is related more to stuff that was just in the reading we've given and specifically to what you've said here, but just that general question that, of course, has been around for a long time that you take up there about whether our primary concern in developing a whole regulatory system should be protection of potentially vulnerable subjects, which protection might, in a sense, deprive them of some benefits of participating in research or whether or not primary concern should be, as it were, making sure that the benefits of participating in the research are available to them.

I took you — I'm not sure whether rightly or not — right near the end of the reading we had to opt to tilt in the direction of allowing to profit from the benefits of it, which even if true, I mean, one might raise a question about whether that's the right tilt in the case of a group like children, for instance. And so I would just on that issue, too, appreciate a little more talk from you about what you have in mind.

**DR. LEVINE:** Two good questions. Let me deal with them in order. What do we mean by a minor increase above minimal risk?

When this criterion was written by the National Commission, it was conceded that no one really knew for sure, but what we thought would happen and what did happen is that we have developed sort of an analogy of common law, what I call a common sense of the community.

As one case study after another has been published on how are IRBs reaching these decisions, and as they go together and have their IRB meetings, usually the largest ones are under the rubric of the annual PRIM&R meeting, Public Responsibility in Medicine and Research, and they share their experiences, we're beginning to get a pretty good idea of what most people consider a minor increase over minimal risk.

Minor increase is one of a — the term "minor" in this case is what some philosophers will call a dispositional characteristic. A dispositional characteristic is something that suggests a category. In the law we have the reasonable person standard. Some people say, "I want to pin it down. What is a reasonable person?"

Well, you know, in England its the man on the Clappam (phonetic) Omnibus or something like that. If you pin this down, if you freeze it in one place, it loses the usefulness of a dispositional concept, and you have to invent a new term to cover what you were talking about.

The example that the philosopher who gave us this concept, Royal, used was elastic. I say "elastic," and you know what I'm talking about. What if someone comes in and says, "Elastic means that a six inch rubber band will stretch no less than one inch and no more than two inches"? All right. Now you've got a satisfactory stipulated definition of elastic. You have to invent a new term to cover the full range of what you really wanted to talk about when you said "elastic."

I put reasonable, minor increase, things like that into this dispositional category. I think the way we kind of evaluated it is as an IRB is sitting and making a judgment about what is a minor increase, they ought to be thinking about what other people on other IRBs. Will they consider our judgment reasonable within the boundaries of what we ought to be permitting?

And that's the main touchstone they have for evaluating things of this sort. That's your first question. Is that satisfactory, or you want me to do better or do worse?

Now, what about —

**DR. MEILAENDER:** Maybe you could do better in one way. Just examples of. There was an example in the reading somewhere that you gave us of bone marrow examination or something like that for somebody who already had it. There was an example that Loretta Kopelman gave years ago in an article about the kids in I think it was the human growth hormone study and the various things that they had to do yearly, I believe, that just to the ordinary lay person might sound like something you'd call more than a minor increase over minimal risk or examining my bone marrow. Even if I've had to have it done a few times for medical reason might sound like it.

How do we know that the case law developing among IRB people reflects what just sitting in probably a less informed way in my living room I might say, "Well, that doesn't sound like a minor increase."

I do think there's still a problem about cases there.

**CHAIRMAN PELLEGRINO:** Well, Loretta Kopelman wrote her critique of that study. This was a
study that had to do with giving human growth hormone injections to children who were short for their age but had no disease. They did not have human growth hormone deficiency. In order to give this stuff, in order to evaluate this stuff, you had to give half the group the growth hormone and you had to give the other half placebo, and this was administered, I think, by subcutaneous injection. Do you remember?

And blurring the two, the other one was the papilloma virus vaccine that had a very similar argument and structure. One or the other of those protocols required that you give these children, eight, nine year old children, two subcutaneous injections a week for a year and a half.

And Loretta and some others thought it was unduly burdensome to give a child two subcutaneous injections of placebo for a year and a half, and so she was part of a committee that was assembled by the National Institute of Child Health and Development, and they reviewed this protocol according to what we call Section — what is it? — 407 maybe of the Subpart D, which is something that meets when you're proposing to do something that presents greater than a minor increase over minimal risk. It requires a full review under the requirements of the Public Advisory Committee Act, and so on.

And they conducted this review, and Loretta was outvoted on it. This is going to happen. I was not a member of that group. So I was not privy to all of the arguments that were presented, but I could see that she had a good point to make there.

Let me get to your other question. There is a tension always between protecting prospective research subjects from harm and developing knowledge of products that will be of benefit for these subjects. There is always a tension, and if I wrote the last part of my paper, which incidentally is in Loretta Kopelman's book; if I wrote the — I think I called the last few paragraphs the epilogue, and if I came out suggesting that I think that developing benefits should always triumph over protecting subjects' rights and welfare, then I did a poor job of writing that epilogue.

I think that they should always be in tension, but what I have to say though is when protection was the dominant approach to evaluating research involving children, we developed what the National Commission recognized as a class injustice. Just because these children were unable to consent, we protected them. We kept them out of research, and from 1962 until the time the Commission was meeting, only two drugs had been approved that had been evaluated in children to the extent that you could say here is our advice on dosing. Here is maybe the children are more or less sensitive.

Why do I pick '62? Because that's the date of the Harris-Kefauver amendments to the Food, Drug and Cosmetic Act. Before that time, you did not have to show a drug was effective in order to market it. You just had to show it was safe.

And so this was not a problem, but as soon as you call for efficacy, that means you're calling for clinical trials. That means if you don't involve children in the clinical trials, you can't provide advice in how to use the drug.

Now, this, I think, I agree with the Commission that it was a class injustice. So I think as we review each proposal to do research on children or any other vulnerable population, we have to be aware of the fact that we're balancing protection versus benefit.

I mean, women got an even worse deal out of the '62 amendments. For many, many years nothing was approved because they ruled out — I hate this expression, but it's what the — women of child bearing potential. One woman said much has been made out of children becoming the therapeutic orphans, but just like children, we as women are being, and I quote, "protected to death." Wish I could have thought of that.

CHAIRMAN PELLEGRINO: Dr. Schaub.

DR. SCHAUB: Robby covered the questions I had. I should go on record with that. Robby covered my question, and it was about anonymous surveys.

CHAIRMAN PELLEGRINO: Thank you.

Dr. Kass.

DR. KASS: Well, Bob, two questions. Less about the presentation, but more about your sense of the state of things with the ethics of governing research using children.

If I'm understanding what's in the documents that you presented and the talk you gave here, certain
misconceptions of previous formulations have been in the process of being corrected. The principles seem to be well articulated. The problem seems to be kind of excessive burdens on the IRBs owing to not so much wrong principles or wrong law, but slavish excess addressing of questions that one ought to be able to expedite.

(a) Is that — let me do it sort of piecemeal. Is that a correct assessment? I mean is there intellectually as opposed to making the system run more efficiently — are there large intellectual ethical difficulties that you think need further addressing or have the people like yourself who have been working valiantly in this field for now 30 years or more, have you more or less gotten these things well in hand?

I made it difficult for you by giving you some praise in the course of the question. I don't mean you to be embarrassed by this. As a person who studied this, do you think that we really have the ethics of using children as research subject more or less in good shape and that the problems are simply the refinement of the applications in the IRBs?

**DR. LEVINE:** I don't see us making much progress in developing the underlying ethical arguments or underlying, if you will, theory with regard to involvement of children as research subjects.

I think what I see now is a turn toward excessive bureaucracy, excessive attention to pointless detail, and I'm going to mention why I think this is happening in a minute.

I think that in ethics generally, the ethics of research involving children was largely formulated in the 1970s, very little by way of advance since then. And the ethics of research involving children is very much the ethics of the 1970s. Some people sneer and call it principalism, but it's very much in that vein.

But if you look at the purpose of regulations, there's something that would have to be enforced by bureaucracies, and you can't get into some of the other types of ethical reasoning that seem to me much more attractive, such things as narratives, such things as what Gilligan would call the care oriented framework as distinguished from the justice oriented framework.

I think I would like to see that sort of ethics become the cornerstone of discussing the ethics of pediatric practice or, for that matter, all medical practice.

I wrote a paper somewhere in the 1980s called "The Teaching of Medical Ethics, Contrast Between What We Want and What We Teach." Everyone wants caring physicians, but we've set up all of our teaching of ethics to create great obstacles to the caring physician.

So I want to see pediatrics; I want to see the ethics of medicine going in a different direction, but I don't see the ethics of research going that way because in the practice of pediatrics, practice of medicine, you're mostly talking about a relationship that can evolve and develop over a period of years, and the researcher, it's not so bad to have what Tolman would call an ethics of strangers for the researcher-subject diad. They are, after all, strangers.

The research defines what he or she wants to do for a certain we call it sample size, and people who meet the entry criteria come in. They relate to each other until they have completed their mutual purpose, and then they go their separate ways. An ethics of strangers seems okay.

Not so for the doctor-patient relationship.

**DR. KASS:** May I continue?

**DR. LEVINE:** Please. Oh, one thing I didn't do, Leon. You asked me to say how did it get this way. Do you want me to do that? Why are we so bureaucratic now?

**DR. KASS:** Maybe a couple of words on that would be useful actually.

**DR. LEVINE:** That's one of my favorite topics. In the 1970s and 1980s, IRBs — in the '60s even — IRBs were there to look after the rights and welfare of the patients. They were very informal. The IRB at Yale New Haven Medical Center was created in 1961.

I became chairperson in 1969. The first protocol that has a number and a file is 1969. It was very informal in the old days.

During the '60s, '70s, almost all IRB chairs around the country were clinical pharmacologists. In fact, most of them were the folks who trained in the same lab I did, and that's because clinical pharmacologists are generalists. They're not looking at one drug. They're looking at all of these
And then in the aftermath of the National Commission, more and more of this was taken over by regulatory oversight. Still the system functioned fairly informally with good people trying to do good things until the time that what used to be called OPRR, the Office for Protection from Research Risks, began to get rather heavy handed in making site visits to university research operations and closing them down.

Well, before that time, the people who were running the IRB were people who were devoted to doing this and had a pretty good knowledge of the field, the relevant ethics and regulations and so on, not that everybody on the IRB knew all of the ethics, but every IRB had somebody who did and could explain things to the others.

What happened when OPRR began closing institutions? It got the attention of the provost. Now, the provost, until the ’90s, people would say to me, "As IRB chair, who do you report to?"

And I would say, "The Dean."

But the way the Dean knows I’m doing a good job is that he never hears my name. It's not a formal reporting. I didn’t walk in once a week and say, "Here’s what we did last week.” But maybe once a year I would chat with the Dean and say what we’re doing.

