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Meeting Transcript

March 4, 2005

The Sphinx Club
1315 K Street, NW
Washington, DC 20005

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SESSION 5: ALTERNATIVE SOURCES OF HUMAN PLURIPOTENT STEM CELLS

CHAIRMAN KASS: This fifth session of this 20th meeting is devoted to a draft white paper of the President's Council on Bioethics entitled "Alternative Sources of Human Pluripotent Stem Cells."

Just to remind everybody and also to put this on the public record, this white paper, a reworked draft of an earlier staff working paper, grew out of discussions that we had at the last Council meeting where we had two presentations, one from Drs. Landry and Zucker, Columbia; one from Bill Hurlbut of our own Council, on alternative ways of deriving pluripotent human stem cells that would not require the destruction of human embryos.

Subsequent to that meeting, staff, in researching the literature, also discovered two other kinds of proposals, one the attempt to derive stem cells by biopsying living embryos, analogous to the biopsy of living embryos used in prenatal genetic diagnosis; and also, activities in the realm of attempts to find ever more de-differentiated or undifferentiated stem cells taken from children and adults, encouraged by the findings now of, I think, three different groups in addition to Catherine Verfaillie's group of multipotent cells found in the bone marrow, some of them bearing markers normally associated with embryonic stem cells.

And the Council prepared a paper reviewing all four of these proposals, first of all, explaining what they are, then conducting an analysis to ask whether each of these proposals were ethically sound, whether they seem to be scientifically sound, whether it was realistic even to consider these matters, and that meant whether these were likely, if successful, to be met with scientific approval, whether they might secondarily be eligible for federal funding.

We did not take up the question of whether these things should be recommended for federal funding. That was a prudential judgment that rested upon answers to the ethical questions and also the next question of how much resources should be invested in these kinds of, for the time being, still speculative proposals.

The major emphasis in this document, since this is an ethics council, has been on the ethical analysis, and the thought was that we are convened here like a body that's conducting a preliminary hearing. The question is: do these proposals pass minimum ethical muster and, second, are they of sufficient possible scientific interest that we could recommend them for further public consideration? That has been the spirit here.

And I want to say a couple of things about why we are doing this. You'll recall that this is a council which is charged, indeed, with upholding certain ethical norms and at least venting all of the important ethical questions connected with biomedical advance. We have been involved in issues that concern embryo research, and early on in our cloning report we prided ourselves, I think rightly, and all of us signed onto this particular part of that cloning report, that we recognize that all parties to the debate about embryo research had something vital to defend, not just for them, but for everybody.

Also, this Council distinguished itself, in my opinion, in our finding common ground in the Reproduction and Responsibility report, notwithstanding the remaining large differences amongst on the moral status of early human embryos, and it seemed to me, and I think this was the sense of the group the last time, that this was a wonderful opportunity for this Council to demonstrate once again the desirability and the possibility of trying to find common ground and also of seriously considering ways that science might advance in ethically uncontroversial ways, in which neither side would have to compromise. And it seemed to me a public bioethics body that could help in attaining such goals would have more than justified its existence.

There have been people who have looked at our discussions, and our discussions have gotten a lot of press, and there are also papers being published about these things even as we speak. There are people who have been cynically saying that all of this is an attempt to distract the country and to divert attention from the need to pursue embryonic stem cell research by the conventional means and that this is a disingenuous conversation.

I reject that in the name of all of us. If there are any of you who are speaking disingenuously, you're

free to confess, but I've been in conversation with everybody here, and it has not been my sense that that is the motive of anybody who has been participating in this discussion.

That's a cynical charge which to my mind ranks really with those who say the people who support embryonic stem cell research over adult stem cell research are really motivated by the desire to kill embryos or to defeat their pro life opponents. That's a canard. I reject that, and similarly, I think we should reject those who would caricature what we're trying to do here as somehow disingenuous and an attempt to deflect research.

I think everybody ought to be interested in finding morally uncontroversial ways for science to proceed if we can and ways that would respect the seriously held ethical opinions of our fellow citizens whether we agree with them or not. Whether these proposals finally pass ethical muster on their own terms is, I think, the question we want to consider. These are serious proposals advanced by morally serious people who are, in fact, committed to scientific progress, and so are we all.

With that as a kind of preface, this is a session in which all of you have had a chance to see the draft white paper. This has been reworked in the light of your comments made on an initial draft, in the light of comments made by three outside researchers whose expertise bears upon the feasibility of these proposals.

I want to thank especially Adam Schulman and Dick Roblin who worked heroically to put together what I think is really a quite remarkably thorough and clear document at least in terms of the analysis.

I think most of our time probably should be spent on the question of the conclusion and what we want to say by way of conclusion, but before doing so, let me see if, on the sort of more general questions, in terms of the ethical analysis and the document as a whole, whether people find this a fair and balanced document, whether it presents a sober and sufficient analysis of the issues, before we take up the particular questions of the conclusion.

Are there any comments about everything up to the sort of conclusion just in terms of the analysis that's offered? I don't mean line editing, but more serious reservations, serious omissions, questions of balance.

Bill Hurlbut.

DR. HURLBUT: Well, it's a small comment, but I think we should take the issue of parthenogenesis a little more seriously than we have because there are some serious scholars and scientists interested in that subject, and notwithstanding its mention in the Dickey amendment, I'm not sure that it has been properly analyzed ethically.

I'm not committed to one view or another on the outcome of that ethical deliberation, but I just think that since we know that there has been successful procurement of embryonic stem cells from parthenogenic primates and now apparently from human productions, I think we ought to recognize it as already having practical import and, therefore, ethical worthiness to at least be discussed more thoroughly rather than dismiss it.

CHAIRMAN KASS: On this very point, anyone else?

PARTICIPANT: Is there a page you could give us reference to or is this just a general omission?

DR. HURLBUT: It's on page 21.

CHAIRMAN KASS: At the center of this is this thought: is a parthenogenetic blastocyst-like entity an embryo? That's, in a way, the conundrum here.

Most people will say this is not an embryo because it cannot, in fact, by your own criteria, Bill, cannot really develop and become an organism. There's really only one experiment, I suppose, that could prove that definitively. You would have to presume the innocence, I think, of that experiment, I think, to try it, and in the absence of this proof, there is a kind of doubt both on scientific and moral grounds about just what this thing is.

And I'm not sure. Maybe there's more to be said on that subject, but I thought we tried succinctly to say what the conundrum is and why that conundrum is probably not going to go away. And at the very least, as a practical matter, there is a certain bar even to investigating this further, at least in this country.

Now, the Dickey amendment wasn't written at Sinai, and even the things that are written at Sinai are

under review, but I'm not sure what more one would want to say here, but we will certainly consider it, and if you have some specific suggestions for enriching that discussion, I think we would be glad to have them afterwards.

DR. ROWLEY: Can I? Just for a point of clarification as to how you plan this morning's discussion, it seems from the way it has begun that we will consider the ethical issues and then at a later time this morning go back and discuss some of the scientific bases for some of these? I wasn't clear.

CHAIRMAN KASS: No. Thank you, Janet.

No, I thought that at least from the mail received before the meeting that most of the discussion that people wanted to have was — well, in fact, it stems really from Michael's comment on the current draft that you have, namely, here we have this extensive ethical analysis, and then it looked to Michael as if it were sort of a cop-out to say, "Well, you know, some of us like this and some of us like that," without our having actually had that discussion.

So it was Michael's suggestion, and I concurred, that we try to see where we are on a limited ethical question and it's also a provisional judgment because some of these ethical judgments depend, indeed, on certain empirical questions. I mean whether some of these biological artifacts are or are not embryos might be discernable from the animal research.

So I thought I would save the bulk of the time for the discussion of the conclusions, and I'll cut this off if it gets too long because the conclusions, I think, are the most important thing. But if there are major difficulties with things prior to the conclusions, this would be a good time to at least mention them.

And so if there are things earlier, Janet, this would be good.

DR. ROWLEY: Well, I think I indicated some of my concerns at least in my first response to receiving a copy of the draft of the white paper, and I do think that there are some serious issues, and I will talk basically only about the Landry proposal and about Bill's. And I think I was particularly troubled that we have ourselves in what I find a quite unusual situation.

And on page 7 in the middle, under Item 3, "yet is important to note that under the Landry-Zucker proposal embryos that divide normally upon thawing but are allowed to die by a human decision, that is, not to transfer them into a woman's uterus, would not be eligible for donation."

So viable embryos are going to die at the same time one would take those embryos that don't divide and, therefore, appear dead for scientists then to be able to see if there's any way to find within the few cells in those dead embryos something that might then go on to be used for an embryonic stem cell line.

And I think that for me this is a strange way of solving an ethical dilemma, that you let something that is useful die and then try strenuously to rescue cells from a dead embryo.

So I think that in the apparently dead embryo it's clear, and it's pointed out here in this discussion, they may have chromosome abnormalities that would prevent their ever developing, certainly not normally, and many of these chromosome abnormalities lead to cell death.

So getting long-term embryonic cell lines out of these would be difficult.

I think with regard to Bill's proposal — and I realize all of this is couched in the terms of this as at present a thought experiment that has no basis in actual experiments — but I think we do have to be very cognizant of the fact that this proposal is based on using oocytes obtained from women, and it does include the possibility that the women would be paid for it, though that's going to be controversial and that's not central. So that it says they can be donated. Women can be paid for them, but the feeling of many individuals in the country and I think the proposal of the National Academy of Sciences that is currently working on guidelines will be that there be no payment for the donation of oocytes.

But I want to just point out what this really potentially means in the real world, and we don't have very good evidence, but based on the paper of Dr. Hwang from South Korea that was published in *Science* in 2004, they used 176 oocytes for SCNT, somatic cell nuclear transfer, and they got one stable cell line and that's using a donor nucleus actually from the same individual who provided the oocyte and under the best possible conditions.

And to say that you're going to go through a series of experiments to identify a gene that will disable a human embryo or a human cell such that it can't develop into an embryo, but it is otherwise functioning, and to figure out which of several or probably quite a number of genes might fulfill that requirement, is going to take many, many, many human oocytes, and I find that an extremely troubling process.

Moreover, once you get the embryo with this defective gene, you're then going to do manipulations, presumably homologous recombination, but there are several possible strategies, to rescue that defective gene later in the course of the development of this cell line. That, too, is fraught with a lot of problems.

So you're going to have enormous wastage all the way along the line, and each wastage is the use of an oocyte donated by a woman, and I think this is not a line of research that I at least am prepared to support.

CHAIRMAN KASS: Let us move to the conclusions. I know a couple of people have to leave early, and anyway, Janet has already begun on the conclusions.

I can't, Janet, refrain from commenting just to the side that ordinary SCNT, which a considerable number of members of this Council were fairly enthusiastic and remain enthusiastic about, also involves a rather large number of human oocytes as you began by indicating.

DR. ROWLEY: I don't deny that, but at least you're giving them the best possible chance of developing into a usable cell line. This takes that thing — and that's why I pointed out the statistics from South Korea — one line from 176 oocytes under the very best circumstances. We're going to talk about one line probably out of 1,000 oocytes.

CHAIRMAN KASS: Bill, do you want to speak to that just briefly?

DR. HURLBUT: You know, Janet, I really welcome your well-expressed concern about your oocytes. Coming from a prominent scientist in our nation, to have such a serious concern about oocytes put forward in plain English is very, very positive, I think.

I, too, share that concern, and in raising the prospect of altered nuclear transfer, I am trying to draw on the best possible scientific possibilities, while being sensitive to the moral concerns. And one of the moral concerns I truly am concerned about is the procurement of eggs.