But any time he heard my name in the role of IRB chair, apart from schedule, this was probably because somebody was irritated about what we were doing.

Now what we have is the provost moves in, and the provost reads the list of observations made by OPRR when they closed Duke University, when they closed Rush Medical Center, when they closed Johns Hopkins twice, and they would read all of these things. In fact, somebody collected all of these observations and counted them up and published them in the *Annals of Internal Medicine*.

Number one, doesn’t do periodic reapprovals at convened meetings. And the provost, not knowing anything about the field, says, "That’s important. That’s the most common observation they made here."

And so from then came this drive toward meticulous responsiveness to everything OPRR ever wrote in an evaluation letter. All right?

I think also the public is getting concerned the way it did in the early 1970s when we had Tuskegee and Willowbrook, you know, Jewish Chronic Disease Hospital. Anyone in the research ethics field can kind of recite all of the classic cases of abuse.

Now what we’re getting is reports by the Office of the Inspector General saying the IRBs are doing a bad job because they’re overburdened. We’re getting all of these stories about closings of university research operations, and we’re getting just like Tuskegee, we’re getting the Gelsinger case. All right? We’re getting the Kennedy-Krieger Institute in Baltimore led exposure. We’re getting the CHEERS study from the Environmental Protection Agency, and there’s a lot of scary stuff that’s being put out there.

But, once again, the public is not getting a full account of things. They are not seeing the denominator. You know, for every case you hear about, there’s 10,000 you never heard about.

Enough. I think I’ve made my point.

So I think the pendulum of public opinion is swinging back toward where it was in the ’70s.

**DR. KASS:** Yeah, I don’t want to preempt comments from others, but could I just follow up? Is there in your opinion something that you would urge upon this Council to do in this area?

And part of the answer to that is is there not a group at NIH who is working on development of some further refinements along these lines to deal with the overburdening of the IRBs and things of that sort?

But in general, this morning we were treated to strong recommendations as to what this Council should or should not say in order to solve a major problem. I’m wondering whether you have not so much a strong recommendation for a conclusion, but a strong recommendation for a piece of this subject that you think deserves the attention of this particular body, or is this something that the field itself is going to be able to work out on its own?
DR. LEVINE: Leon, I have not gathered my recommendations into the form of an overarching recommendation of here's what you ought to do, but given the opportunity to say something now what I would do is ask the Council to take steps to reel in this runaway bureaucracy; to have the IRBs stop dissipating all of their energies in doing the pointless things, some of which I specified for you.

Give them the opportunity to spend some time thinking about real ethical issues. We're finding as a result of some of this that people are becoming less and less willing to serve on IRBs.

I quoted Norman Foster earlier. At the same meeting that he presented his informal survey of the results of review of periodic reapprovals, he said that he actually had two members of his IRB stand up and walk out in the middle of an IRB meeting saying, "This is not why we joined the IRB, doing what we're spending all of our time doing. This is not the thing that attracted me to serve on IRBs."

I've made that statement in public before and somebody said, "That's self-serving. You're trying to make life easier for your friends, colleagues."

It's not self-serving. It's not at all self-serving because the only thing, the only thing that allows the IRB to do what good it can do is to have the dedicated, learned people find it's worth their while to get together from time to time and to discuss the ethics and to some extent regulatory compliance.

I think if you could find a way to restore the status of the IRB and to restore the attractiveness of service on the IRB, that that would be a great contribution. I don't want to seem totally innocent of the realities of everyday life.

Another thing that's making it hard to get people to serve on any committee is the budget crunch. When you tell the members of our clinical departments that you've got a quota, you've got to bring in this amount of money and if you don't, we're going to cut your salary, well, they're not bringing in any money serving on the IRB or the Admissions Committee.

So there's other things going on, but I think it's within your capacity to make a statement about what is within the control of the federal human subjects protection community, I'll call it.

DR. FOSTER: That's very helpful. Everything you've said has been really, really helpful, and I think Leon was driving to the issue where we had thought — he and I talked a little bit about it this morning — well, maybe there's not so much importance about the research in children because of the fact that there's so much already written about it. It's hard to know whether there's anything really new about it.

But the idea about restoring the importance, I mean, to give time to do what has made it relatively safe, which is at jeopardy because of all of these what you presume is largely mindless activities of the bureaucracy, that might be something that we could do something on.

And I'm not myself very enthusiastic about pursuing protection of adults or children anymore. I Mean it has just been going on for so long. You know, you've got the Jesse Gelsinger case, you know, mistakes like that. There are always, but the denominator is very large.

So I think the most important thing that you have said is the last thing. I don't know whether Leon or the rest of the people agree with it, but I would think that would be — and it wouldn't take a whole lot of work to do that, but it would — if it came from a group like this, which is not filled with bioethicists to argue the point that you have made, it might have more impact than if a person like yourself, who has been such a stalwart, to do it.

I just want to thank you for bringing that up, whether we do it or not. I think that's a very important point to bring up.

DR. LEVINE: Well, thank you. You know, the Gausier case is a very good case to consider for a minute. After this unfortunate young man died, everyone said, "Well, if there had been an adequate IRB review, this would not have happened."

This young man died because there was an investigator who told lies to the IRB and who told lies to the FDA. This guy did a double jump in a Phase 1 gene transfer evaluation even though there were adverse events at the dose level from which he did his double jump.

This gives the whole human subjects protection field a black eye because the journalists are saying, well, the IRB could have done it, could have stopped this if it was adequate.

I can go on and on. May I tell one more story about —
CHAIRMAN PELLEGRINO: Yes.

DR. LEVINE: — a problem? How many of you know about the UCLA schizophrenia placebo study? How many of you have heard of it? Astonishing.

When the litigation was filed about two — it was a class action suit with two named plaintiffs who were damaged by being in a placebo or receiving placebo instead of an antipsychotic medication. This was banner headlines in almost every American paper. This was high level coverage on "60 Minutes," everywhere.

I've talked about this in front of groups of IRB people. They all have heard of it. Then I say, "How many of you know what the final outcome of this dispute was?" Nobody.

The final outcome, they asked for $70 million. The final outcome is that UCLA settled with the plaintiffs for $199,000. Why? Because their lawyers advised them that it would cost them $200,000 to win the case. Okay?

All right. We don't need all of this fuss. We'll give you 199 if you go away.

What does this translate to? This translates to not one nickel for the plaintiffs. The lawyers got $199,000 and estimated that their actual out-of-pocket loss was $2 million.

The meaning of this is that these lawyers knew they didn't stand a chance if they argued this in front of a jury, but the point I'm trying to make is that when somebody makes an allegation about our human subjects protection system you get "60 Minutes," you get headlines, and when the case is resolved, you can't find it in the classified ads because it's note even there.

And that's part of our problem.

CHAIRMAN PELLEGRINO: Thank you very much, Bob.

Well, I think we're right on time. So we'll regather now at 3:45.

(Whereupon, the foregoing matter went off the record at 3:30 p.m. and went back on the record at 3:50 p.m.)

SESSION 4: CHILDREN AND CLINICAL RESEARCH

CHAIRMAN PELLEGRINO: It's time to reconvene. We're actually five minutes late, but we'll get back on schedule.

Our next speaker is Dr. John Lantos, who is Professor of Pediatrics and Associate Director of the Medical Center for Clinical Medical Bioethics at the University of Chicago.

Dr. Lantos is going to address us on the question of children and clinical research, continuing something of the discussion we've had a little bit earlier.

John.

DR. LANTOS: Thank you.

So I'm a general pediatrician and a former associate chair of the IRB at University of Chicago, and that discussion at the end of Bob Levine's talk was pretty interesting because I quit being chair of the IRB after they imposed the regulation on us that the IRB chair had to read at a convened meeting all of the amendments that had been submitted. And if any of you have ever been on the IRBs, the amendments tend to be wording changes in the informed consent form. There would be 200 or 300 every meeting, and at the end of every meeting the chair would go through them reading, "This was submitted. Here was the old language. Here is the new language," yelling, "aye," approved. Here was this, and the rest of us would go get coffee or cookies, and this was read into the tape recorder so that when we were audited it was clear that this was discussed.

So the concerns about IRBs and their current function in relation to their mission, I think, are important ones to address.

In my own work, I look at innovative therapies in pediatrics, things like neonatal intensive care, growth hormone, cancer chemotherapy, bone marrow transplants and that sort of stuff, and really focus my scholarly work on that gray zone sort of just beyond what's usually considered research and sometimes called innovative therapy in some of the dilemmas that arise in that area.
So I'm going to talk today about where I think we are in the regulation of pediatric research, where I think we should go, and come out at a little different place than Bob Levine came to. I think there are some important things to be done that this Council might be able to speak to, and I'll tell you where I'm going so that you can then listen wondering how I might ever eventually get there.

I think today — and this is partly in answer to Leon's question at the end — I think today we have a marvelous set of moral guidelines for research in children and people like Bob Levine helped develop them, and a lot of the people who he cited helped put them together. And they're marvelous, in part, because they're half written and, therefore, require interpretation in order to be operationalized. And unfortunately, there are only about a couple dozen people in the country who understand them and are familiar with them, and they meet regularly and write articles about them and regularly disagree, quite often passionately, and they'll have discussions about 45 CFR 46 and Subpart D and what the latest 407 Committee did, and everybody else will sit there shaking their head going, "What in the hell are they talking about?"

(Laughter.)

DR. LANTOS: But they're sort of important, subtle distinctions about what sort of research is permissible, and as a result, there's a set of robust but arcane understandings by this small group of highly trained professionals which incorporate ethics, but don't necessarily apply it in their day-to-day work.

In a way it's a little misleading to have someone like Bob Levine come here speaking as if he's a typical IRB chair since most IRB chairs did not participate in this process, are not steeped in the history of the ethics, where it came from.

Our chair at Chicago is an anesthesiologist who proudly claims to know nothing about ethics and works closely mostly with the compliance officer in making sure that the institution is protected from risk management.

So what we have is a good set of rules and an abysmal system for operationalizing the rules, and that's, in my opinion, where the action is and what this Council should think about ways to address. So let me explain how I think we got there and then offer some specific suggestions about how we might address the problem.

So the modern debate about the ethics of children's participation in biomedical research began as a theological debate. Paul Ramsey and Richard McCormick, both of whom were rooted in specific religious traditions, but neither of whom was arguing on the basis of their particular theology, framed the issue, and this was in the late '60s, early '70s, as one of finding the balance between the obligations of adults towards children and the obligations of children to their community.