I think if my project ends up inducing the superovulation of a single woman to produce eggs, I will be disappointed. Now, there are other possible ways to get eggs. There are leftover eggs from the IVF clinics. There's talk of *in vitro* maturation of eggs after ovaries are removed surgically or from cadavers. There's talk of putting ovaries from such sources into animals, and because of the conservation of the hormonal systems, there may be ways to induce the formation of eggs.

All of that is science in rapid transition, and I think my project would depend on morally acceptable ways to procure eggs. I completely agree with you. The egg issue is a very, very serious issue, and yet at the same time, the scientific community has promoted the important possibilities of SCNT, has said that it's a far superior technology to harvesting ES cells from IVF lines which cannot be designed by genotype to serve as disease models, and so forth.

So the reason I put forward my proposal is because it seemed to offer the greatest spectrum of possibilities while preserving the moral notion. But I completely agree with you about the eggs.

So if that's a preemption for my project, it might also be for all of SCNT, and then we're back to the starting block, but I put forward my proposal in the spirit of defending both the science and the ethics.

CHAIRMAN KASS: Let's proceed in the spirit of Michael's suggestion that we see where we are on the individual proposals.

I'm going to say in advance that depending on how this discussion goes, we would either modify the conclusion to express the sense of the Council on these various proposals or go back to the more wishy-washy formulation suitably modified to meet various people's approval. I don't want to prejudge the wisest course until we hear where people are in the discussion.

Charles.

DR. KRAUTHAMMER: Well, perhaps I can just start it off by saying where I stand on the proposals.

First of all, I endorse the effort. I read Mike Gazzaniga's objection that it is a distraction. I don't think he meant it as a disingenuous distraction, but a distraction from science, and I think he's missing the point that we have a deep difference in the country among large numbers of people over the ethics of these procedures, and if we can find what's essentially a technical fix, which is kind of a magical solution to an ethical issue, we ought to pursue it, not to the exclusion of other research, but we ought to pursue it.

So I think what you're proposing Leon is that at least we look at the four proposals as extremely useful.

I'm rather inclined to support the first and the fourth, Landry-Zucker and the de-differentiation. The last one is very obvious because it's rather simple. It raises no ethical dilemmas, the de-differentiation to the point of pluripotency, but not totipotency. So I think that one is pretty obvious, and I'm sure there will be consensus on that.

I'm intrigued by Landry-Zucker simply because it gets us around the problem of destruction of embryos. If there are cells in what we might call clinically dead embryos that can be used reliably, there are tens of thousands of these embryos left over. It solves our problem, and it would allow people who are not troubled by the ethics of this to pursue traditional use of discarded embryos, live embryos if they wish, perhaps without federal support, and those who are troubled, to use the cells of the deal embryos.

And I say this as someone who has spoken here publicly and written that I support the use of discarded embryos, living discarded embryos in IVF clinics in stem cell research. I disagree with where the President drew the line in his August 9th speech, 2001, although I respect the reasoning behind it.

But even though I support the use of discarded embryos, I think we ought to look seriously at whether or not Landry-Zucker could work. If it does, it would allow us to pursue it in a way that would be ethically untroubling to large numbers of Americans, and I think that would be a great advance.

Oh, I might say on the others, too, that I'm a little bit troubled by the biopsy notion, and also by the proposal that my friend, Dr. Hurlbut, has proposed about the creation of what are essentially teratomas. I find that troubling ethically.

I agree also with Janet's objection that, just on practical grounds, it would involve the use of very large numbers of eggs, but I think my objection is more that I'm not sure we ought to be creating these bizarre organisms as a way to harvest stem cells.

But anyway, I'll stop there. Thank you.

CHAIRMAN KASS: Someone want to respond or go next? Michael.

PROF. SANDEL: I agree with what Charles has just said, and I think we should follow that suggestion.

I want to, having raised a question about a portion of the conclusion, I want to say something about the analysis in the document prior to the conclusion. I think it's superb and thoughtful and carefully done. And I'm speaking here especially about the ethical analysis. I'm less equipped to judge the scientific analysis, but I think the ethical analysis of these four proposals in the white paper is very powerful and extremely well argued, I would say the best and most carefully and, to my mind, persuasively argued of the documents that we've put out. So I think that's something we can be proud of.

My objection was to the conclusion and to the lack of fit between the ethical analysis presented in the white paper and the last paragraph of the conclusion.

And what I would propose, and this is consistent with Charles's suggestion just now — I would also want to draw attention, by the way, to Leon's memo where he summarized as a point of departure for our discussion the ethical evaluation of the four, and I think that's a perfectly reasonable statement of the ethical position.

I'm referring here to Leon's memo, and I would much prefer that we substitute for the last paragraph of the conclusion something that captures Leon's summary of our ethical analysis in the memo, and I actually have specific language drawn from the two to suggest if it's of use, and it would embody, I

think, the view that Charles has just stated.

If we go to the last paragraph, the thing I objected to was simply saying "where ethically appropriate," as if we were agnostic on that question as a bioethics body, and I think that problem is corrected precisely by Leon's memo.

So what I would suggest is that we amend the conclusion, beginning in the second sentence, the one that begins "because the Council is wholeheartedly committed to both the advancement of science for the betterment of humankind and to the defense of human freedom, dignity, and the value of life," comma, and then I would say, "We encourage public discussion of any proposal to achieve these ends," period, and then say, "Of the proposals we consider in this paper, we endorse scientific exploration of Proposals 1 and 4," in line with what Charles has suggested, and then drawing on what Leon has summarized in the memo something like the following:

For reasons stated in the ethical analysis, we consider Proposals 2 and 3 ethically unacceptable in humans at least for now.

CHAIRMAN KASS: Robby.

PROF. GEORGE: Yes. I'd like to say a word on behalf of the altered nuclear transfer proposal that Bill has put before us. I think it's important to understand what that proposal is, as Bill described it to us in the last meeting of this Council.

It is not a proposal to go forward at this point with the use of human cells. Rather, it is a proposal to conduct animal experimentation precisely with a view to determining to a high degree of certainty that we can create non-embryonic entities that are capable of generating embryonic type, pluripotent stem cells.

Bill also said then what he has reiterated this morning in response to Janet, that he would not like to see his proposal go forward if it did involve having to obtain eggs by subjecting women to superovulation.

Now, I think what that means is that in endorsing Bill's proposal, we are simply endorsing going forward with that basic animal research to take things to the next step while at the same time hoping, as those who support SCNT no doubt hope, that we will be able to come up with ways to meet the need for eggs that don't involve subjecting women to dangers and exploitations.

So I think with that understanding of Bill's proposal in mind, we can add to what Michael has just said, an endorsement of the continued discussion of Bill Hurlbut's proposal or continued investigation of Bill Hurlbut's proposal as well.

CHAIRMAN KASS: In animals.

PROF. GEORGE: Yes, precisely in animals. I would reiterate what Bill said last time on this score, that the only way that the proposal is being put forward only on the assumption or in the hope that what will be created, the teratoma-type entities that would be created, are truly non-embryonic entities.

Bill himself said very clearly on the record that he would not want the proposal to go forward. He would not want this to be practiced if it turned out that what was being created was merely a defective embryo or an embryo that's pre-programmed for an early death. It would have to be a distinct non-embryonic creature for Bill to — not "creature," but an embryonic entity — for Bill to endorse it, and that would certainly be true for me and I suspect for other members of the Council who share our view.

DR. KRAUTHAMMER: I'm afraid it was that slip that really troubles me about this proposal.

CHAIRMAN KASS: Charles, would you speak up?

DR. KRAUTHAMMER: I'm afraid it was that slip of the tongue which troubles me about this proposal. You call it an "entity." I see it as a "creature," and I think that's a fundamental difference, and that's why I'm repelled by it in principle, apart from all of the issue of obtaining oocytes.

PROF. GEORGE: Could I ask Charles a question?

DR. KRAUTHAMMER: Yeah.

PROF. GEORGE: Yeah, just to be clear, do you consider teratomas and complete hydatidiform

moles created in nature to be creatures as well?

DR. KRAUTHAMMER: I think it was a targeted missile that went wrong. It was perhaps — look. It's philosophical here. It's on point — it was an attempt at a human that didn't go right. I'm not sure we ought to want to reproduce that.

I mean there are other ways to deal with our problem of obtaining stem cells without killing embryos, and this one I find is simply the most troubling.

It could be what Leon calls sort of the wisdom of revulsion, and I haven't, you know, done an extensive philosophical analysis, but if you've seen a teratoma or you think about development, I'm not sure we want to be in that business.

PROF. GEORGE: Well, let me just point out in response to Charles that I think that there are two distinct questions here. One is: do we, in fact, have a creature or was my slip of the tongue telling?

And I think the answer to that is, frankly, no. We don't have a creature here precisely in the same sense we do not have a creature in the case of a teratoma or complete hydatidiform mole.

The second question is the one I think actually bothers you. It's not the question of a creature. It's the question of: is it ethically acceptable to create something that even in nature is repugnant and weird.

Now, I don't share your principled ethical objection to that, although I understand —

DR. KRAUTHAMMER: Repugnant, weird and somewhat human. If it's just repugnant and weird, it's just an aesthetic issue. If it's somewhat human, it's a moral issue.

PROF. GEORGE: Somewhat human in the sense of possessing a human genome?

DR. KRAUTHAMMER: Yes, and is an aborted attempt to produce a human essentially. I mean, it is an attempt to produce a human that went wrong.

CHAIRMAN KASS: Just procedurally, because I think we have probably started the discussion that is the one most to be sustained, let me see if I can get agreement. Let's see if the Council agrees on the other three things so that we can spend all of our time on this and see where we are.

The provisional formulation which Michael has at least endorsed on one, two, and four is as follows. And, by the way, I would like to modify slightly that we don't recommend for scientific exploration. That is not finally the judgment. Ethically acceptable for investigation —

PROF. GEORGE: Yes.

CHAIRMAN KASS: — that's kind of a minimal threshold I think we should say.

The rest is the matter of prudential judgment of resources and the like, which I don't think we're in the position here to do.

DR. KRAUTHAMMER: But couldn't we say that we encourage this research in the name of finding some ethically consensually accepted way of obtaining stem cells?

CHAIRMAN KASS: I think that's what —

DR. KRAUTHAMMER: It's implicit. So why not say it?

CHAIRMAN KASS: It's implicit partly because I think this was a question raised by Janet already in the comments on the last draft. Resources are going to be put into this.

DR. KRAUTHAMMER: But it would be stronger if we were explicit in what is obviously implicit here, that this ought to be looked at without giving it a dollar figure.

CHAIRMAN KASS: We now have a new question for deliberation. Let me put that one last, but —

PROF. GEORGE: Leon, could I finish one remaining thread with Charles just very quickly?

CHAIRMAN KASS: It won't be quick, but go on.

PROF. GEORGE: No, no, it will.

Charles, just to —

DR. KRAUTHAMMER: It's not fair. He was thinking on this while you were talking.

(Laughter.)

PROF. GEORGE: On the objection to the creation of the entities, just to be clear, your objection is precisely to creating such entities. It's not the objection that I and others have to the use of embryos in this regard where the objection is to killing the embryos.

You're not objecting to killing teratoma-type creatures. Your moral objection is to creating them. So they're on a different plane.

DR. KRAUTHAMMER: The answer is yes.

CHAIRMAN KASS: The first proposal, cells from organismically dead embryos, it's ethically acceptable for investigation in humans, but with the IRB-type caution about the need for observing the stringent guidelines, Janet, we will deal with you directly on that other question that you have raised about the way the text reads at that particular point.

DR. ROWLEY: Yes, but I emphasize that because that's exactly what's going to happen. So I think to be honest, you have to say that perfectly normal, viable embryos, at least as determined at the four-cell stage, will die, whereas you will then spend vast efforts to try to rescue some cells, potentially normal, but potentially abnormal, from these dead embryos.

I just raise the question: is this an ethically appropriate way to proceed?

CHAIRMAN KASS: Okay. The somatic cell de-differentiation studies, ethically unproblematic. Is there anybody who would disagree with the conclusion on the second proposal, the blastomere extraction from living embryos, ethically unacceptable in humans at least for now owing to the reasons given in the unethical analysis?

Most especially, we should not impose risks on living embryos destined to become children for the sake of getting stem cells for research, not even for their eventual speculative benefit to the donor child. Okay to study this in animals.

Is there anybody who would dissent from those sort of provisional conclusions?

Janet?

DR. ROWLEY: I don't want to dissent, but I think that one should omit the last phrase because it's much more effective to get cells that could be potentially useful to the child if they were needed by that child in the future from cord blood, and this is done as a standard procedure everywhere.

So to take a blastomere to set up a cell line that may be useful for the child is not something I think that the Council should be considering or endorsing because saving cord blood is much better and safer.

CHAIRMAN KASS: Thank you very much, and that will be added. That's an important omission.

Are we okay on the others? Bill.

DR. HURLBUT: I'm not quite clear what we're doing here. Are we — you sent the note at the last minute about evaluation of each of the proposals individually. Are we now talking about including that somehow in our white paper, adding it on as something, or are we just discussing how we feel about things?

Because from a practical perspective, I think we're making summary statements that are at this point in our deliberation on this, whether we intend to go forward in it or not, we are not prepared to make, and I would cite even just one and four, which have been given a nice endorsement thus far. I personally think that many of the same concerns that Charles has raised could be raised reasonably about one and four.

I mean, take four, for example. De-differentiation; at first glance we use a certain understanding of what's going on biologically to say, "Oh, that's nice. We add a few chemicals and it becomes pluripotent."

That's not at all clear what it would involve, de-differentiation, that is. We don't know if there's a

sequential patterning like the building up of a building that's necessary for establishing pluripotency. That is very likely, as *embryogenesis is a process.

We don't know whether we would need eggs, for example, to do it because cytoplasmic factors from oocytes are probably the chemicals you need to do that. So it might involve huge numbers of eggs to do de-differentiation.

The objection that is sometimes raised about my proposal is that it's very close to human, although indeed it would not be human by the understanding that Robby and I share. Well, if you take de-differentiation, you take it down to within one molecule of being totipotent, then is that not close to human? Just because you came from above?

I think, in fact, the little dialogue that went on there a few minutes ago points to the difficulty of all of these discussions, and just to step back for a moment to proposal number one, if you read Janet Rossant's comments, she's not clear about the moral meaning of proposal number one either. She says that the scientific definition of the word "organism" is not at all clear.

Besides that, there are interesting and important ethical questions about the practicality of actually knowing if a single cell is either totipotent or if, when taken out of the culture and placed into a womb, it might actually grow. If you talk to the people who work in IVF clinics, which I've done extensively, they say it's pretty hard to predict. As Janet Rossant clearly says, they've been searching for this marker of lethality or no longer viability of the embryo and they haven't found it yet.

That's not to say that's not an empirical study, but it also involves a deeper ethical analysis than we've done here.

My understanding of our whole project was not that we were going to do the natural process of a serious ethical Council like ours, which would involve hearing proposals, taking testimony, doing serious deliberation and then comprehensive moral analysis. We surely have not done that yet for any of these proposals.

What we have done is a pretrial hearing to say whether there's a case that merits serious consideration. I think we should say that all four of these proposals do merit serious consideration, and at this stage, nothing more for any of them really, except maybe observing embryos; nothing in the way of humanly involved engagement because we're not quite there yet.

If we end up by adding summary statements about individual views of each of these proposals, we will be jumping way ahead of ourselves as a serious ethics council into statements that will be taken by the public and the press as being conclusions, and we're not ready to make judgments.

We've done the pretrial hearing. We say there's something worth investigating. To stop at this point would be to stop halfway through the trial when we only have sort of hearsay and a few comments, not cross examination, not cross-testimony.

I think many of the things that have been raised about my proposal I think I can easily answer, but I've not had a chance to do so, and that might change people's point of view. After all, the whole point of this difficult debate is that we talk it through, not just politically posture.

CHAIRMAN KASS: Jim Wilson.

PROF. WILSON: Would it be helpful if instead of revising the last paragraph of our conclusions we cut it very short by ending it with the first sentence? So that we would say, "Despite these differences among us, and we recognize there are differences, the Council shares the view that the proposals here discussed and others like them that they may stimulate deserve careful and serious consideration," period. Go no further.

CHAIRMAN KASS: Does someone want to speak directly to — no, wait. It's Jim's point in response to Bill's concern.

PROF. FUKUYAMA: Well, I guess it kind of depends on what you then expect to do afterwards. I mean, is this a prelude then to another council meeting or two in which we actually do, you know, what Bill suggests and do a much deeper analysis of each of the four, or do we just throw it out there and say, well, someone — because I do have some sympathy for the point that Michael made that if we don't do this analysis, who's going to do it. I mean, it does seem to be that that's kind of our charge here.

PROF. WILSON: Well, Michael, I believe, has said that, given the present state of our knowledge,

the ethical analysis of these four proposals is, I believe he said, sharp, clear. I forget the exact adjective, but it was quite positive. To do more than that requires a substantial advance in scientific knowledge so that we know what we're talking about.

We can't even adequately describe these things. We're inventing names as we go along, and unless there is more research, we can't have a trial. We are saying that there's probable cause to go forward and look at these matters, but we don't know whether any of them will pass the test of useful beyond a reasonable doubt. And that can only come about when science has advanced much further than it is.

So I'm saying all we can do at present, even if we spent another ten days on this, is essentially the analysis we have because that's based on all we know, and therefore, we should simply say these matters deserve careful and serious consideration.

Now, at some point the Council should continue its existence, may gather more information and you can come back and take a closer look, if not us, then other bodies. But I don't imagine this is going to happen for some time because the research is going to be time-consuming.

DR. KRAUTHAMMER: May I just interject here, Leon?

But to be completely agnostic here, I think, is a little bit disingenuous. In the absence of new scientific evidence, would we not here unanimously agree that the removal of a blastomere from a living embryo in order to produce these stem cells would be unethical. I mean, do we need a lot of evidence on that one?

Is that number three or number two?

CHAIRMAN KASS: Two.

DR. KRAUTHAMMER: Number two. I mean, what's the scientific evidence that's lacking that prevents an ethical decision here?

CHAIRMAN KASS: Gil.

PROF. MEILAENDER: It may just be that I'm sloppy, but I think we've done a good bit actually. We haven't done everything you might want, Bill, but it's not as if we haven't done a decent amount.

And I think, therefore, that I agree with Michael's general point that we should not simply punt at the end, but we should reach some conclusion.

I actually think — I mean, as you know, I'm not ordinarily one who cares whether we reach consensus or not, but I think we're not that far from a kind of consensus here. I don't have a problem with language something like the language Michael suggested that we're prepared to endorse two or three in humans right now.

I'd be happy to say something more positive about three with respect to animal studies rather than just let it go as an assumption, say, you know, it would be good to do the animal work in order to try to determine what actually is happening.

So it seems to me that, whatever reservations different ones of us may have with respect to one or four, those are not reservations that lead us to say science should not conceivably go forward investigating these more. I mean, after all, our mantra has generally been that science proceeds on as many fronts as are ethically acceptable, and we're trying to figure out whether there are insuperable ethical objections here.

And it seems to me that, whatever differences we have with respect to, well, three in particular, I can't see that there are insuperable objections to our saying something positive about doing animal research in connection with it while regarding it as for now unacceptable in human beings.

So that, granting that there is more that could be done on discussing any of these, I do work with the assumption that we have actually done a good bit, that we've not done nothing, and that we're not that far from conclusions which almost all of us could share even with slightly different intonations about, you know, how we feel about them.

CHAIRMAN KASS: Jim wants a brief response.

PROF. WILSON: Thank you, Gil.

I very much share your general view. Perhaps my effort to reach a conclusion by getting rid of language led me to get rid of too much of it. Perhaps we could take that first sentence in the last paragraph and say that the Council shares the view that Proposals 1, 3 and 4 here discussed and others like them that they may stimulate deserve careful and serious consideration, and then perhaps add, if you wish, an explicit reference to animal studies.

If you all feel now that two is ethically dubious, I don't believe three at the present stage is ethically dubious from the point of view of further research. Two from my most elementary scientific knowledge could fall on the other side of the line.

CHAIRMAN KASS: Dan Foster.

DR. FOSTER: Well, you know, I think we can have some statement about animal research, but you know, the world of science, if it's perceived that any of these ideas have potential, it will be explored. I think Bill and a colleague are already planning studies. I think I read it in some press. So those studies are going to go on whether we say it or not if there's thought to be scientific viability.

I don't mind mentioning it as a guardian thing, but I don't think that that is a big deal because that's what scientists do, I mean, and this stuff, you know, has been in the papers and so forth. So I think it's sort of automatic that that will go on whatever we say.

I mean, if it is thought that somebody can do that whether they have moral inhibitions or not, you know, they might go ahead and do that. So —

PROF. WILSON: The science may go ahead, but our job is not to direct science. Our job is to direct policy makers and the attitudes they should have about science.

DR. FOSTER: I understand that, Jim, but I mean, you and others have brought up about the fact that we need to encourage or we should encourage scientific experiments in animals to see where these things are going.

When altered nuclear transfer came up at the last meeting, I was tremendously enthusiastic about it, and I still really admire Bill's thought about it. The more I've thought about it and read about it, I've somehow come a little more towards the view that Charles has expressed.

And I wonder if in terms of the conclusion one might alter it a little differently along what Michael has said, that with our current understanding that we believe that one in four have no immediate ethical restraints for potential use in humans; that the issue on three is such that it may well move into this category, but because of the number of questions that have arisen, some in my mind, some are worried about making something that's — in a way, I sort of thought that even though one understands why we use the term "teratoma" and so forth, it might not have been the best analogy to what we're trying to do, I mean, it seems to me.

So I would myself be in favor of the proposal that has come from Michael and Charles to say that, at this state in our knowledge, one and four appear to us to be ethically acceptable and that the potential for three may well move into that category, but at this point we are not willing to do that.

I think I'm in that stage, even though I probably was more verbally supportive of Bill's idea, or somehow it has begun to bother me a little bit. So I just raise that possibility.

CHAIRMAN KASS: Peter and then Paul.

DR. LAWLER: I like the image of the pretrial hearing, that we really don't know enough to make a judgment about any of these, and the more we move towards definite judgments, the more I back away.

I'm not sure I would segregate Bill's proposal, enough though I have objections to it or concerns, and not so different from the ones Dan has, and two big ones that have been mentioned. I wonder about the prudence of engineering a third category that's not life or non-life but kind of a near-life experience. This may not be deeply morally problematic, but I wonder about the prudence of doing that.

And I also wonder about using reproductive materials for reasons having nothing to do with their natural purpose, which I think Bill's proposal suggests he would do.

Having said this, this proposal still has promise. It merits research in animals, and it merits Bill's persuasive work. He hasn't persuaded us yet, but he's an energetic guy. He will continue to try to persuade us.

From my point of view, it passes the pretrial hearing test. It's ready to go to trial, and it's going to be a long trial, a difficult trial, I hope a nationally televised trial.