In a sense, their differences about where we should come down on this reflected their different views, in my opinion, of the meaning of children's innocence. In Ramsey's view, we should treat the child as radically innocent and pure and, therefore, as someone with different obligations to the community than those demanded of adults with full-fledged community membership. To be a member of the adult community is to be autonomous, and by implication both selfish and also capable of sacrifice or altruism for the community.

And this was important because for Ramsey, participation in research was seen as an altruistic sacrifice. Innocent children were seen as in special need of special protection from the moral taint of selfishness that the adults suffered from.

So the moral dilemma of selfishness versus altruism was something an adult could struggle with, but a child could not.

McCormick's contrasting view was that the child was already a full-fledged member of the moral community even though he or she was unable to exercise some of the prerogatives of that membership, and as a full-fledged member, he or she deserved the same protection as an adult, but not more protections.

And more importantly, he or she had obligations to that community. In particular, the child had an obligation as would an adult to participate in relatively low risk research projects that could benefit others.

So McCormick's view was different in that it shifted the notion of obligation and made it reciprocal from day one. Note that neither theologian based their arguments on any notion that there was
benefit to children or to the child who was participating in a research protocol, although both talked about the possible benefits to the community of children, but research was seen by both as an endeavor in which the risks to the subject inevitably outweighed the benefits, therefore as a selfless or self-sacrificing or altruistic act.

So Ramsey's view led to the conclusion that it was always wrong to conduct research with children as subjects, although sometimes we should do so anyway with trepidation but without, as it were, a clear conscience.

McCormick's view seemed to be that it was sometimes right because children, like the rest of us, have moral obligations to the community, and it's sometimes right for each of us to make sacrifices for the community.

Now, a number of things have happened in the world of research and research ethics since this Ramsey-McCormick debate that in my opinion shift in significant ways our understanding of the proper response to this dilemma of research involving children, but their central insight remains powerful, but the fundamental issue is one of the relationship between children in the community and the question should be what, if anything, do we owe our children and what, if anything, do they owe themselves and us, and what can we do theoretically or ethically or legally or politically or economically in order to make sure that these obligations are duly and fairly discharged? How do we best take care of them so that they will some day grow up and be able to take care of themselves and, as these things often go, take care of us some day as well?

This basic argument or responses to this question in modifications to the Ramsey-McCormick framework over the years have been framed in three different ways: one that I will call utilitarian, one that we might call epidemiologic, and one that is more bioethical. And I'm going to talk a little bit about these three revisionist framings that present the dilemma in terms that are somehow, I think, more conducive to, say, a secular society's preference for scientific or utilitarian language or other non-theological conceptual framings.

The utilitarian framing of the issue looks at the net welfare for children, and we talked a little bit about that in Bob's session. We say that the community of children overall would be worse off if no children participated in research, and then by a sort of implicit calculation that is the central and centrally problematic feature of all utilitarian reasoning, we argue that since each child is a member of the community of children, each might be harmed by the use of inadequately studied medical interventions, and that each child would or could be incrementally worse off if no research gets done.

So the direct and immediate harms of participation in research are weighed sort of metaphysically against the potential benefits that might accrue if the results of that research benefit each particular child. We carry out the mediphysical calculations in our head and end up with the result that some research must be permissible as long as it doesn't involve too much risk or as long as the benefits to the individual research subject outweigh those risks.

And then we go to great pains to try to precisely quantify the risks even though we know that the very nature of research dictates that the most important risks may be unanticipated and, therefore, unquantifiable.

Sincere attempts to balance risks and benefits in order to minimize the net risk and to stipulate some threshold of permissibility seems to me to be the correct solution to this problem, and this is the line of reasoning that generated the federal regulations that talk about minimal risk and minor increase over minimal risk and some increase over the minor increase over minimal risk that leads to the 407 committee review and incorporate, in my opinion, deep moral insight and are full of wisdom. I even like the vague fussiness of terms like "prospect of direct benefit" or "minor increase over minimal risk," and the wisdom here seems in part to be the wisdom of moderate ambiguity.

I was reminded of this at our Seder this year where we were talking about what constitutes a cup of wine as a moral obligation to drink four cups of wine, and at least according to one source the rabbis gave a precise answer to that. A cup of wine has to be at least the size of two olives.

(Laughter.)

**DR. LANTOS:** And that sort of answer that is a non-answer but that gives, you know, an inclination. Some guidance, I think, is what we're looking for.

Another modification of the Ramsey-McCormick framing of the issues and the one that I call epidemiologic has been through discussion of a concept that I called in a paper I wrote, and it's in
Empirically, many people have observed that many subjects in clinical trials who are in the placebo group do better than patients who are not in the trial at all and, therefore, it seems should be receiving the same treatment as those subjects in the placebo group, and yet they have better outcomes.

hey have a better outcome? A number of explanations have been proposed. All remain unproven, speculative, high theoretical. One explanation is that placebos actually work. Another the accoutrements of study design, monitoring, standardization of care, attentiveness to side effects and that sort of thing are what lead to the improved outcome.

Some believe that it's all selection by us or artifact that subjects who were recruited into studies are in some fundamental way different even though they're not supposed to be from patients who are not.

And all of these explanations and a bunch of others seem plausible, some more plausible than others, but epidemiologically it doesn't really matter because epidemiology doesn't necessarily seek explanations, just associations, and there seems to clearly be an association between inclusion in a clinical trial and better outcomes.

Now, the underlying question raised by this concept, the ethical question, the concept of inclusion benefit, is one of the true nature of the risk of participation in clinical trials. If for whatever reason study subjects who receive standard therapy actually do better than patients who are not in the study, then the whole basis for the concerns of the Ramsey-McCormick debate and the whole justification for the regulatory apparatus that those concerns spawned based as it is on the idea that research is riskier than therapy becomes irrelevant, invalid, and misguided.

Instead, research subjects are in a safer condition than patients receiving therapy. They don't have to be altruistic. Instead they are rationally self-interested. They don't participate out of moral obligations of the community. They don't need to be protected. Instead, they should be required to give informed consent not to participate in a clinical trial, and children's whose best interest must be protected in ways that adults don't, might be mandated to be enrolled in clinical trials even against their parents' preferences.

Parents who refuse may be thought of as neglectful. I push this to an extreme, but maybe not an outlandish one because I believe that in general, and across the board, subjects in clinical trials are today safer than the average patient getting treatment either in the hospital or in the out-patient setting.

And if that's true, then the way we're going about regulation is at least misguided, if not worse.

There's a third revision to the Ramsey-McCormick paradigm for thinking about research risk, one that might be called the moral dictates of equipoise argument, and it goes like this. If a doctor or the medical community is genuinely uncertain about which of two treatments is best, then the most rational and efficient way to insure that each patient gets the best treatment is to randomize patients, collect outcomes, analyze the data, and alter treatment choices only after one treatment has been proved superior to the other.

By this argument, randomizing as soon as possible and with each and every patient is the best way to do what's in the patient's best interest, and this is an approach that is essentially used in pediatric oncology today, where virtually all patients are treated on protocols because doctors believe and parents come to believe that the protocols are, in fact, the best way to make sure each patient gets the best treatment in a situation where doctors are genuinely uncertain whether Treatment A or Treatment B is better. Randomizing them maximizes the chance for a good outcome, and by this approach, the Ramsey-McCormick sorts of conflicts disappear as well.

Interestingly, the concepts of inclusion benefit and the argument from equipoise, powerful as they are, have not changed the prevailing regulatory paradigm about research risks at all. If anything, the paradigm seems to be moving in the opposite direction, imposing more and more protections to still regulate research as if participation added risks to subjects rather than diminishing them.

This seems irrational, but perhaps it isn't. Perhaps instead it reflects a deeper fear of research than the one we generally analyze and regulate, that is, the fear of direct physical or psychological harm to study subjects. And what might that deeper fear be?
I think it's a fear that has come up in a lot of the deliberations of this Council, that somehow the whole medical research enterprise suffers from a sort of hubris that we are up to no good, that we are going to get ourselves into trouble, that mad scientists are going to hijack not just our tax dollars, but our cherished notions of what it means to be human. It's a fear that we're trying to steal fire from the gods, that we're upsetting the order of nature and that we will be punished for it, fears that perhaps medicine is not working to enhance human dignity but to undermine it.

And by this view the only way that we can avoid punishment is by recognition of an anticipatory expiation of our sinfulness by identifying it in our research enterprise and ruling it out. We don't use hubris language generally, but we are possessed with risk in ways that go beyond quantitative analysis of what these risks might be.

Even if you don't think research is beneficial, the operationalization of these concepts of minimal risk and minor increase above minimal risk has a quantitative absurdity to it that was highlighted in a recent paper in JAMA where they tried to quantify the risks of everyday life which is the standard against which participation in research ought to be measured, and they took all of the data on known risks of being in research projects based on reported adverse events and compared them to things like riding a bike or riding in a car or playing on a school football team and found that our tolerance for risk in research is probably an order of magnitude lower than our tolerance for the actual risks of everyday life.

And part of what we're doing it seems, is, if this sort of fear of hubris and seeking of absolution argument makes any sense, is we're arbitrarily designating one domain of medical innovation, the stuff we call research, which takes place in formal research protocols, as the only place where this sinful hubris rears its ugly head. And then we treat those who engage in research as if they were doing something morally much dicier than what those doctors who are doing routine clinical care are doing, and they need to be carefully supervised. They are not safe, and by implication everybody else sort of is.

Now, even a cursory look at what goes on in pediatric medical centers today shows what a precious and inadequate view this is. Most of what we do in tertiary care or pediatrics today is radically and thoroughly nonvalidated. Most drugs used in children's hospitals today are used off label. They've never been studied in children and are not approved by the FDA for use.

We don't know, for example, such basic things as the proper dose of oxygen for a premature baby or the best blood pressure at which to maintain those babies, that is, what use of dopamine or dobutamine or other pressors are the best way to treat pain for children with complex chronic conditions or psychological problems. We don't know the best medications, though we use scores of them, or the drug-drug interactions that might arise.

Nevertheless, we use such interventions willy-nilly, treating problems in ways that may make children better or may make them worse, and we do so with impunity as long as we don't have the hubris to think that we might better care for children if we studied the effects of these interventions in order to use them more rationally.

Better research could answer many of the questions, but oddly, we place daunting regulatory barriers in the way of those who would study those matters, but none in the way of those who would use the interventions without study. Or as one doctor put it, "I need IRB permission to give a nonvalidated drug to half my patients, but not to give it to all of my patients."

As long as one doesn't have any desire to learn, that is, to create generalizable knowledge, one is free to do whatever one wishes.