(Laughter.)

DR. LAWLER: And I think all of the other proposals finally are in that category, too. We don't endorse Bill's proposal in terms of experiments on humans now, but he's not asking for that. It's not like it's something he wants.

With respect to the dead embryos one, that demands investigation, I mean, observation of human embryos.

Number four seems to me in such early stages of development we don't know what we're talking about. Nonetheless, we can't help ourselves, and number two, the ethical objection raised by Charles and others, I think, is obvious for now, but that, too, can change through further scientific development.

DR. FOSTER: Well, in terms of four, let me just interrupt there. There are at least three and maybe four papers that I know about that with small molecules you can at least with myotubules move back to make a myotubule, you know, make fat and bone and so forth. So I don't think that we're devoid of evidence that that might work. I don't know about the issue of pluri- to totipotential cells. I mean, I don't know, but I do think that there is enough evidence on four that you could say that that's potentially a useful thing.

CHAIRMAN KASS: Excuse me. Paul is next in the queue, but Charles I know has to leave. Are you watching the time? Do you want a last comment before you go?

DR. KRAUTHAMMER: I'm going to stay another 15 minutes and then go. I'll wait a little bit longer then.

CHAIRMAN KASS: Thank you.

Paul.

DR. McHUGH: Well, I want to come back really into the discussion that Michael gave and make the issue of this product more personal. I read it and thought it was a wonderful document, very clear, very coherent. It included all of my concerns in relationship to all of these, and I was so pleased with what it had done, Michael, that I simply read the last paragraph as your sentence, Jim.

And then I think Michael made a wonderful pickup, in other words, in a kind of editorial pickup that we would have, if it were sent out the way we had originally, we would have been marked by other people, and we might well have woken the next day and said, "How did we forget that?"

And so I'm very interested in going beyond Jim's sentence to express what Michael has proposed, and I think Charles and Michael and I are seeing commonly these clear themes as being easily expressed in terms that are the charge of this Council; that these are clearly things — at the present time if new knowledge came around, we might well change our mind in relationship to it, but one and four seemed ethically coherent at the moment.

Two seems to me unless — two is on life supports. As far as I'm concerned, in order to have two, you'd have to do something very radical to save it.

And three, Bill's suggestion, I think, has sufficiently problematic issues, sufficient red lights, as I put it before, to make us say that has to be something that will go forward in animal research to find out, just as Janet said, that no scientist — for example, I share Charles's view about these things as being creatures. I share the idea that it's also a kind of pollution of the human genome that I have a yuk factor towards, and I am equally concerned that fundamentally it has — since I think the SCNT normally without fooling around with it also won't become human — I think this is painting the lily, and I think scientists will soon learn that.

On the other hand, I think Bill has made a persuasive argument to do more research. I come back fundamentally to supporting what Michael said. The combination of what we did added to the thoughts that Leon's memo had would be a very appropriate final product for this session to achieve.

CHAIRMAN KASS: Bill, do you want a quick response? Yes.

DR. HURLBUT: You know, first of all, I want to say plainly that in raising my proposal, I'm trying

to defend the important goods being defended by both sides of this issue and differently expressed by all of us in this Council.

I personally believe that a decent society does not build the foundations of its biomedical science on the intentional creation and destruction of human embryos. That's a fundamental starting point for me personally, but as a person trained in science, as a physician, as a father of a handicapped child, as a person who has seen the possibilities of the science, I also want to try to open the science.

I think some of you are raising prudential concerns, and you have to put into the balance of the prudential concerns about my proposal the tremendous possibilities and positive goods that could come from it.

Now, I know that, getting down to the crux, I resonate with what Charles is saying and what you're saying. Red flags go up in my mind, too, but as Leon expressed, some concepts of manipulation of human life are unbeautiful.

Disease is also very unbeautiful, and we do things in medicine that are strange and unintuitive. We give people a dose of disease for vaccination. We send in reengineered cells like targeted toxins. We grow great sheets of skin from cells harvested from foreskins. We cut the body. We do things that are not easily and intuitively aesthetically pleasing for the very purpose of a higher good, which is healing.

I, on the other hand, would never favor the creation of something I thought was a living human being for its destruction, but the very point of this difficult dialogue, and I think it was characterized in this exchange here, is we have not as a society nor even as a Council actually contended seriously with the question. We have not reached a consensus conclusion, nor really even properly deliberated on what is the definition of an organism, an embryo and the moral thing we're trying to defend.

We are in a transition time. We are at the beginning. We've gone from genomics to proteomics, the genes, the proteins they produce. We are at the beginning of the era of developmental biology. From here on out, those questions, what is an organism, are crucial questions. I think it's going to be evident in our next session. What are the boundaries of humanity with regard to chimeras? What are parthenotes? What are you going to do with the products that you produce with embryonic stem cell research? Once you differentiate them, are you going to reaggregate them? Are you going to grow human parts apart from bodies? Are we going to have factories of kidneys? Are we going to grow brains in vats? It's just simply challenging conceptual issues here that we have not yet contended with.

And just one final point. Paul, you yourself have argued and, you know, with a certain sympathy from my side, that what we call cloning for biomedical research, or SCNT, is not really a reproductive process. It's a lab process. It's not really the production of a new human being, you've said. It's an extension of bodily being of the individual.

I have some sympathy with your perspective on that, but am uncomfortable because it's clear that Dolly, if she was a sheep, Dolly was once an embryo.

So I agree it's a proposal called altered nuclear transfer. In fact, in July 2003, Rudy Jaenisch came to our Council and explained that all cloning for biomedical research, all SCNT, in fact, involves altered biology, and I've got the quote from you here, and these are the words of Michael Sandel, who says, referring to Jaenisch's comments and how your attitude had all along been right, and that, in fact, this produces an entity that is not capable of becoming a human being and, therefore, is moral.

Michael speaks of the vindication of Paul McHugh's attitudes. Remember? And then he goes on to say of Rudy Jaenisch's comments, "And he argued that there is a difference." He's affirming now that this entity produced by cloning is not a human being. "And he argued that there is a difference, a biological difference, with a possible ethical significance between a zygote and a clonote, between a fertilized embryo and an artifact created in the lab, and he was told that this is an eccentric position," namely, you were told that it was eccentric.

Well, you argued this. Rudy Jaenisch confirmed it, and all I'm trying to do is really confirm it biologically.

Janet Rossant has —

DR. McHUGH: Let me just say, maybe just finish that point. That's a very good point, and my

point is this then becomes making an ANT; it becomes painting the lily, and no scientist will bother to do it for all of the reasons that Janet has said, that is, that it will consume eggs. It will ultimately — you know, it is my opinion the SCNT does produce, in the primate, a nonviable organism.

Other people disagree with me on that, but I don't think that the step to then poison it further .-

DR. HURLBUT: Poison it?

DR. McHUGH: — is even necessary.

DR. HURLBUT: What are you talking about? It has already got five percent of its genome improperly expressed even in the newborn form of clones. There's a massive reorganization of the epigenetic factors. This is just adding a sure confirmation of it.

DR. McHUGH: Okay. Well, I mean, there is our distinction. I don't think you need to do more than is already damaged in it.

CHAIRMAN KASS: I'm going to try to hold a bit of order.

DR. KRAUTHAMMER: I'm sorry, but may I make just a final statement because I'm going to need to go, if I could just respond? I don't mean to interrupt.

CHAIRMAN KASS: Your final statement, not everybody else's.

DR. KRAUTHAMMER: Yes, I did mean mine. I wasn't speaking on behalf of the Council.

CHAIRMAN KASS: No, thank you.

DR. KRAUTHAMMER: Look. I'm sympathetic to Bill's seriousness and his attempt to bridge the difference between our ethical concerns, our scientific concerns, and I happen to share the principle that you enunciated, that we ought never create human embryos in order to destroy them, which is why I support the use of discarded embryos in IVF clinics, because I consider that a different category, and why I oppose research cloning.

But I believe that a teratoma is a tragedy, and we ought not be creating tragedies deliberately. That's just a shorthand.

Given that that view at least has some support here on the Council, I'd suggest that we not be entirely agnostic; that we speak, if we have a consensus, as I think we do on numbers one and four, express it explicitly. I think it's an advance. It will help to encourage that research and legitimize it.

I would also add the word "encourage." I think you want to discuss that a little bit later, Leon, but I don't see any reason why that ought to be only implicit.

We ought to explicitly rule out number two, which I think we have a consensus on, and of course, when we preface all of this by saying that the science is shifting, and if the science evolves in a way that causes reconsideration, we're open to reconsider all of these numbers one through four and perhaps end up with three.

I happen to oppose it in principle, but I'm speaking only personally, but perhaps we could state consensually that there are some ethical issues still unresolved, and we would, therefore, perhaps permit it in animals and not in humans, although I would oppose — I mean, I would not oppose, but I would be a little bit troubled by pursuing it in principle.

But I would offer that as a way to perhaps bridge our differences, have a statement that would be strong, and would launch an area of thinking in research that I think would be extremely useful and beneficial.

And I apologize for leaving in the middle of a brawl. It's always interesting and enjoyable, but see you next time.

Thank you very much.

CHAIRMAN KASS: Thanks, Charles.

I have Ben Carson, Diana, Janet, Gil, Michael, Frank. I want to hear from everybody. That means Rebecca and Alfonso, too, before we break.

What did I say? Ben.

DR. CARSON: Okay. First of all, I thought the white paper was well done. It was a good overview and very easily understood. I think that's very important.

I would like to say that, you know, three years ago many of the things that we're discussing in terms of these four proposals would not have been on the table, and yet there was a raging debate going on about stem cell research and its potential for good.

I think we need as a Council to make sure that we do ferret out those things in these proposals that we agree with unanimously because we want to maintain our relevancy, and we don't want to be so tentative that nothing we say means anything.

But I think at the same time we need to recognize that there are more than just these four proposals. There are going to be a lot more than just these four proposals, and we don't want to give anybody the impression that these are the only things that are being looked at and considered.

CHAIRMAN KASS: Thank you very much.

Diana.

DR. SCHAUB: Yeah, it seems that there are a number of suggestions on the table about how to slice these, and some want to put one and four in one category and two and three in another category, a yes category and a no category. Others would slice it differently and put one, three, and four in the yes category and two in the no category.

I guess it seems to me that the way it's stated in Leon's memo is pretty good. I would be in favor of not trying to lump them into categories, but discussing each one separately.

And I think the statement that's given here is maybe pretty accurate about what the consensus is. I would be in favor of somewhat strengthening the endorsement of number three. I mean, the three elements in there should remain that we think it's as of now ethically unacceptable in humans, but despite the serious ethical concerns that some folks have about the proposal, we do think it's worthy of being pursued in animals.

I mean, I guess I'd sort of like to know is there a consensus about that, about pursuing it in animals, and if there is, then that could be stated somewhat more strongly in the assessment of number three.

CHAIRMAN KASS: Thank you.

It is how to find the right balance that this discussion is supposed to give guidance, and that was a very useful suggestion.

I have Janet, Gil, Michael. Michael, do you want a last word before you go, too?

PROF. SANDEL: I apologize that I have to leave early.

First, two comments. First, on the moral arguments, I think it's very difficult to read the pages 16 through 19, the ethical analysis contained in the white paper unless one has, as Bill may feel he has, persuasive arguments to each of those four ethical objections and not to regard proposal number three as morally dubious.

Those are devastating arguments, I think. I'm talking now about the ethical analysis in Proposal 3 on pages 16 to 19, not about the conclusion.