The implicit moral question seems to be that harms that result from our ignorance are more forgivable than harms that result from our attempts to lift the veil of ignorance. Ignorance, it seems, has a pristine, naturalness to it. Attempts to gain knowledge have a corrupt ambitiousness to them.

I wish I could phrase these matters in terms less hoary or spiritual, but it seems that the phenomena in question, the actions and the descriptions of those actions that come down to us, aren't well explainable in other terms.

Now, my framing of the argument in these terms suggests something perhaps about my own view of where we should go from here. My colleague in Chicago, Lainie Ross, recently wrote a book about ethical issues in pediatric research and her subtitle to the book was "Access Versus Protection."

The subtitle implies that these are opposing choices, that if we enhance children's access to research, we somehow diminish their protection and place them at risk. I fundamentally disagree with that
framing. I think the best way to protect children from the risks of uncontrolled medical innovation is to make pediatric clinical research easier to do.

That doesn't mean it should be unregulated. It means it should be better regulated. How might that be achieved? How might we nudge the system that we have now towards more generous, less inhibiting approach to research regulation? I think we are today at a very interesting point in the public policy regarding research regulation in children. As we discussed in Bob's session, we understand the problem. We have some good and sophisticated federal regulations. There are quite thoughtful debates about how best to implement these regulations, what minor increase above minimal risk or something might actually mean. There's little disagreement today, I think, about the underlying paradigm. Nobody really wants to blow the whole thing up and start over, but what we need today is a way to best operationalize these standards of risk and the balance between access and protection, and the efficient implementation of the procedural paradigms that will help generalize the knowledge that now in my opinion is held by this small coterie of experts in the field.

What we need, in short, in my opinion, is to develop a more formal and robust casuistry of research ethics. We need case based studies that open up to us the choices about how the principles should be applied in each specific protocol, and we need to find a way to capture or a better way to capture and to institutionalize the wisdom of these smart people who have thought a lot about this in ways that, as Richard Epstein might put it, increase net social utility.

This can only be achieved through a formal, transparent and trustworthy system of case review, commentary and adjudication, something that does not exist in the current system of research regulation.

The balance to be struck now then in my opinion is quite different from that imagined by Ramsey and McCormick. It's not about sinning bravely. It's not about deciding when children should be exposed to risks for the benefit of others. We've moved beyond that.

Instead what we seem to be debating today is the proper locus of regulation, whether it should be decentralized local regulation as embodied in the IRB system where each IRB sort of has its own autonomy, or whether there should be a more centralized and, therefore, consistent but distant approach that is some sort of appeals process for IRB decisions, reporting of the rationale behind decisions, and opportunity for public discussion.

The former, the local IRB approach, seems more like what bioethicists in the '60s and '70s had in mind, and their idea was that there would actually be sort of moral deliberation taking place at the IRB level about these protocols. As we heard in the earlier session, we've moved away from that.

The latter approach, the one that I'm advocating, seems more legal than bioethical, and generally I think anything that's more legalized is a bad idea, but unfortunately, I think what we've ended up with today is the worst of both worlds, that is, we have nonaccountable centralized control, that is, the federal Office of Human Research Protections (OHRP) that as best I can tell answers to nobody, but that oversees the local IRBs that operate with inconsistence and idiosyncracy.

Many studies show wide variation in the way local IRBs actually apply these regulations with things like the question that came up. What counts as a minor increase over minimal risk? And people have done studies where they have sent IRBs various protocols and shown that they're all over the map in whether a particular protocol would pass or not, based on their understanding of the criteria. And these are published in JAMA or other peer reviewed journals, and everybody goes, "Huh, yeah, it's random." Not much you can do about.

Many investigators, I think, correctly view IRB chairs as despots with absolute power and minimal accountability, and even if they are benevolent despots, there's no way to know it.

IRB chairs tend to view OHRP the same way. That is, they see their task not as applying their own moral insights, but as protecting the institutions from random audits and the fear of draconian punishments for relatively minor transgressions, that is, not reading out every amendment to a protocol at a fully convened meeting leads to the shutdown of entire institutions and all of their research protocols.

And so what we've come to is a climate of caution, self-censorship and the domination of institutional risk management approaches over careful moral reflection. It's a counterintuitive result because the rules that led to this system were meant to preserve the local control of IRBs to make them exquisitely sensitive to the local conditions in the way that a federal or centralized IRB might not.
But what they have led to is this inconsistent application of highly technical federal regulation in ways that are not reviewed, not disclosed, and therefore, not available for public critique.

The reasons why we have ended up with this are complex, but let me just briefly suggest two, and then I will try and finish up and hopefully have some discussion.

One of the reasons is that the mandate for IRB review is an unfunded mandate. So IRBs are staffed by volunteers from academic institutions and that may have made sense when the process was more informal and the group could meet, but as it works today, with every protocol having to be reviewed every year, with every amendment having to be reviewed, with every adverse event having to be reviewed, we have an IRB that used to meet once a month, but the meetings were running ten hours. So how they’ve split up into three separate IRBs, and even with that they’ve gotten the meetings down to about four hours. There’s about 15 faculty members on each of the three IRBs putting in four hours a month of committee time, plus all the review time with no compensation.

And I think you get what you pay for. In this case it’s amateurish, idiosyncratic, and often bizarre reviews or the jobbing out of the real work of the committee to a paid staffer who is usually basically a compliance officer.

So that’s one, the unfunded mandate. If this system is going to work, there has to be some way to put some funding in it to make it work better.

The second reason I think they don’t work is sort of more interesting in some ways from a legal perspective, and that has to do with the reason why IRBs preserve privacy and confidentiality.

It’s hard to come up with a good explanation for this that’s framed in terms of the protection of research subjects, and the usual explanation is that it is necessary to protect the careers and the intellectual property of the investigators. There’s no other reason I can think of to make these deliberations confidential, and that’s possibly an important concern, but to the extent that research in children is to become a more publicly accountable enterprise, there must be ways to protect investigators’ intellectual property that are consistent with a more open, transparent, and publicly accountable review process.

So in place of the current system what I would propose is a system that was more formal in its adjudication methods, but also more transparent to research institutions, to investigators, to parents in the case of pediatric research, and to the public. In short, we need something like an appeals court system, a system called pediatric research courts, and the goal of such a system would be to help researchers apply agreed upon and quite satisfactory standards, and it would do this by hearing cases, publishing rulings, establishing precedents, generalizing interpretations in a way that was truly public, meaningfully accountable, and transparent.

Such a system would have to be collectively subsidized in a transparent way, too, because it would certainly cost money, but I think it would be a tangible expression of our commitment to protecting children from both the risks of research and the risks of unstudied innovation.

And in that sense, it would return full circle to what I see as the central question raised by Ramsey and McCormick: What do we owe our children? And it would answer it by saying we owe them a functional system for the oversight of pediatric research that maximizes the opportunities for children to receive the latest treatments, the best treatments, and the safest treatments, even if and especially when these treatments are given as part of a carefully designed, carefully monitored, and adequately reviewed research protocol.

In my opinion, we owe our children this much at least.

Thanks.

(Applause.)

CHAIRMAN PELLEGRINO: Thank you very much, John.

Dr. Lantos’ paper is open for discussion. Dr. Meilaender.

DR. MEILAENDER: Thanks very much. That was nice in a lot of ways.

But I have two questions that probably may sound to you as if they are willing to reckon with blowing up the whole system, which you clearly don’t want to do, but they have to do with the inclusion benefit, your discussion of that, and with the equipoise issue.
You said about what appears to be the case with respect to the inclusion benefit that it really makes the issue in that earlier debate irrelevant. I don’t actually think you believe that because of some things you said you wrote in the pieces that we had. But nevertheless you did say it, and I mean, I understand why you’re saying it.

But doesn’t saying that depend fundamentally on believing that the only important moral question is the one that has to do with harms rather than wrongs? At least in some ways of thinking morally, it is possible to wrong someone without harming them.

And the structure of your argument with respect to the inclusion benefit is a structure of argument that deals entirely with the issue of harm. As it turns out, they're not really harmed. So they can’t be wronged in anyway, but it might be that using subjects who cannot consent in any ordinary way wrongs them nonetheless.

And that was, of course, part of that earlier debate. I don’t think you actually think that’s irrelevant because you recognize in your written work that there's a difference between seeking generalizable knowledge and giving particular care to patients, and if I use my patient for generalizable knowledge, I might be wrongdoing them even if in another sense they weren’t harmed.

So I’d like you to think about the structure of that argument and whether the whole basis of your argument on the basis of the inclusion benefit already presupposes a certain approach to the moral life that may or may not be acceptable. That’s the one.

The other with respect to the equipoise issue, I sometimes wonder, you know, whether any two possible treatment modalities are ever in equipoise for a particular patient or how one knows that, but in particular, you mention that most of the care in pediatric oncology is done through randomized trials of one sort or another.

I remember reading an article a few years back about breast cancer research with adult women in which in several cases the researchers were delayed by years having trouble doing the research because they couldn’t find women willing to be randomized in it, but the article mentioned that this wasn’t a problem in oncology research with respect to children. They had plenty of research subjects.

And it struck me that there’s a reason for that. The risks or whether the risks are not even — I don’t know what the right way to describe them is, but the procedures that we’re unwilling to run for ourselves we seem quite willing to let children run, and if you think about that, it raises once again the question about whether the issues at stake in that earlier debate don’t remain real issues in a way. I’m not saying necessarily they must be resolved in one way, but I do think that they haven’t become irrelevant.

So maybe you could comment on both of those points.

DR. LANTOS: Thanks. Those are great questions.

Harm versus wrong, I mean, to a certain extent my discussion today focused on research that has a prospect of direct benefit, and I think the farther you get away from prospect of direct benefit the easier it is to imagine a wrong that might not necessarily have a harm associated with it.

I’m trying to imagine a protocol research project. Maybe you can help me if you have one in mind where there was a prospect of direct benefit. There was no harm, but a child would be wronged in some way by participating.

DR. MEILAENDER: Well, if you were Ramsey, unconsenting touching was a wrong whether it resulted in any harm or not.

DR. LANTOS: Even Ramsey wouldn’t have considered clinical care a wrong. I mean, every day I touch children who don’t consent when I do my physical examination on them and they scream and squirm and try to get away. I’m not sure how my gathering data through my physical exam that I then try to generalize would sort of kick me up a level of wrongness in Ramsey's view.

DR. MEILAENDER: Well, he thought their parents had reason to consent to that because it was part of parental nurture of their well-being. Now, you may be able to be on your way to an argument that placing my children into a clinical trial, at least if they’re of an age where I can explain to them that they're helping others, would be similar parental nurture, but that's what made the touching okay there. It wasn't anything to do with the consent of the child.
DR. LANTOS: Well, in that case, if the concept of inclusion benefit has some validity and the parent gave consent for a child to be in a pediatric oncology protocol because they correctly believed that that was the best thing for their child and, in addition, we would gain generalizable knowledge, I don't see, if that's what Ramsey said, then I would disagree that that's some incremental wrong.

Let me say one other thing though about inclusion benefit that's important and may explain a little better why I don't think the notion of inclusion benefit means we should blow the current system up.

I think part of the reason why there is an inclusion benefit, part of the reason why it's safer to be in research protocols is because research protocols are highly regulated so that a world in which we said, "Oh, it's better to be in protocols than not. So let's get rid of IRB review."

All of this stuff about making sure protocols are safe is clearly nonsense. Everybody who goes into a randomized controlled trial would not achieve that end. Putting people into randomized controlled trials that had been scrutinized, have been reviewed, I think, would.

As far as the argument for equipoise, I'm not sure I'd draw the same conclusion. I mean, I think about people willing to subject their children to risks or wrongs or harms that they're not willing to subject themselves to. I mean, I think the breast cancer example is an interesting one because I think if we're talking about the same study, it was randomizing to a lumpectomy or mastectomy, and I think what was driving that was people's assessment of the cosmetic results and saying, "I don't care if these two therapies from sort of a five-year survival perspective are in equipoise. From the perspective of how I'm going to look afterwards, they're not, and that's why I'm not willing to be randomized."

So in that sense, the researcher's failure to take that into account as part of what should go into their equipoise calculation just made it a badly designed study, in my view.

I think there are clinical situations where it's probably impossible to get a group of people who are in equipoise. It is an incredibly fragile and somewhat ambiguous concept, but I think the fact that parents are willing to sign their kids up for cancer chemotherapy protocols doesn't necessarily mean they're willing to allow their children to undergo risks that they wouldn't be allowed to undergo themselves. It may mean that they're making better decisions for their children than they make for themselves, as parents often do, I think.

CHAIRMAN PELLEGRINO: Dr. Kass? Oh, I'm sorry. Paul.

DR. McHUGH: This may be a question that's only the product of a long day and since I've had a lot of experiences that you've touched upon and have been touched upon before on IRBs and relationships to institutions and external forces and the like, I reverberate with all of the things you're saying.

For example, not to go too long on this matter, but I was on an ars ago for a number of years, and it was a wonderful experience because it introduced me to all of the different investigators (and investigations) that were going on in the institution from across all kinds of disciplines, and it was terrific.

Not only that. I appreciate my institution better. I also appreciate my fellow investigators and my fellow doctors in the sense of the imagination that they were showing and things of that sort, and things seemed to go quite well.

Now, it's very hard to get anyone to go on an IRB because not only is it not of this sort anymore, very, very long and arduous process in the sense of doing a bureaucracy's job is very unpleasant for people who see and appreciate that they have much better things to do for the benefit of patients, given that most of us do still have a vocational commitment to helping patients.

So, as well, from what we said this morning when we see this huge discrepancy between organs and the availability of organs and the demand for organs, it's clear to me that the method that we're using, even if toned up, is not going to solve this problem. This seems to me this is happening with the same thing here.

We've just got ourselves stuck into a process which is just going to get worse and worse and worse as the bureaucrats imagine further and further things that could go wrong. No industry could survive with this method if it hoped to be productive and safe.

The car industry couldn't work this way, given that, you know, it makes mistakes, too, but ultimately makes progress and makes progress sometimes through the mistakes.
Are we getting to the point of where we should be thinking of another approach entirely? As I say, this might be off the wall at the end, but you know, in medicine now, we are very accustomed, all of us who were in medicine are accustomed to the Joint Commission’s demands on us to look at our practice and particularly look at the ethics of our practice, the quality of our practice, and where it goes wrong.

It does it with this root cause analysis that is, by the way, extracted from the automobile industry, incent events with what you were saying, case studies in which when something does go wrong the case is studied from top to bottom, not just from who made the mistake here, but who gave this person authority to be in that position, what were the resources that were needed to do that properly, what wasn't made, and the like. And ultimately those get circulated around the country and our medical practice, just like our industrial practices, get better.

Has the time come for us, appreciating that being part of research is very helpful — by the way, there are plenty of examples where you can show that the placebo class really got better. The whole study of insulin shock for the treatment of schizophrenia was brought to an end when it was demonstrated that the placebo people did just as well as the treated people and both of them were doing well because they were backward schizophrenic patients that were now brought forward and people were now worried about their blood sugars for several hours a day, and when you did that, they improved.

And now we have this ridiculous business about where Paxil is producing suicidality in a small proportion of children, but no one knows what they mean by suicidality, and we have a black box label on this. The pharmacologists are not being drawn into.

I mean, that’s a real signal, by the way. It really is happening out there with certain forms of the SSRIs, but you know, we’re not doing what we ought to do and we would if we were running an automobile industry, that is, saying, "Okay. What’s happening here?"

So the long and short of this tirade — I’m sorry about it at one level, and it’s probably not very helpful — is to ask if we are an Ethics Council and if we are saying can we begin to blow a whistle on a process that is inherently going to run in a particular way and run us out of the business of doing better in research for the benefit of our children and for the benefit of everybody else?

DR. LANTOS: One quick comment, just to be clear, on the placebo versus control. I mean, many studies show placebo do as well as the control group. What I was talking about is the placebo group doing better than the people who weren’t in the study at all. So that’s slightly different.

I mean, my solution to the overburdened bureaucratic thing would be to say 90 percent at least of what IRBs do could be done just as well by a single compliance officer. Ninety percent of it could be done by the IRB administrator, and I’ll bet if you did a randomized controlled trial you’d find that the outcomes were exactly the same.

It’s basically making sure that the protocol meets fairly straightforward regulation. So one interesting question is why, given that, we have this system where like really expensive people with no expertise instead gather around and listen to the compliance officer tell them what they have to do.

That seems to be sort of a remnant of sort of an idea of what we wanted to imagine the role of a research ethics committee ought to be with regard to some of these more interesting questions about harm versus risk and the moral ambiguity of medical progress and stuff like that.

So if there was a way to sort of flag the ones that need that kind of review, you could imagine using the resources of an IRB to focus on those, and those would be the ones that I think might end up going into my appeals process generating essentially case law that could then sort of capture the wisdom of those deliberations in a way that isn't being captured now.

What's happening now is it's both a waste of time while the committees are meeting and then it's a waste of any outcome because it's kept secret and nobody gets to learn from the deliberation.

So I mean, in that sense I think blowing up the system might work, but I guess I would see that more as a tweaking of the operationalization of —

DR. McHUGH: And the bureaucrats would find some other way to consume your time even more because it isn’t the work of obsessional bureaucrats to imagine troubles. I mean, that's what they have, and so they could imagine all kinds of stuff, and if good cases are not studied, studied thoroughly about what really went wrong so that you can appreciate how unique those were and how everybody once read about them would remind themselves of how they should practice and do
research in the future, we could accomplish just as much, but it requires a trusting interaction that perhaps is impossible for these people to use if this method is persistent.

You know, at Hopkins we had a terrible disaster, but once it was really studied, where the mistake happened and what was the error and how the literature should have been better studied and all came to light for all of us. It was a distressing set of events, but it wasn’t protected by the IRB. It wasn’t going to be protected by making the IRB do more things which we now do.

Many people still don’t know what went wrong at Hopkins in the best sense. So at one level maybe we’re — I’m repeating myself, but just this system might not be the right one for an industry that is so beneficial and as much beneficial as engineering and other kinds of things that know how to do this better.

CHAIRMAN PELLEGRINO: Dr. Kass and Dr. Foster.

DR. KASS: There’s several things that I could raise with you, John, but let me pick up those quasi-theological remarks suggesting that you might have detected certain things in other works of the Council as possibly explaining why it is that we are so nervous about experimental subjects through discussion of the fear of hubris and the expiation of that sin.

Hey, I by the way don’t think that has in any form been operative in here, but that’s another matter. I don’t think that people who worry about the use of human subjects in research are primarily trying to use the research scientists as the focus of their anxiety about where science might be taking us. Maybe some people do and think about the mad scientist.

I think the major thing really comes down to the human use of human beings on which you yourself are, in fact, toward the end of the article, as I read the passage — I think it’s the thing Gil is alluding to — research is considered hazardous because the physicians who conduct research are using the patients as a means to an end. Their goal is no longer solely the well-being of the patients. They are also, perhaps primarily committed to the creation of generalizable knowledge.

And let’s grant the humanitarian ambitions. Let’s not dwell too long on the fact that in addition to the humanitarian ultimate goals there are careers to be made and self-advancement which depends upon this kind of research.

I think that what we’re dealing with here is not so much the nervousness about the ends, but real questions about the means and about quite apart from the hazards what it means to make especially a child an object of investigation for someone else’s benefit.

It’s very different, as Gil points out, when you bring your child sick to the doctor. There’s a laying on of hands with a specific goal in mind. The other is, for better or for worse, however lovingly you make the situation, lovingly you treat the child and however attractive the situation is, the child is a research subject.

Now, clinical trials in oncology where it is not clear which treatment is better, that’s different. But what about the things that Bob Levine says are somehow ruled out by the old principles, studies in pathology, pathophysiology, studies in the neonates where you aren’t to sort of look at the parent and say, "I don’t know really which treatment here is best, but in order for us to get to the point where we can even begin to imagine certain treatments for this, we’ve got to subject your child for no benefit to him or her so that we can gain this knowledge even, by the way, if no harm comes from it.

Even if no harm comes from it, I as the father of a child would be reluctant, however much I understand the goodness of knowledge, I would be somehow reluctant to make my child an experimental subject, period.

And I think that in your final analysis of the things that we owe our children, that wisdom of this comment and this thing that Gil is trying to distinguish between harms and wrongs — I’m not sure of the language I would use — there are ways of mistreating people even if you don’t hurt them, even not laying a hand on somebody.

And I don’t think it’s egregious. I think by and large people do a pretty good job. I’m inclined to think that because the ethics has come through the law, through the regulations that we now have acquired a system which doesn’t really do what it’s supposed to do, but I think that before you simply say what we really have to do is get out of the way and let the research go forward, we shouldn’t lose clear sight of what is the ethical good here in addition to harm. That’s terribly important whenever human beings use other human beings for purposes that are not somehow intrinsic to that relation, and especially with children who we have to somehow give consent — I’m talking about small
children — have to give consent for their being your objects.

However much you pretty it up, that's the fact of the matter, and I think that's a reluctance on the part of parents, and it's not because they're hostile to science, suspicious of scientists. They have something vital to defend. They don't even want their children to be subjects of voyeuristic experimentation.