And different of us weigh those, find those arguments some more persuasive than others, but the one that I find most persuasive, just to go to the moral merits for a moment, I think that regardless of our other disagreement about the moral status of the embryo, there were some of us who have an equal moral status view and others who had an intermediate status view, and we had long arguments about that.

But it seems to me that even on the intermediate moral status view, on that view to do the stem cell research and to destroy the blastocyst does carry a certain moral burden that requires that the use be restricted to lifesaving and morally weighty purposes so that it couldn't be used, for example, to develop a new line of cosmetics. That's the intermediate moral status view.

Even on that view, there is something, and here I speak just for myself, something morally creepy about genetically engineering a mutant embryo-like being and then saying with that being you remove even the moral weight of justification that this must be used only for especially important

lifesaving purposes.

And so I think that's captured in Charles's invocation of the kind of saying it's weird. If it's somewhat human, it's weird.

Number three, objection number three doesn't depend on any scientific discovery. Number three, it's the third ethical objection laid out worries about it, regardless of what the creature or the being or the thing created, the artifact.

So I just wanted at least to state why even — well, I don't think it depends what moral status one attributes to the embryo; that it's still possible to make sense and be moved by some among the four moral objections laid out in the white paper.

CHAIRMAN KASS: Thank you.

On that point, I'm going to keep Bill from responding on this.

DR. HURLBUT: Please.

CHAIRMAN KASS: Very briefly, but I really want to keep — there are people waiting to get in on this.

DR. HURLBUT: Michael, you're saying that the slight difference between what I'm proposing and what Paul called the gilding of the lily; you're saying that that is more of a mutant human being in some sense, those loaded words? You're saying it's more than what you've called for publicly, the endorsement of SCNT?

And second —

PROF. SANDEL: Yes.

DR. HURLBUT: — I want to ask you. I assume you've read my comments that I made for the President's Council's first report. Have you, in fact, read through them carefully?

PROF. SANDEL: Yes.

DR. HURLBUT: And you don't find any of those — can you cite back for me my arguments perhaps?

CHAIRMAN KASS: Bill, I think —

DR. HURLBUT: I mean, it's like I don't think you've read them, frankly. I don't get the sense of —

PROF. GEORGE: Bill.

CHAIRMAN KASS: Bill, I'm going to intervene, and let me say that I think Michael has pointed to the place in the analysis where there are ethical objections to ANT itself, not depending on slippery slope, not depending on the egg question, not depending upon the question of whether answering this question which can only be empirically or at least partly empirically answered. Is this artifact really a defective embryo or something else?

There are people who have these kinds of concerns. Here is the place where I think the document has been one-sided, and if Bill has answers to these objections, as he says he does, then that document has to be corrected so that those particular objections can be countered. I think that's simply only fair.

We've made the slippery slope arguments and then finished by remarking that, look, slippery slope arguments always presuppose that people cannot find the means of finding some boundary where you can hold the line between what's acceptable and what's objectionable, and I think we ought to balance this up and similarly add something on the egg question.

But I think, look, everybody has to acknowledge — Bill has to acknowledge, and I think Michael is speaking for himself and perhaps others — that there are some people who do find this particular kind of practice aesthetically or morally troublesome to the point of dubious and in some cases unacceptable, and that's a difference of ethical perspective on this which we simply have to acknowledge.

Now, there are other people in the room who have already spoken, who notwithstanding their worries about this are prepared to say with you that we do lots of peculiar and aesthetically

problematic things in medicine, some of them even morally complicated, and that doesn't necessarily rule them out, especially if the animal research shows great human promise, and I think there's a way of fixing this document to make sure that this particular kind of — Michael reads that, and he says it's sort of devastating, and it's partly devastating because the other side has not been presented in that particular paragraph, and I think if Bill can give us a response to that, that fills out this document and improves it.

I'm simply going to go to the queue.

DR. HURLBUT: May I —

CHAIRMAN KASS: No.

DR. HURLBUT: I'd like to withdraw my last comment to Michael.

CHAIRMAN KASS: No.

DR. HURLBUT: May I withdraw my last comment?

Michael, I'm sorry. I didn't mean to imply you hadn't read my statement, but I do think that I have serious arguments that have not been discussed properly.

CHAIRMAN KASS: Okay. I have Janet, Gil, Rebecca and who else has been hiding out? Frank and Alfonso, and I'd better say something, too, at the end.

So, Janet, please.

DR. ROWLEY: All right. Well, I'd like to deal with the issue raised on page 19 under the rubric of is it scientifically sound because I think Charles and several others in the text of this part of the document talk about teratomas.

Teratomas are chromosomally very abnormal, and that's not what we're talking about here. So I think the analogy with teratomas is potentially an unfortunate one because the ultimate goal of this research, of all stem cell research or most of it, is to think about ways that stem cells can be used to treat very devastating human disease.

And the proposal here is going to take a nucleus before it is introduced into an oocyte or an oocyte-like cell. It's going to change, potentially change only one gene that then prevents that cell from developing into an embryo, but the critical thing, as pointed out on page 19, is that this has to be fully reversible without residual abnormalities in the derived cell.

So you want to make the smallest possible genetic change to prevent the cells from forming an embryo and a change which will be fully reversible so that the cells that you finally give to a patient to treat a disease are, in fact, functional cells.

Now, that's like saying that an embryo that has a defect, say, in the disease of hemophilia, for example, the embryo has 29,999 genes, all normal human, all going to lead to a normal developing human with brain function and things of that sort, but one gene is abnormal. The proposal to work has to be that a single gene that is essential for developing an embryo is disarmed, if you will, before the nucleus is inserted into the oocyte, but then is fully reversible afterwards.

And I don't see how one can look on the developing cell with essentially all normal genes except one as any different from an embryo carrying a defect that leads to hemophilia, that leads to muscular dystrophy or something else.

So it's a fully human embryo with one gene defect, and for me that's the equivalent of a human embryo.

CHAIRMAN KASS: Let me continue in the queue. Gil and then Rebecca.

PROF. MEILAENDER: As far as I can tell, everyone or almost everyone agrees that the basic structure and analysis of this paper is very good. I mean, everybody thinks it's well done.

And I've been trying to figure out sort of how to describe what exactly it is that we're arguing about. I think in some ways we're actually arguing about some old questions and not about the question that's here.

I haven't heard any proponents of or any of those who are favorable toward alternative three argue

that it should for now be done in human beings. I have not heard that.

I have not heard any of those who have reservations about it argue that it would somehow be morally wrong to proceed to do it in animals, though even if those studies proved to be promising, they might still have the yuk factor and have a moral objection to proceeding in human beings, but I haven't heard arguments that it shouldn't be done in animals.

If that's right and, you know, subject to correction from anybody who thinks differently, whether they're favorable or unfavorable toward alternative three, it doesn't seem to me that we have a deep disagreement. We may have a difference in tone about how many exclamation marks we want behind the sentence that says it would be fine to proceed with this in animals, but that's about what it amounts to.

The only thing that would be disingenuous would be somehow to say, while we normally say that science should attempt to proceed on every ethically acceptable front, we know in advance that this is not an ethically acceptable front. I mean, that, I think, would be a mistake.

But if you say do the basic work in animals, see what happens with however many exclamation marks we together want at the end of the sentence, I don't think that we have a deep disagreement about that.

So to me that's where it seems we are, and it doesn't seem to me to be a bad place to find ourselves.

CHAIRMAN KASS: Why don't you hold off, Bill? Okay.

DR. HURLBUT: My one comment to Gil is I agree with you, but I think that equally applies to all four proposals.

Until you are clear about what four is producing you certainly can't say it's ready for human use, and in a way that's true also of one. Until you're absolutely clear that the single cell from an eight cell embryo is not totipotent, for example, you can't say that you can go proceed with human use of this technique.

All four proposals, with maybe the exception of two, offer promising prospects, but also are at the stage of being investigated.

CHAIRMAN KASS: I think I know how one could write such a conclusion that makes it perfectly clear that these are provisional findings of a preliminary hearing, and that this is not the end of the ethical analysis or the ethical discussion. "On the other hand. . . ."

There's a way to write this that begins from where Diana is and where Gil is and takes into account your precautionary concern that this ethical conversation, even about the ones that seem to us relatively innocent, may turn out not to be so innocent on further reflection, but that they pass a certain kind of minimal ethical threshold to say these are things worth considering talking about, and the Council is not just punting, having done this analysis.

I think there is a way to do this and find a kind of general acceptance around the table, and I certainly welcome the chance to try to produce such language, not here on the spot today, but in short order, and the troops in the office know how to do this very well.

Rebecca, you've been very quiet.

PROF. DRESSER: Well, I don't have deep disagreement with much of what I've heard. I don't have an objection to saying it's permissible to go forward with these investigations in animals.

I think we should acknowledge that science is always or often very surprising, and it's not clear that any of these things will develop to the point where people are seeing clinical applications.

If certainly three — and, of course, I share the concern about two and the risk to any children who might be born from any procedure — but for some of these others, especially three because it requires eggs, if the science does go forward and prove to be promising and then the question comes, well, should we try these in humans, I think there will be very serious ethical considerations, just as there will be and are with SCNT in the fact that you have to use the human eggs.

So I would go along with the trend of your proposal in terms of no ethical objections to looking at this in animals. There could be some serious issues, depending on how the science turns out, if the step toward humans occurs.

CHAIRMAN KASS: Thank you.

Alfonso.

DR. GÓMEZ-LOBO: My apologies for coming in late today.

My overall inclination is to endorse the document. I find it very good, very clear, and ultimately solid. But my main reason for endorsing it is because, contrary to an E-mail circulated by Michael Sandel, I don't think we're in a position of making any definitive moral judgments, but I know that by now we have a consensus on that.

Let me just mention this. Of course, there are questions of the development of the science. If some of these proposals simply don't work from a scientific point of view, of course, it's going to be moot and, thank God, we're not going to have to worry about it.

But we need time not only for the science, but also for the ethics because I think that these are quite new ethical problems, and we need time to consider externalities, if you will, or other aspects that are not considered here.

Let me just give one example. I have very serious problems with Proposal 2 because of the reasons just mentioned. It's a case of battery really to go into the body of a human being and extract cells.

But number one also has its problems because there are important disanalogies between the practice of extraction of organs for transplantation, say, after an accident and the circumstances of the waiting for the death of an embryo in order to extract the organs.

I think that one can imagine several scenarios that would make it morally very problematic. Up to now in transplantation ethics, one of the key demands is that there be a drastic separation between the physicians dealing with the person who has died and the team of transplantation surgeons that move in to extract the organs, whereas here we'd have practically the same team as if around the deathbed of someone waiting for that embryo to die in order to extract the cells.

Now, that's just one example which occurred to me is the kind of problem that needs time. There may be others, or they may be resolvable.

So basically, you know, I praise the document, and there may be need to include some responses from Bill and then to modify the last paragraph.

Thank you.

CHAIRMAN KASS: Thank you.

Frank.

PROF. FUKUYAMA: Well, I don't know. I guess I'm not so sure I'm happy with the document just from listening to this discussion today, and I'm not quite clear, Leon, what you think the procedure from here is, that if we endorse the document, you're just going to get some language from Bill to strengthen, you know, his objections.

Because as I'm listening to this discussion, I'm even more confused about what I think about this issue because there's a huge difference between creating something that looks like a teratoma and creating something like what Janet suggested, which is basically a complete embryo with just a kind of minimal, you know, number of genes changed.

And I would think that it's also something where the scientist creating this entity could actually use some ethical guidance because I presume that there's a certain, you know, range of variation in exactly how many genes they could change that would make it look, on the one hand, more like a teratoma and, on the other hand, more like a real human being.