I serve on — the IRB I served on was actually in the social sciences division of our university where — if anybody reads the transcript I'll be flogged when I get back — no one can make the argument that the research being done there is of immediate and important humanitarian benefit to anybody.

(Laughter.)

DR. KASS: They don't try to make that. They try to say they want to understand certain things maybe in the long run, and people were scrupulous to a fault about things that I thought shouldn't bother anybody, but when you start talking about taking children under 2 and 3 and even 4, for certain kinds of yearly observational studies where there's no harm at all, you're wondering what is your attitude to the child and what are you subjecting him; what are you thinking about in these things?

It's those kind of softer things that pale in comparison to the real value of finding cures for Wilton's tumors, but I don't think the people like Paul Ramsey who are concerned about these things were — I think they were onto something, something very important. It didn't depend on a theological notion of childhood innocence.

I think you can give an account phenomenologically in terms of the experience of being a parent into whose care this new life has been entrusted, and what are you willing to subject them to and for what purposes.

I'm not sure I've done it very well, John, but I think in your writings and your thinking you've spoken more richly about this than you have in the presentation to this point, and I wonder what you say.

DR. LANTOS: Thanks for pointing out what seems like a contradiction although I think is partly contextual, that is, both where it's at in the article and to whom that paper was addressed in a pediatrics journal.

I think a lot of the problem for most pediatrician clinical researchers is they don't see why any sort of regulation ought to be applied. Hey, I'm a good person. I'm just trying to do what's best.

And so I strongly support the need for rigorous oversight of research involving children for the reasons in that article and because I think things like the inclusion benefit only apply if there is rigorous clinical oversight.

But at the same time, I mean, I guess I should throw the question back to you in a way, but in my opinion, we have developed a stringent set of regulations that would prevent most of the risks, most of the harms. The wrongs, I guess I don't quite understand that concept yet. So that may be where we'd at least have to talk more to see whether we agree or not.

But I think this regulatory framework with its ambiguous terms of minimal risk and minor increase above minimal risk is quite restrictive, takes into account what we owe the children in terms of protection, what we owe the parents in terms of explanation, getting their permission, their fully informed permission and the child's assent when the child is old enough to assent, and that those kinds of protections adequately address the major risks that you'd get to in treating the child solely as a means to the creation of generalizable knowledge.

The challenge today, it seems to me, is more one of figuring out how to apply those in ways that people would agree upon, and I mean, I think what will happen here tomorrow when you discuss an actual case protocol is people around this table will have differing interpretations of what those concepts mean, and you may find them inadequate to address some of the things, but in the end, you know, you'll take a vote and it will be eight to six on whether this protocol should be allowed to go forward or not.

And the discussion that you'll have will be quite illuminating and important, and then maybe in this one it will eventually get published, but it will have no precedential effect. It will have no regulatory effect. It will be sort of your opinion or this group's opinion or the President's Council's opinion and people will be free to agree with it or disagree with it, and that's been happening now for 30 years.
And so we have these concepts. They're applied daily in pediatric centers across the country, and the same issues keep coming up again and again, and we don't get anywhere. So if there are errors of overprotection or denial of access or if there are errors of enrolling children in protocols where they ought not to be enrolled, we don't know it, and we only find out about it in the sort of egregious cases that end up, you know, with the death of a subject or a lawsuit, and bad cases make bad law or bad precedent of any sort.

But all of the good deliberation and all of the casuistry, all of the case based reasoning about what a minor increase over minimal risk means and sort of a system in which the best insights can be reviewed, scrutinized, modified, and generalized so that all children benefit from them doesn't exist now.

Is that sort of an answer? I mean it's kind of —

**DR. KASS:** Let it be. It's okay.

**DR. LANTOS:** Okay.

**CHAIRMAN PELLEGRINO:** Dr. Foster and Dr. Gazzaniga.

**DR. FOSTER:** Let me change the direction for just a second. In your presentation there are two things that seem to me to be a little bit — I'm not sure which way you want to go. The last thing you said was — and I think I used to chair an IRB myself like Paul and so forth — you said, well, probably a compliance officer could do 90 percent of the work or 95 percent of the work just to be sure that, you know, the Ts are crossed and so forth.

And then, on the other hand, earlier you said that it might improve the system if we had some sort of I think you used an analogy like an appeal court or something in which there would be an increase in transparency, and it may be some way that decisions could be passed on.

I want to understand a little bit more how you think that that court could be done and a word about does the fact that most of the things that using the compliance officer would mean that you could have the freedom to have people serve on such a court about assessments and so forth.

And finally, if you've given any thought at all about how one might come up with the money to do this.

One of the questions is whether the appeal court is going to be sort of locally or whether there's going to be some published thing like a lawsuit or an ethics journal or something that would come there. I just wanted to hear a little more about that aspect, which I don't think we've heard suggested by anybody.

**DR. LANTOS:** I don't think it should be local. I think it should be regional or national. So whether it's — and I think it should have regulatory teeth. That is, once the decision is published, it becomes binding regulation. That is an interpretation of whether giving injections of placebo to somebody in a randomized trial of growth hormone is minor increase above minimal risk or not could be adjudicated. People could disagree.

But it doesn't seem like it serves anybody's interest to have sort of ongoing, never ending disagreement that never gets resolved in a way that has regulatory bite.

So let's work on this together societally. If there's a debate, have the debate. Come up with an answer sort of like the Supreme Court comes up with an answer. You may like it; you may not, but once they speak it's done, although you can bring another case that readdresses some aspect of the issue if there's confusion.

How would it be paid for? I mean, the only way to pay for it would be out of tax dollars. I guess you could imagine user fees or something, but some collective subsidization of this as an important societal function.

What it would do, I think, would be to make explicit the expenses that are implicit in IRBs and their functioning.

**CHAIRMAN PELLEGRINO:** Dr. Gazzaniga.

**DR. GAZZANIGA:** I don't want to leave Paul alone and into the day open-ended questions. Dr. Levine, that was a terrific talk, I thought very illuminating, and I want to go to Leon's question, if I may, and try to look at this wrong-harms issue because it's a tough one to get your head around
mainly because I guess we're not dealing with two or three examples here that drive the point home. But let me try something out on Leon. I want to see if he will see where I'm going and see if this might help illuminate it. Are we not talking there about Leon when he's talking about caring for his child, that it's the theory that Leon has in his head about the well-being and caring of his child that is being really dealt with in this psychological situation because the child is obviously oblivious to 99 percent of what's going on here.

So what we're dealing with is your theory of how all of this should transpire, and the harm or the wrong has to do with the potential theory you come up with about what might have transpired or what kind of future psychological damage may occur from the clinical trial you're in.

And it's so hard to deal with that because let's imagine I was your son and I grew up to be who I am. I would want you to put me in a clinical trial because hanging around the medical community, you really realize how hard it is to do medical research, completely difficult enterprise.

And I'll use as an example one that Paul can relate to. I was once at a medical center with two of the world's leading neurologists who could not agree to do a randomized trial on the efficacy of coumadin because one of them simply refused not to give it to his patients.

And so here we have adults all worrying about a clinical issue that should be resolved and still hasn't been resolved as far as I know, and it's hard to get it off the ground. It's hard to do it with adults. And now we're going down to children. It's hard to do the research that is crying out to be done. So what I'm suggesting is in trying — I'm really asking a question — in trying to think through this harms-wrongs issue, are we talking about you or are we talking about the wrong to the child or only your theory about the wrong to the child that you're carrying around in your head?

**DR. KASS:** That's in contrast to the theory of you're running around in your head about the difference between your head and mine.

(Laughter.)

**DR. KASS:** If it comes down —

**DR. GAZZANIGA:** I guess where is the locus of the wrong?

**DR. KASS:** No, it's late in the day, and I didn't come prepared for this. My friend Robby will help me out, but let me fish for something for a moment.

By the way, I don't deny for a moment the importance of the research of its value. I mean, if you're going to treat children, you should know what you're doing. If you're going to treat anybody, you should know what you're doing. And there's no substitute for good science to learn how that is. We don't have a disagreement about that.

The question is whether we make things easy for ourselves in doing that work by blinding ourselves to certain aspects of those human relations in which the people who we hope eventually to benefit are for the time being at the very least — and forgive me — to make the point luridly, they are our guinea pigs.

It's not a nice way to put it, but they are experimental subjects for the gaining of this knowledge, and we can dress it up any way we like, but that's part of the essence of it, and it's much better if you're going to do it to have that clearly in mind.

And by the way, I do think that the regulations were in a way designed with part of that clearly in mind, and they are meant, in fact, to protect against the mere treatment of people in this way and to make sure that the harms to which they are exposed are minimal and justifiable in terms of some kind of benefit, however much you try to do that.

But you in a way raise a larger question about ethical conversation altogether. I advance some suggestion that there is a way to do wrong to a person without doing them bodily harm or psychic harm, and you want to know is this my peculiarity. I'll wear it.

But part of what you do in these conversations is you try out certain arguments and examples in the hope that you're not just talking about your own nervous system, I mean, because we're looking for a kind of collective wisdom on this.

Now, I give you a biblical example, which means I'm going to lose with you right away, but —
DR. KASS: — but a wonderful story of drunken Noah and his sons. Noah has three sons after the flood, you know. The poor man, it’s an ordeal. He planted a vineyard. He drank of the grape. He got drunk, and he lay naked in his tent.

And one of his sons comes in, sees the nakedness of his father, and goes out and blabs to his brothers. Now, it’s a trivial story in some respects. I think it’s a profound story. The son who goes and uncovers his father’s nakedness and blabs about it has participated in the unfathering of his father. He has ratified that and celebrated that without laying a hand on Noah’s head. He has committed an act of metaphorical patricide.

The father lies there no longer as a father. He’s just drunken sower of seed, and the son reveled in it. The two other sons walked backwards with a cloak on their shoulder and covered the father’s nakedness, refusing to participate in it.

Now, there’s no harm in the sense of bodily harm. Yet there is a wrong. That would be a suggestion.

And part of it seems to me what we want to do in our interpersonal relations is to somehow look upon people, never mind talk to them, even the way we look upon them, the way we speak to them, the way we relate to them, to somehow do honor to the human person that’s there.

Those things are at least as important, I think, to all of us whether we would immediately recognize it or not as finding the cures for the diseases that afflict us.

I’m sorry, Mr. Chairman. I rose to the bait.

CHAIRMAN PELLEGRINO: Oh, no, no, no. John and then Dr. George.