So I don't think it's simply enough to say, well, we can't say anything more ethically about this until the science goes ahead and, you know, does a proof of possibility study in animals. I'm just not at all certain that we've really explored this whole set of issues adequately.

Second, just a brief comment I'd like to make. I know this is an ethics council, and we're not supposed to deal with politics more broadly, but the political landscape on this really has changed since we first started discussing stem cells at the beginning of this Council because this proposal back then was a way to break this logjam at the federal level where the funding was blocked.

Now we're in a very different landscape where it looks like, I mean, first of all Proposition 71 has opened the floodgates to stem cell research in a much more straightforward way. Every state is reacting to that. The university that three of us, you know, teach for is under big threat because all of the postdocs now are going to be heading out to a university in California to get, you know, some of this, and some of the senior researchers may be departing Maryland as well.

And what we're heading towards is actually — Gil and I were discussing this yesterday off line — but a kind of blue state/red state federalism in which different types of scientific research under different ethical guidelines are going to appear in different parts of the country because of the blockage and the inability to get a federal policy.

And so it's something to bear in mind that, you know, I'm not quite sure who we think we're giving guidelines to because, in fact, the nature of the political landscape in this country is such that we're actually going to have about 50 different, you know, state policies on this issue.

And it does weigh a little bit in the ethical considerations because if you think that stem cell research in a much more straightforward way is going to be lavishly funded on a state level, then this as a solution, you know, Bill's proposal, number three, as a solution to the blockage, you know, it becomes a little bit less salient because there is really an alternative way to get to the same, you know, body of scientific knowledge. You just have to move jurisdictions a little bit.

CHAIRMAN KASS: Thank you. Peter, I think, and I will have a comment, and then we'll take a break.

Peter.

DR. LAWLER: In light of what Frank just said, it's perfectly true, right, that every thing we're doing today presupposes this. It would be a good thing if we could acquire embryonic stem cells without destroying embryos. That would be an improvement in our present situation.

CHAIRMAN KASS: Pluripotent, not embryonic.

DR. LAWLER: Sure.

CHAIRMAN KASS: Okay.

DR. LAWLER: Pluripotent. It would be better if we could do that. That would be an improvement on our situation. For some, that improvement would be merely prudential. You could get funding. That may be becoming irrelevant. I admit that.

But it may be good simply because the moral division in the country, which is tragic in a certain sense because there are well-intentioned people on both sides, would come to an end. It might be a good thing; I think it would be a good thing if there could be a technical solution to our moral problem, and it's reasonable to hope there could be a technical solution to our moral problem simply because the moral problem exists, it would seem, at a certain level of technology.

So there's a reason to hope that technology will cause us to be able to overcome or surpass this problem, but we also have to admit, I think, that none of these four possibilities are anywhere close to being acceptable at this point. It remains to be seen. It remains to be proven, and from that point of view I agree with many of the criticisms or reservations expressed about Bill's proposal.

I'm not so clear it should be treated differently finally from number one and number four because I think they're fairly problematic in different ways, too. So I would encourage further research in one, three, and four, with the acknowledgement that none of this has been proven useful in terms of overcoming the moral problem we have now. I mean it really is, to repeat, a pretrial investigation. I think one, three, and four do give us probable cause and we should go forward.

CHAIRMAN KASS: You want a comment and then I'm going to wind up.

DR. HURLBUT: I just want to make it clear I never proposed making teratomas. Teratomas I drew as an example of how nature produces an entity that is not in my mind a living being. I would not as a physician have any problem doing a therapeutic preemption of that process.

I just used it as an analogy. What we're talking about is something that is more like an inner cell mass. Janet Rossant in her comments to us said, and I quote, "Each cell has its own course of action and will continue to divide and differentiate even if isolated from other cells."

It should be possible with a small change that has a very dramatic effect on the coordinated

coherence of the integrated unity of the process of its organization to preempt the organismal nature of what's created.

We do not know yet how pluripotent cells or embryonic stem cells are actually formed. Is it just a matter of having the cytoplasm in the cell and then just waiting until it grows like Janet Rossant implies, that each cell has its own trajectory, or does it need the perfect and synchronized interaction of the entire organism?

That's an empirical question, however, one that can go below our argument about whether or when the embryo had moral status to whether or not it is an organism at all.

It's the idea that is to get below our problem. This is a transition time in the history of science. In the end of the 19th Century, we overthrew a simplistic vitalism in favor of studying biochemistry. It's a little harder for us to understand and to intuitively grasp with our natural moral sentiments that developing trajectories, too, can be separated off from the totality of the organism.

But we will learn that in our era of developmental biology, if we're going to go forward at all in developmental biology, we're going to have to do the same thing they did in biochemistry, that is, break the parts apart from the whole so that we're not violating human dignity while we have a tool to study it all.

I admit that my proposal, as with all of the other proposals, raises interesting and important questions. My proposal also offers a tremendous breadth of flexibility and could provide much or most or all of what the scientists hope and I hope we can proceed forward investigating.

It raises important questions. Our role as a Council, given to us by the President, was to engage and educate the public. This document does that in that it initiates an important conversation. It was never intended to be a comprehensive analysis. If that were true, we would be at fault for having done an inadequate job, never hearing testimony, never really having a proper deliberation.

But, in fact, what we've done is we've produced an initial cursory view that raised some questions like little red flags for sure, as does all of SCNT, as does all of harvesting of IVF embryos that are left over, all these things, but just saying that in the deadlock of our country, the serious question could be perhaps solved by a third option that we hadn't really thought through carefully enough yet, and wouldn't that be instead of red state medicine and blue state medicine, instead of people having to come into the hospital 20 years from now and checking a box and saying, "I don't want anything developed in California," wouldn't it be better if we found a way to go forward in a coordinated, collaborative research on a national level, funded by the NIH with proper peer review, proper ethical overview? Wouldn't that truly be a triumph for humanity?

If that's true, then it makes it worthwhile doing the hard work that we have initiated in this Council that should be taking place on a broader level in our society, the hard work of thinking through these serious proposals.

CHAIRMAN KASS: I'll try to be brief. I think I concur with — well, let me say this. I think we should try to find a way that the conclusion does a little more than what it does in this particular draft where it says some of us this and some of us that, et cetera, but do so in a way that indicates the strict preliminary character of these judgments, since there's a great danger that what is going to be written in the conclusion, especially in this town, will be treated as dictum, and everything else, the analysis, just disappears, and it will look like the Council recommends thus-and-such.

That I don't think we are exactly in a position to do for the reasons that have been so both well expressed and well reflected in the comments. I think there is a way to go partly from this second memorandum to the Council, to introduce certain kinds of greater ethical cautions about the proposals that we think pass the minimum test, to revise the way in which the discussion of the biological artifacts — when you indicate that there are these serious concerns, but to adopt something like Diana's approach so that what's written at the end really reflects the diversity of opinion here, the tentative character of the opinion here.

I think no one has answered Gil's challenge. No one here has really said that Bill's proposal should not now be investigated in animals, that we think that there's an ethical bar to doing that, which was all that that proposal was in the beginning.

And I think if the Council is willing to trust me and the staff to produce a revision of the conclusion for your consideration, we could do the rest of this by mail. Is that an agreeable thing?

And of course, line edits and things of that sort are welcome, but we had better have them soon.

Frank.

PROF. FUKUYAMA: Okay, but then do we just drop the subject after that? What happens subsequently?

CHAIRMAN KASS: Well, it seems to me let us undertake — let's step back from what we've done here, think about it a while and see where one wants to go next on this matter.

None of these individual proposals may pan out. Landry and Zucker, by the way, have submitted their proposal for IRB approval at Columbia and they are, I think, planning to go ahead with this. I know that Bill is in collaboration with some scientists who meet already to try to do some of his work in animals.

And to my astonishment, the various kinds of findings of these multipotent cells now in multiple places has just not gotten the kind of attention that I think it deserves simply from a scientific point of view to try to understand why is it so easy to find these multipotent cells in bone marrow, in addition to the mesenchymal cells, in addition to the hemopoietic cells, and what do they mean?

But the interesting thing is, in fact, to suggest that there really might be room for creative thinking, that these proposals might, indeed, stimulate other ones, and no one is saying that we're not going to continue to perhaps have our disagreements about embryonic stem cell research. There will continue to be political battles over it, I'm sure, in this session of Congress. The states will do as they will.

Some of them will produce bans and other ones will, you know, produce a windfall, and that's the way we are, but we do have an audience here. We have monitored stem cell research. Here is something that contributes to that discussion, and I think we do a service if we put out this document suitably concluded, suitably corrected, and then think further down the road what would come next.

Let's take a break. We're 20 minutes over, but I think it was important that everybody get their views expressed.

Could we make this break short? I know people have to leave early. Let's come back in 12 minutes or so, and we have a session on chimeras.

(Whereupon, the foregoing matter went off the record at 10:20 a.m. and went back on the record at 10:34 a.m.)

SESSION 6: HUMAN-ANIMAL CHIMERAS COUNCIL DISCUSSION

CHAIRMAN KASS: The last regular session before the session for public comments is on human-animal chimeras or hybrids, this time in the context of basic research in developmental biology.

I remind you that the Council last discussed this topic in connection with our recommendations in the reproduction and responsibility report. You'll recall that we all agreed that there should be restrictions on fertilizing human eggs by animal sperm and vice versa, and on placing human embryos into the bodies of animals.

The question of producing chimeras by introducing human stem cells or their derivatives, for example, neurons into animals or animal embryos came up for discussion, but it wasn't fully treated.

There has been a fair amount of recent journalistic attention to this topic, as well as presentations on chimeras at a workshop of the National Academies of Science's Committee on Guidelines for Stem Cell Research last October and an anticipated report from the academies, I think to be released fairly soon, if I'm not mistaken.

Janet would be able to tell us since she is a member.

We'll probably speak to this subject, and therefore, I thought it was reasonable that we should have another look.

In preparation for this meeting, I should have suggested that you do likewise. I went back and read the transcript of our meeting in October of 2003, where it was on the plane of whole animals and humanzees, but we didn't get down to the kinds of questions which are of immediate research interest, but it turned out to be for a first pass really one of the very rich and interesting conversations, and I'm looking forward to the conversation that we have today to see if we can make

some progress on basically two questions.

If people say mixing the human and the animal, the general public responds with some, to say the least, with some kind of unease or disquiet, and the question is: what, if any, is the reasonable basis of any unease over or objection to such kind of mixing? And let's be clear: even at the very beginning of life in this kind of developmental research.

And second, could one develop and articulate reasonable boundaries between what would be acceptable and what would be objectionable; what would be the acceptable and what the objectionable kinds and degrees of mixing in this research.

To get the conversation started, we've asked several people to open up with some comments, and first Diana and then Alfonso, which I assume will be more on the first of these questions rather than on the second.

So, Diana, please.

DR. SCHAUB: Leon asked me if I would make a few opening remarks for this session in which we're considering human-animal mixing and developmental research. In trying to figure out a way into this topic, the standard approach seems to be to focus on human dignity, the boundaries of the human and possible transgressions of those boundaries.

But I want to start less anthropocentrically. Whenever human dignity is involved, some humans at least get mighty concerned. They get on their high horse about it. So I wanted to ease our way into figuring out our unease or possible unease by reflecting a bit first about animal-animal mixtures.

We should remember that the original mythological chimera was altogether beastly, a she-goat with a head of lion and the tail of a serpent. There were, of course, mythological human-animal mixtures as well, like the Minotaur and the Manticore. But let's take the chimera first, especially since she now gives her name to these new biotech possibilities.