DR. LANTOS: I have a clinical analogy to the Noah story. I mean, in the growth hormone trials one of the aspects of the trials was annually they’d take nude pictures of the kids in a trial on the, you know, background so they could measure arm length, and they’d cover their eyes with black tape, and one of the big debates in IRB review of this was, you know, was this portion of the study necessary was one question, but harm or wrong or sort of unacceptably demeaning so that it should be negated.

I think that’s an important debate. So in that sense I think there are wrongs that can be done that researchers could propose that would be important for the study. I mean, all of the endocrinologists said crucial, crucial information if we’re ever going to evaluate the results, and I think people should have debates and discussions and decide, given what the goals of the study are, is there a less invasive way to find it out? How important is it? And ultimately come up with a judgment about whether it’s a good thing to do.

But I don’t think every center every time this is proposed should have to debate it again and again and come up with their own idiosyncratic result that’s then binding without having to explain how they got to the conclusion that they got to.

That’s all I’m trying to say.

CHAIRMAN PELLEGRINO: Dr. George.

PROF. GEORGE: Well, yes. Thank you, Dr. Pellegrino.

I was originally jumping out of my chair to defend Leon from Michael’s question, but Leon proved with that eloquent statement that he certainly doesn’t need my help or anyone’s help in defending his views on this very, very important issue about the nature of wrong and its relationship to harm and the possibility of there being wrongs that aren’t strictly harms.

So instead of jumping into Leon’s defense since he doesn’t need it, let me just toss something on the table for Leon and Michael to maybe think about.

Does it in the end come down to whether one’s essential view of benefits and harms and of those creatures who are capable of experiencing benefit and harm in the human way, does it come down to whether benefits and harms are in the end material or, if not material, psychologistic realities or whether there is some category that is distinct from the material or merely psychological of human good and, therefore, of the privation of human goods that can be offended and thus a wrong done to a person in whom the good is instantiated?
And to test that, I might try an example somewhat different from Leon's biblical story since it will put it into the context of research and, indeed, pediatric research, and I also think somewhat different from the example that Dr. Lantos just raised about the children who were photographed in the nude, and that would be something like this.

Imagine that you are the parent of a severely retarded child who is also spastic in some ways and you had a research team that was seriously interested in understanding the phenomenon of other children ridiculing retarded children who are spastic, and so an experiment was designed reasonably under the terms of which retarded children were put behind a one-way mirror and other children, ordinary children, were invited to come in and we could see which ones ridiculed the child and laughed at him and made fun of him and so forth and so on, and you as the parent were asked to volunteer, contribute your retarded child.

Now, the retarded child, let us stipulate, is not going to know this ever went on, is not going to know that he was ever ridiculed, jeered at by these people, doesn't know anything about the reason for it because he doesn't know it's happening at all.

Now, on a certain non-materialistic and non-psychologistic account of the human good, that child, if the parent volunteers, is participating on at least — it's reasonable to think, it would be a reasonable view — that that child is being subjected to a wrong.

But on a view that really restricts the scope of our understanding of human benefits and their privations to the material or at least the psychologistic, it becomes puzzling at best and probably kind of superstitious to suppose that that child has been subjected to anything that could qualify as a wrong.

CHAIRMAN PELLEGRINO: Paul.

DR. McHUGH: Surely the children that are being encouraged to make fun of him have been done a serious wrong, and —

PROF. GEORGE: Well, let's stipulate that they're not being encouraged to. In other words, we're bringing in perhaps a randomized group of children because we're going to try to figure out what it is about backgrounds and so forth that leads some children to ridicule and perhaps other children to look with pity or sympathy of some sort on him.

So we're really sincerely trying to figure this out. I mean, it sounds to me like not an unreasonable — I don't do this kind of work. So I don't — so, I mean, it doesn't seem to me that that's an unreasonable way of structuring an experiment if we factor out the ethical dimension of the question.

DR. LANTOS: In some ways we have an investigator at our place who is trying to study how pediatric residents' attitudes towards children with severe disabilities are formed or changed over the course of their pediatric residency, where the equivalent to the other children who are being brought in in your hypothetical study are the attending physicians who are hypothesized to be the ones who sort of teach the residents their attitudes.

So I guess the question would be: Would your judgment of that sort of study depend on the goals? I mean, if the goal of the study was to develop educational interventions that could sort of change discriminatory attitudes to the better, and therefore, the research was designed to improve lives for all children with severe disabilities, would that be different than, you know, if the goal of the study was to see whether catecholamine levels rose in the child who was being, you know, treated in a disparaging way?

PROF. GEORGE: Well, I think that is a very interesting and perhaps important distinction, but it wouldn't be a distinction that would be relevant to our getting at the question of whether there could ever be a wrong that's not a harm in materialistic psychologist terms.

DR. LANTOS: Right. It would take the next step of asking whether there could — we had acknowledged there was a harm. The question would be could there also be a benefit that balanced the harm.

PROF. GEORGE: Sure. It would open a range of questions. I agree.

DR. GAZZANIGA: I remember going back three years — how long have we been doing this? It's four and a half — and I remember talking to Paul. The Council was talking about human dignity and you know how you rotate us so that there's no coalitions formed.
DR. GAZZANIGA: Anyway, so I was sitting next to Paul and someone was going on about human dignity, and I turned to him, and I said, "Paul, you work in a hospital. I've worked in a hospital. There's no human dignity in a hospital."

Can I quote you?

And you said, "You're damned right there's not. The first thing you come in and you tell a guy to drop his pants, get on the table. It's terrible. You check it at the door."

So there's a context. I mean he's being his usual humorous self, but there's a context, and what is being undercut here, and I think what you were trying to get at is the guild of physicians have under oath the patient's best interests in mind, and I think 99.9 percent of them practice that.

And we have this whole apparatus around produced by rogue doctors that have made us supersensitive to some issues and are having the result of not allowing solid research to go forward.

And I think that to footnote that, I think the concept of a non-physician bureaucrat running an IRB is the worst idea I have heard this year because you will take away from, it that matter, the whole understanding of the medical mission and the whole understanding of medical research and the whole caring function in a way that is truly interpersonal between a physician and their patient.

So what I'm saying is that if you look from the real context of medical research knowing that dignity has been challenged by the very nature of our medical procedures, but on the other hand, balance that out with the commitment that all physicians have made, these questions that we're talking about today, take on a different color and a different meaning, and I think they're hard to talk about in the aseptic sort of non-medical environment that we're holding this conversation.

There's something in there somewhere.

DR. LANTOS: I think it doesn't matter whether it's a physician or non-physician. All of the good things you just described have been taken away by the definition of the role. So the physician who does it can no longer pay attention.

But the idea of responsible investigators being punished because of the transgressions of the rogues I think is an important idea, too. I mean, I think while there are conflicts of interest for investigators and people build their careers, and there's fame and fortune to be made by doing good studies. There is also, I think, the moral imperative generally to gain knowledge in order to improve care of children as part of that very mission of the medical profession, is, I think, an important part of the motivation of most clinical researchers, and the sole motivation for many of them.

I mean a lot of the people I know who are trying to do good clinical research aren't going to win any Nobel Prizes. They're not getting famous. I mean, they get a paper every couple of years, but their motivation is to take better care of their patients, and in the care of their patients, they come across unanswered questions that can be answered by good clinical trials, and often the clinical trials raise the kinds of issues that we're talking about today, and the regulatory apparatus puts roadblocks in front of those responsible investigators that I think often don't protect subjects, in fact, leave subjects exposed to all the harms of nonvalidated therapy, even though it's carried out by unconflicted though necessarily ignorant, well meaning physicians.

CHAIRMAN PELLEGRINO: Thank you very much.

We're finished our time.

(Whereupon, at 5:17 p.m., the meeting was adjourned, to reconvene at 8:30 a.m., Friday, April 21, 2006.)
EDMUND D. PELLEGRINO, M.D.

COUNCIL CHAIRMAN

Dr. Pellegrino is Professor Emeritus of Medicine and Medical Ethics and Adjunct Professor of Philosophy at Georgetown University.

He has served as Director of the Center for Clinical Bioethics at Georgetown University; head of the Kennedy Institute of Ethics and director of the Center for the Advanced Study of Ethics at Georgetown; President of Catholic University; President and Chairman of the Yale-New Haven Medical Center; Chancellor and Vice President of Health Affairs at the University of Tennessee; founding Chairman of the Department of Medicine at the University of Kentucky; and Founding Director and Vice President of the Health Sciences Center, State University of New York, Stony Brook, where he oversaw six schools of health sciences and the hospital, and served as Health Affairs Dean of the School of Medicine.

He has authored or co-authored 24 books and more than 550 published articles; is founding editor of the *Journal of Medicine and Philosophy*; a Master of the American College of Physicians; Fellow of the American Association for the Advancement of Science; member of the Institute of Medicine of the National Academy of Sciences; recipient of a number of honorary doctorates; and a recipient of the Benjamin Rush Award from the American Medical Association, and the Abraham Flexner Award of the Association of American Medical Colleges.

In 2004, Pellegrino was named to the International Bioethics Committee of the United Nations Education, Scientific and Cultural Organization (UNESCO), which is the only advisory body within the United Nations system to engage in reflection on the ethical implications of advances in life sciences.

Throughout his career, Dr. Pellegrino has continued seeing patients in clinical consults, teaching medical students, interns and residents, and doing research. Since his retirement in 2000, Dr. Pellegrino has remained at Georgetown, continuing to write, teach medicine and bioethics, and participate in regular clinical attending services.
FLOYD E. BLOOM, M.D.

COUNCIL MEMBER

Floyd E. Bloom was until March 2005, Chairman of the Department of Neuropharmacology at the Scripps Research Institute. He is currently professor emeritus in the Molecular and Integrative Neuroscience Department at TSRI, and the founding CEO and board chairman of Neurome, Inc. He previously was Director of Behavioral Neurobiology at the Salk Institute and Chief of the Laboratory of Neuropharmacology of NIMH.

He has received numerous awards, including the Pasarow Award in Neuropsychiatry and the Hermann van Helmholtz Award, the Sarnat Award for Mental Health Research, as well as a number of honorary degrees from major universities. He was the editor-in-chief of Science magazine from 1995 to 2000.

Dr. Bloom was born in Minneapolis, Minn., in 1936. He attended Southern Methodist University in Dallas, Texas, where he received an AB degree cum laude and then an MD degree, cum laude from Washington University in St. Louis, Mo.

He is a member of the National Academy of Science (1977), The Institute of Medicine (1982), The American Philosophical Society (1989) and the Royal Swedish Academy of Science (1989).

Dr. Bloom has authored or co-authored a total of 32 books and monographs, 415 original research articles, 256 solicited articles and reviews, 59 editorials, and more than 300 abstracts.
NICHOLAS N. EBERSTADT,
PH.D.