I did look back at the Council's earlier discussion from October 2003 when this topic was first broached, and the humanzee, our version of the Minotaur, was much talked of, but the geep, the combination of a goat and a sheep that is our rather less indominatable version of the chimera, was not much mentioned. No one seemed too bothered by the geep.

So let me just say that geeps do make me uneasy and uncertain. I can state my confusion in the form of a somewhat tongue-in-cheek question. When and if a geep behaves like an old goat, is he sheepish about it?

(Laughter.)

DR. SCHAUB: In other words, does he feel sheepish about his goatish behavior?

What I mean to suggest is that species' integrity can be thought of not just genetically, but characterologically. We know of the identity struggles and dilemmas of transgender persons. I suspect certain transgenic creatures would also feel themselves displaced or find themselves displaced, uncertain of what form of animal happiness to pursue. Maybe mules are mulish for good reason. Maybe they aren't happy about their betwixt and between lot in life.

The hybrid I know the most about is the wolf-dog hybrid, and from what I know, I would say that one does the animal no favor by mixing the wild and the domesticated.

So of the readings for this session, I very much appreciated the Midgley (phonetic) article for its sensitivity to the species specific character of animal flourishing and for its warning about the consequences of a wanton disregard of that character. Feeding sheep's brains to cows is as much a violation of species integrity as breeding sheep to goats.

There is an ethics of animal husbandry which ought to be a part of bioethics.

By contrast, I found the Cohen article much too facile in its dismissal of the species argument. The authors want to take human dignity seriously, but I don't see how you can make an argument about human dignity without some fundamental understanding of what it is to be a human being and what it is to be some other kind of being.

Nonetheless, I think I agree with the policy position laid out in the Cohen article. I don't like the geep because it confounds two creatures that make perfect sense in their own right, but as far as I can figure out right now, I don't object to the creation of human/non-human chimeras in neural

stem cell research so long as adult human stem cells are used.

The reason I don't object is that they aren't, strictly speaking, chimeras. They are pseudo chimeras or, more accurately, they're chimeras at the cellular level, but not at the level of function or temperament.

According to the Kennedy Institute paper, and I am trusting here that its authors are correct, the mixing that is being done so far, introducing small numbers of dissociated human stem cells into non-human animals or embryos, has not resulted in the emergence of altered human-like features or functions in the non-human.

And interestingly, the reason why the new material has not produced a new compound creature seems to be that species are to a certain extent at least fairly impervious to tampering. Monsters aren't so easy to create.

According to the paper, the overall architecture of the host animal's brain would not be affected by the presence of these cells. It did make me wonder how informative these experiments are if, quote, the non-human host governs the way that these cells function, end quote, and because of things like host mediated recruitment, the human cells become, quote, the practical equivalent of mouse or monkey cells, end quote.

And it seemed to me that the authors admit the limitations of these experiments when they say that the human stem cell chimeras are not so much a test of human neural characteristic development as a proof of principle that human cells can contribute to a non-human animal's development.

So transplanting human neural stem cells into a mouse no more transforms the mouse than transplanting a pig heart valve into a person transforms the person. All of the rules that the authors recommend seems to me sensible, and although they don't acknowledge it, those rules are based on preserving species integrity. Transfer the smallest number of cells necessary; use dissociated human stem cells rather than larger tissue transplants; and select host animals carefully, preferring distant relations over our nearer primate cousins.

The Council has already spoken out forcefully in opposition to any attempt to create a true human-animal chimera, like a humanzee. It might be worth remembering that the Minotaur, that murderous half man/half bull, was the offspring of Pasiphaë, the Queen of Crete, and a beautiful bull. In other words, the Minotaur was the monstrous issue of an act of bestiality.

In calling for a prohibition on the production of a hybrid human-animal embryo by fertilization of human egg by animal sperm or of animal egg by human sperm, the Council was simply calling for a ban on high tech bestiality. One hopes that is one tabu still intact.

I do have a question. I had hoped that Mike Gazzaniga would be here, but there may be other scientists present who can answer it.

In the Council's earlier discussion, Mike suggested that one should view the mouse as simply a big, interesting, and better tissue culture system, but if I understand the Cohen article correctly, it sounds that this medium is an unusual medium in that it is not neutral. The animal host is said to govern or rule the interaction and to rule in its own favor, co-opting the human cells.

My question is: is that a help or a hindrance to learning what we want to learn about human neurons?

And if it's a hindrance, will there be pressure to relax the kinds of regulations recommended by Cohen so that the operation of the human cells is given larger scope within the animal host.

In other words, would these regulations and limitations that they recommend be readily accepted and observed or not?

CHAIRMAN KASS: Thank you very much.

Are there people who want immediately to put questions either of clarification or comment on Diana's or shall we have Alfonso's presentation and then proceed?

It looks to be the latter. Alfonso, please.

DR. GÓMEZ-LOBO: Thank you.

I guess there will be considerable overlap with what Diana has presented, but my exposition is

geared more towards the second question, the aim to articulate reasonable boundaries, and this is just a first attempt at it.

In thinking about ethical perplexities involving human-animal chimeras, it is useful, I think, to start with the distinction between two symmetrical cases: (a) the transplantation of animal stem cells into human embryos and (b) the introduction of human cells into animal embryos, and I'm leaving aside those other cases that we have commented on right now.

The ethical concern about modifying a human embryo by inserting into its cells from another species falls within the domain of the ethics of embryo experimentation. It is one more experimental procedure that must be judged in accordance with the principles that should govern what is done to human embryos.

What principles apply will depend, of course, on the ontology of human embryonic life, that is, on what a human embryo is taken to be, and here, of course, the waters part. We know of three positions here on the Council.

One, anyone who holds that an embryo is a kind of being that does not deserve respect will be inclined to hold that to produce a chimera presents on special difficulty, providing that such an embryo not be implanted nor be allowed to develop to later stages of fetal life.

Then there's number two. For those who admit that a human embryo is a human organism at an early stage of her life and hence that she deserves respect, the introduction of foreign cells for experimental purposes represents a serious violation of ethical norms, in my view. It is analogous, again, to battery, to the violation of the physical integrity of a person without her consent.

And number three, for those who hold the intermediate status of human embryos and the thesis of special respect, I honestly do not know what follows because of the indeterminacy of the position. I suspect that many upholders of this position will give in to utilitarian pressure and admit that this form of xenotransplantation may be done for good reasons. Acceptable reasons will surely include some reference to expected therapeutic results for a large number of people.

In the alternatives, just examined, what I had in mind were instances in which the human embryo would remain basically what it is and would receive dissociated animal cells that would be incorporated into a human life. The resulting organism would still be human, though modified to a lesser or greater degree.

I find this morally troubling because I think that human embryos deserve respect. In other words, as you know, I uphold position two above; and that an invasion of the body of this sort is, indeed, a violation of respect.

But more troubling is the possibility of introducing undissociated animal stem cells that replace the inner cell mass of the human embryo so that they take over the whole organism, and Diana addressed this. This would amount to a loss of identity, a loss of identity of the host organism. That organism would cease to be human and become animal, an animal of the kind to which the donor of the cells belongs.

It seems to me that intentionally transforming a human being into an animal in this way would be an extreme instance of reducing humanity to a mere thing that can be obliterated at will. Indeed, it seems to me that this would violate even the weakest form of the special respect claim.

Now, I move to Case B. The ethical considerations for the second case, that is, transplanting human cells into animal hosts, do not follow so neatly from the diversity of opinion concerning early human life, and the reason for this is that the key moral features of the action do not depend on the host organism, but on the manner and type of transplantation of the human cells.

Let me start with the most extreme and highly unlikely case. Suppose human neurological stem cells are transplanted into a primate so that the animal acquired some key human features. It seems to me that this would be morally troublesome in spite of the often heard argument that there's nothing wrong with enhancing the capabilities of an animal.

In my opinion, this procedure should be viewed the other way around. It is not that an animal is thereby enhanced, but rather that what is essentially human is really debased. It is closer to the production of a human being in the wrong body.

And I often imagine what it would be like to wake up one day only to realize that I have the body of a chimpanzee. Luckily, we're told that this is virtually impossible because the human body as we know

it seems to be absolutely necessary for the development of the human mind, and I'm thinking about size of the brain, the cranial space, et cetera.

The insertion of human cells in a host animal does not produce specifically human capabilities, but works in the manner of a genetic magnification. If by xenotransplantation pigs are made to have human blood flowing through their arteries and veins, I do not see an equivalent moral problem.

If such chimeras are generated not arbitrarily, but with a clear goal of benefitting human beings, for instance, by providing a source of blood transfusions, they would be one more instance of putting animals at the service of mankind.

Our dominion over animals, however, is not without moral boundaries. If our stewardship of nature becomes a form of tyranny, we'll not only be turning against our own humanity. We'll probably risk initiating partial ecological disasters as well.

Even if there's uncertainty about the notion and status of biological species — I'm making a little concession to the Cohen paper here — even if one grants that, it seems reasonable to respect species as they are, as we know them, because we know too well that there are myriads of checks and balances in living organisms that we do not quite understand. Upsetting those balances often brings about undesirable consequences.

The generation of Chimeric animals by transplantation into them of human cellular material with the aim of putting some of their tissues and organs at the service of human health then seems to me to be in principle morally correct. This includes the use in research that should precede the therapeutic applications.

However, again, we also have a moral obligation to be cautious and to bound ourselves to certain limits. Among them I would mention the following. For instance, I think that the number of Chimeric animals to be generated should be as few as possible, as few as possible and, secondly, should be kept under strict surveillance and, third, they should not be released into the environment.

Moreover, they should not be subject to avoidable pain. Their use in experiments should be carefully scrutinized to determine whether there might not be alternative research avenues, et cetera. In other words, many of these boundaries would overlap with standard principles for use of animals in research.

Mixing of animals from different species, on the other hand, with no specific human good in sight, such as, for example, the production of the geep, seems to me, as far as I'm informed, seems to me arbitrary and really morally unjustifiable.

Maiming or deforming animals just to show that we can do it seems to me deeply disturbing. It is simply an exercise in arrogance and lack of respect for other living beings.

In sum, it seems to me that any Chimeric mixing in which human organisms are made partly animal while retaining human identity or are transformed into animals, losing their identity is objectionable.

The same holds, I submit for animal chimeras that run the risk of acquiring human capabilities. On the other hand, the generation of animals with tissues and organs that through early transplantation of adult human stem cells makes them of service for human cures seem to me to be acceptable.

Finally, the Chimeric mutilation of animals when no human good is in sight can hardly be justified in my opinion.

Thank you.

CHAIRMAN KASS: thank you very much.

Let me just open the floor for comments on either of the presentations or an elaboration of some of the arguments.

Robby and then Frank.

PROF. GEORGE: I want to begin by thanking both of our colleagues for those splendid presentations. Very informative and thoughtful.

I have a question that I think is mainly for Diana, though I'd be very happy to hear Alfonso's response or any reflections that it generates in Alfonso, from Alfonso as well.

It's this, Diana. It goes to the question of species integrity as a moral concern or principle. There is a conception of morality, one that I happen to share, which is broadly speaking humanistic. Under that conception, what moral norms do is specify the integral directiveness of principles that, in turn, direct our action toward things that are intrinsically worthwhile for human beings and away from whatever is a contradiction or violation or whatever damages things that are basic forms of human flourishing because they're intrinsically good for us as humans.

Now, Alfonso, when he gets to the point in the analysis where he's talking about species mixing in geeps and so forth, resolves it in a way that does not go beyond that humanistic conception of ethics. At the end of the day, the points that Alfonso adduces against the mixing, where he thinks there are problems with the mixing, have to do with the violation of human goods.