COUNCIL MEMBER

Nicholas Eberstadt is the Henry Wendt Chair in Political Economy and Government at the American Enterprise Institute in Washington DC. He is also Senior Adviser to the National Bureau of Asian Research, and for many years was a member of the Harvard University Center for Population and Development Studies.

His areas of inquiry include demography, economic development and international security. He has served, inter alia, on the Board of Scientific Counselors for the US National Center for Health Statistics, the Visiting Committee for the Harvard School of Public Health, and the Global Leadership Council of the World Economic Forum.

His many books include Poverty In China, Fertility Decline in the Less Developed Countries, The Tyranny of Numbers, Prosperous Paupers and Other Population Problems and The Poverty of "The Poverty Rate": Measure and Mismeasure of Want in Modern America.
Daniel Foster, M.D.

Council Member

Daniel Foster, M.D. John Denis McGarry, Ph.D. Distinguished Chair in Diabetes and Metabolic Research, University of Texas Southwestern Medical School. Dr. Foster, whose research is in intermediary metabolism, has received the Banting Medal, the Joslin Medal, the Tinsley R. Harrison Medal and the Robert H. Williams Distinguished Chair of Medicine Award for his work. He is a member of the Institute of Medicine of the National Academy of Sciences and is a Fellow of the American Academy of Arts and Sciences. He was chairman of the Department of Internal Medicine at UT Southwestern for 16 years.

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MICHAEL S. GAZZANIGA, PH.D.

COUNCIL MEMBER

Michael Gazzaniga, Ph.D., is the outgoing David T. McLaughlin Distinguished University Professor in Cognitive Neuroscience and Director of the Center for Cognitive Neuroscience at Dartmouth College and the incoming Director of Sage Center for the Study of Mind at the University of California, Santa Barbara. Dr. Gazzaniga conducts research on how the brain enables the mind. He is a fellow of the American Neurological Association, as well as the president of the American Psychological Society and a member of the American Academy of Arts and Sciences and the Institute of Medicine. His publications include *Cognitive Neurosciences III* (2004), *The New Cognitive Neurosciences* (2000) and *The Mind's Past* (1998). His new book, *The Ethical Brain*, was published in 2005.

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ROBERT P. GEORGE, J.D, D.PHIL.

COUNCIL MEMBER

Robert P. George is McCormick Professor of Jurisprudence and Director of the James Madison Program in American Ideals and Institutions at Princeton University.


In 2008, Professor George received the Presidential Citizens Medal at a ceremony in the Oval Office of the White House. He is a winner the Bradley Prize for Intellectual and Civic Achievement; the Sidney Hook Memorial Award of the National Association of Scholars; and the Philip Merrill Award for Outstanding Contributions to the Liberal Arts of the American Council of Trustees and Alumni.

A graduate of Swarthmore College and Harvard Law School, Professor George earned a doctorate in philosophy of law from Oxford University. He was elected to Phi Beta Kappa at Swarthmore, and received a Knox Fellowship from Harvard for graduate study in law and philosophy at Oxford. He holds honorary doctorates of law, letters, science, ethics, civil law, humane letters, and juridical science.

Professor George is a member of UNESCO’s World Commission on the Ethics of Scientific Knowledge and Technology. From 1993-98, he served as a presidential appointee to the United States Commission on Civil Rights. He is also a former Judicial Fellow at the Supreme Court of the United States, where he received the 1990 Justice Tom C. Clark Award. He is the recipient of a Silver Gavel Award of the American Bar Association, the Paul Bator Award of the Federalist Society for Law and Public Policy. In 2007 he gave the John Dewey Lecture in Philosophy of Law at Harvard. In 2008 he gave the Judge Guido Calabresi Lecture at Yale and the Sir Malcolm Knox Lecture at the University of St. Andrews in Scotland.

Professor George is a member of the Council on Foreign Relations, and serves as Of Counsel to the law firm of Robinson & McElwee.
ALFONSO GÓMEZ-LOBO,
DR. PHIL.

COUNCIL MEMBER

Alfonso Gómez-Lobo, Dr. phil. Ryan Family Professor of Metaphysics and Moral
Philosophy, Georgetown University. Professor Gómez-Lobo specializes in Greek
philosophy, Greek historiography, the history of ethics, and contemporary natural law theory. He is
the recipient of several awards, including a research fellowship from the Guggenheim Foundation.
His latest book, *Morality and the Human Goods*, was published by Georgetown University Press in
2002.
William B. Hurlbut, M.D. Consulting Professor, Department of Neurology and Neurological Sciences, Stanford Medical Center, Stanford University. Dr. Hurlbut's main areas of interest involve the ethical issues associated with advancing biotechnology and neuroscience, the evolutionary origins of spiritual and moral awareness, and the integration of philosophy of biology with theology. He has worked with the Center for International Security and Cooperation on a project formulating policy on Chemical and Biological Warfare and with NASA on projects in astrobiology. He is the author of "Altered Nuclear Transfer," a technological proposal to our nation's impasse over stem cell research.

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Leon R. Kass, M.D., Ph.D., is the Addie Clark Harding Professor in the Committee on Social Thought and the College at the University of Chicago and Hertog Fellow in Social Thought at the American Enterprise Institute. He was chairman of the President's Council on Bioethics from 2001 to 2005.

A native of Chicago, Dr. Kass was educated at the University of Chicago where he earned his B.S. and M.D. degrees (1958; 1962) and at Harvard where he took a Ph.D. in biochemistry (1967). Afterwards, he did research in molecular biology at the National Institutes of Health, while serving in the United States Public Health Service.

Shifting directions from doing science to thinking about its human meaning, he has been engaged for more than 30 years with ethical and philosophical issues raised by biomedical advance, and, more recently, with broader moral and cultural issues. From 1970-72, Dr. Kass served as Executive Secretary of the Committee on the Life Sciences and Social Policy of the National Research Council/National Academy of Sciences, whose report, Assessing Biomedical Technologies, provided one of the first overviews of the emerging moral and social questions posed by biomedical advance.

He taught at St. John's College, Annapolis, MD, and served as Joseph P. Kennedy, Sr., Research Professor in Bioethics at the Kennedy Institute of Ethics at Georgetown University, before returning in 1976 to the University of Chicago, where he has been an award-winning teacher deeply involved in undergraduate education and committed to the study of classic texts.


His widely reprinted essays in biomedical ethics have dealt with issues raised by in vitro fertilization, cloning, genetic screening and genetic technology, organ transplantation, aging research, euthanasia and assisted suicide, and the moral nature of the medical profession.

Dr. Kass is married to Amy Apfel Kass, Senior Lecturer in the Humanities at the University of Chicago and Senior Fellow at the Hudson Institute. The Kasses have two married daughters and four young granddaughters.
Peter Augustine Lawler is Dana Professor and Chair of the Department of Government and International Studies at Berry College. He teaches courses in political philosophy and American politics and has won several awards from Berry for doing so.

He is executive editor of the acclaimed quarterly journal, Perspectives on Political Science, and has been chair of the politics and literature section of the American Political Science Association. He also serves on the editorial board of the new bilingual critical edition of Alexis de Tocqueville’s Democracy in America and on the editorial boards of several journals. He is a member of the Society of Scholars at the Madison Center at Princeton University, the George Washington Professor on the American founding for the Society of Cincinnati for the state of Georgia, and he is a member of President Bush’s Council on Bioethics.

He has written or edited ten books. His newest book, Aliens in America: The Strange Truth about Our Souls is a starred, featured selection in Booklist, the journal of the American Library Association. Another recent book, Postmodernism Rightly Understood, was also widely reviewed and praised. His very long introduction to a new edition of Orestes Brownson’s The American Republic is now available.

His American Political Rhetoric (edited with Robert Schaefer) is used in introductory American government courses at a sizeable number of colleges and universities. The fifth edition was just published.


Some of the topics of his recent articles and chapters include Shakespeare’s The Tempest, William Alexander Percy, Walker Percy, Alexis de Tocqueville, biotechnology, bourgeois bohemian virtue, religion and conservatism, compassionate conservatism, conservatism, the filmmaker Whit Stillman on nature and grace, disco and democracy, Casablanca and the American dream, the future of human nature, the utopian eugenics of our time, the rise and fall of sociobiology, Richard Rorty, grade inflation and the Ivy League, Harvey Mansfield and Carey McWilliams, caregiving and the American individual, Christopher Lasch, virtue voters, culture wars, Flannery O’Connor and nihilism, Orestes Brownson, and postmodernism rightly understood.

Lawler has given invited lectures at more than 50 colleges and universities. He has received a large number of grants from both the Liberty Fund and the Earhart Foundation, as well as numerous other foundations.

PAUL McHUGH, M.D.

COUNCIL MEMBER

Paul R. McHugh, M.D. is the University Distinguished Service Professor of Psychiatry at the Johns Hopkins University School of Medicine. He was the Henry Phipps Professor of Psychiatry, Director of the Department of Psychiatry and Behavioral Sciences at the Johns Hopkins University School of Medicine, and psychiatrist-in-chief at the Johns Hopkins Hospital from 1975-2001. He is the author of 4 books and more than 150 papers.
GILBERT MEILAENDER, PH.D.

COUNCIL MEMBER

Gilbert Meilaender, Ph.D. Richard & Phyllis Duesenberg Professor of Christian Ethics at Valparaiso University. Professor Meilaender is an associate editor for the *Journal of Religious Ethics*. He has taken a special interest in bioethics and is a Fellow of the Hastings Center. His books include *Bioethics: A Primer for Christians* (1996, 2005), *Body, Soul, and Bioethics* (1995). He has recently edited (together with William Werpehowski) *The Oxford Handbook of Theological Ethics*.

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DIANA J. SCHAUB, PH.D.

COUNCIL MEMBER

Diana J. Schaub is a professor and chairwoman of the department of political science at Loyola College in Maryland. From 1994 to 1995 she was the postdoctoral fellow of the Program on Constitutional Government at Harvard University. In 2001, she was the recipient of the Richard M. Weaver Prize for Scholarly Letters. Ms. Schaub has taught at the University of Michigan at Dearborn and served as assistant editor of the National Interest. She has her A.B. from Kenyon College, where she was elected to Phi Beta Kappa, and an M.A. and Ph.D. from the University of Chicago. She is the author of Erotic Liberalism: Women and Revolution in Montesquieu's "Persian Letters" (1995), along with a number of book chapters and articles in the fields of political philosophy and American political thought. Ms. Schaub’s work also appears in the New Criterion, the Public Interest, and The American Enterprise.