But I think you were different. I think your analysis is one which holds before us the possibility that precisely something beyond the humanistic concern is at stake here, is that species integrity is itself the stuff at least of a moral principle, if not a moral principle itself, because it gives us a reason for action or a restraint quite independently of the impact on the human good; that there's just something about species mixing itself that is troubling even if moral goods are not at stake there.

I'm not suggesting at all that that's idiosyncratic. I mean, there's a strong tradition that's contrary to my own that says that the humanistic principle isn't the uniquely correct touchstone of ethics.

But I wonder if you could say a word about why you would embrace that, what argument you would give for treating species integrity, if I've read you correctly, for treating species integrity quite apart from any impact on human goods as providing something that will morally constrain our actions.

DR. SCHAUB: Yeah, I don't know that I can give you an argument. I mean, I think you're right that I am making a slightly different argument than Alfonso. I think there's such a thing as animal happiness and particular modes of animal flourishing, and that we should come to understand and respect those modes.

PROF. GEORGE: For our sake or for theirs?

DR. SCHAUB: For both probably.

PROF. GEORGE: Is it because there's a sense in which our fate is bound up with theirs? Do we have some kind of solidarity or communion with them that is at least analogous to that which we have with each other, which provides the foundation?

Dan Callaghan and I were getting into this a little bit yesterday, the foundation for principles of justice and charity that govern human relations.

DR. SCHAUB: Yeah, I mean, I suppose if you began from a kind of stewardship argument. I mean, that's why I mentioned about animal husbandry being part of bioethics. That would be beginning from what our responsibilities are toward the rest of creation.

PROF. GEORGE: I wonder if Alfonso would have a word on this.

DR. GÓMEZ-LOBO: Well, as my argument showed, I share your basic humanistic approach, although I'm willing to argue that a case can be made for the entirety of nature in terms of something, for instance, like the internal teleology (phonetic) that makes it questionable that we should, for instance, mutilate animals in a way that they would not acquire their usual flourishing.

But in this discussion, I prefer to keep it within these boundaries and the reason is this: is that many people who have completely divergent positions in ethics would totally reject that view. Many people view nature simply as a big repository of genes or whatever, where you can do whatever you want.

So I prefer to — but those people would accept, say, liberal principles of respect for persons, and that's where I would like to meet the challenge.

CHAIRMAN KASS: Frank.

PROF. FUKUYAMA: I would just like to say on that last question if you're going to defend species integrity, then you're going to have to take on the whole agro-biotech industry because they're already doing things like inserting jellyfish genes into corn plants and so forth, but that wasn't the main point I wanted to make.

It does seem to me — I appreciated the two presentations — it does seem to me that it's really not possible to take on this issue systematically unless we revisit a question that we never really came to closure on in the first term of the Council, which was the whole question of what we mean by human dignity, and that, of course, is a criticism that was made, you know, of various reports that the Council issued without really defining, you know, what the term meant.

And it's important in this respect, because, you know, that's what's under threat by mixing human and animal, and there are several things that can be said to it.

It is historically and culturally, I think, a byproduct of Western Christian civilization. I mean, that's the historical origin of the concept of dignity. If you look at most Eastern religions, that boundary simply does not exist, the boundary between this bright line between human and non-human, and it has a lot of interesting ethical implications for how they think about human rights and also the rights of non-human nature, but that's a separate discussion.

And what I think that we really need to have is a discussion about what we mean by human dignity, and particularly those of us that do not want to root it, you know, in Christian doctrine. I believe that it is possible, you know, to retain a concept of human dignity.

In my mind, a non-religious version of this would be that human dignity is in some sense an emergent property of higher creatures, the highest of whom is a human being that cannot be explained in terms of, you know, any kind of reductive reference to the biological substrate, you know, that produces the animal.

So simply understanding, you know, the biology of the human brain does not explain the origins of human consciousness, and I think that then if you define human dignity in those sorts of terms, it gives you some moral guidance because it could entirely be the case that neurons, whether animal or human, are simply wires. You know, that's all they are. They're just wires, and so if you had a human brain built out of mouse neurons but organized as a human brain, that you would get the same emergent properties of consciousness and, you know, human emotion and experience.

We simply empirically don't know whether that's the case or not, but it seems to me that's quite possible, and if you define human dignity in those terms, then you know, you would actually have no objection to a medical procedure that tried to use, let's say, mouse stem cells to produce, you know, damaged human neurons to replace, you know, some neurological disorder.

On the other hand, it may turn out that, you know, the material substrate affects the emergent properties in ways we simply do not understand, and so that's an area that, you know, we'll just have to await further research.

But as I said, I really don't think that unless we come to some kind of a further discussion of what it is, what we mean by human dignity that we're trying to protect in these discussions, that you can have any kind of systematic approach to this whole question of mixing human and animal.

CHAIRMAN KASS: Let me just see if I can get another couple of sentences from you. The paper that was distributed from the soon to be published Kennedy Institute of Ethics journal, and our thanks to the authors for permission to circulate this prior to publication.

They, in fact, do try to articulate something of what's to be meant by human dignity, giving it a somewhat functional definition. Most of the functions connected with things of the intellect and consciousness and the like, and tend to short circuit or at least to put down things that would be matters of species.

I think Diana alluded to that in her comment, however pointing out at a certain point that — let me see if I can find the page — it's very doubtful that a human brain could be developed outside of the human body, which suggests that the human body is not simply a contemptible vessel in which a human brain and, therefore, personhood resides, but that something like the totality of the human being given not in terms simply of these functions that especially brainy people seem to elevate above all other things would be the measure of human dignity.

So are you committed when you introduce that? I mean is your intuition that we need an account in terms of the distinctive functions that are somehow dignified, or would you go with Diana who seemed to be suggesting that there is a kind of species being in which the human body and the possibility of the embrace, as well as the ability to write the B Minor Mass counts.

PROF. FUKUYAMA: Well, my instinct is always to assume that these things are much more complicated than we ever imagine, and so any simple functional list I am sure, you know, those

functions will actually depend on all sorts of things that we simply do not really comprehend, including, you know, many aspects of the body that may not seem immediately relevant.

So, yes, so I think that there probably is a certain thing like species integrity, although, you know, species do evolve and you can imagine the same kinds of functions being maintained under very different kinds of somatic characteristics, and so I think you have to be open to that also.

CHAIRMAN KASS: Thank you.

I have Jim and then Gil and Ben and then Peter.

PROF. WILSON: I think Frank is right that we have to come to grips with the concept of human dignity. The animal world is filled with if not geeps, then deliberately arranged mergers. Horses and donkeys produce mules, and mules are very different from both horses and donkeys. If you have ridden them, you know, what the differences are.

In zoos we have ligers and tions, and I'm not aware that an important moral principle has been violated by these combinations, though the one that occurs in nature, the production of mules, is different from what occurs in zoos since what occurs in zoos would not occur in nature, as Hertz Meyers pointed out.

In this paper they talk about humanity from a Kantian perspective. That is to say they are moral agents whose actions can be imputed to them. People, human beings have the ability to act on principles, not simply on instincts, impressions, social pressures or the like.

And I think that's a very good place, and it is hardly a functional argument. It is a profound argument to begin. There are, of course, other religious arguments that one could make.

What I find troubling about the paper from the Kennedy Institute is that when it tries to defend human dignity, however defined, the definition I prefer or one that one of you prefer, it tends to fall apart.

For example, on page 23, it says we can at least envision that some investigators might attempt to transplant a whole adult human brain into a non-human animal in order to study certain important neurological questions.

But then on page 30 it says the rule for Chimeric experiments should be to limit to the smallest number necessary the number of human brain cells that are required to reach a reliable scientific conclusion.

Now, if they reject the idea of putting a human brain in a non-human animal, it seems to me they have already rejected the principle they state as the conclusion of their argument. So that though I agree with their that human agency and human dignity are the crucial principle, I don't think this paper does a very good job of supporting it.

CHAIRMAN KASS: Thank you.

Gil and then Ben and then Peter.

PROF. MEILAENDER: Well, I originally got on the list to say something about the exchange between Robby and Diana, and I still want to say a word about that, though first may be just a word about Frank's comment.

However one ends up characterizing human dignity, as emergent property or whatever, one does with it, I think it's going to be important to keep in mind that there I'll just say may be — I think is — a significant distinction between whatever the distinguishing characteristics or capacities are that constitute this property of dignity which we ascribe to human beings, to the species. There's a distinction between those characteristic capacities and the criteria for membership in the species which is so dignified.

That's going to be a crucial distinction because otherwise a large number of members of the species will lack the quality of human dignity. So, I mean, if we're going to sort that notion out, that's an important distinction to keep in mind from the start.

Now, of course, everything is arguable, but it would be an important issue to keep in mind.

Now, just a word on the Robby-Diana exchange because my own intuition is that actually it may not be sufficient to just count on the dignity language to handle the chimera problem, and we may need

to get at the other kinds of arguments that the paper that we had took up only to dismiss, although I thought not always very persuasively.

In terms of your humanistic approach, as you called it, Robby, the animals are the other animals. They're not just the animals. They're the other animals because whatever else we are, we clearly are animals as well.

And maybe you're going to think this is just a round about way of bringing some human good in finally, but one might argue that it is in some way degrading for the human animal to fail to appreciate the bios, you know, the biological life of those other animals.

And it's not that there's any particular human good that's at stake there so much as it is imply that we don't act in a way fully in accord with the fullness of our own nature, which is animal as well.

I don't know. You know, I don't have that argument all sorted out yet, and there would be more to say about it, but that's the route I'd want to try to take if I were going to try to tie into the suggestions Diana made. It seems to me that there's something there worth trying to develop more fully, though I may not be able to do it that well right now.

CHAIRMAN KASS: Ben Carson.

DR. CARSON: Well, first of all, as a brain surgeon, let me say we don't have to worry about transplanting human brains into other animals because we're already dealing with billions and billions of neurons and hundreds of billions of interconnections, and it's not going to happen.

Now, you know, in terms of, you know, the integrity of the different species and why we should have respect for them, I think we have to look at environmental factors. You know, when you look at environmental stability, obviously it has a great deal to do with how the various species interact, and when we begin to tamper with them, we'd better know what we're doing in terms of what's going to happen subsequently downstream.

I think in terms of let's say we got rid of all the snakes because we all hate snakes. Well, we'd be overrun by rodents, and that's just, you know, one small example of that. So we obviously need to be extremely cognizant of what happens when we interfere with natural environmental factors.

Now, is there, in fact, something different about human species versus animals? And I guess some of that depends on where you think humans came from. Obviously if we evolved as a matter of some promiscuous biochemicals from a slime pit a long time ago and just gradually changed until we reached the stage where we are, then perhaps there is not a great deal of difference between a human species and other animals.

If there is more to us than just our physical being and our mental being, if in fact there is a spiritual being as well, which in fact does allow us to compose the B Minor Mass and do a number of other things, then maybe that is the thing that distinguishes us.

Why is it that if we're dealing strictly with physical beings like animals, why is it that a human being going through a forest seeing another human being that they don't know drowning will jump into that river and try to save that person? That would make no sense from a natural selection point of view.

So is there something different about us and other animals? And I'm not sure that you can totally divorce that from a religious or spiritual aspect.

CHAIRMAN KASS: Someone want to join this directly? Peter, please.

DR. LAWLER: First let me say something about animal happiness, which to my shame I had never thought about before. Pardon?

Plant happiness which I'm not going to think about even now.

(Laughter.)

DR. LAWLER: I think Diana is onto something here, although it is of no public policy consequence whatsoever. There are animals which are dependent on us psychologically, like dogs. The happiness of the dog is obviously arguably not purely physical, and we do some moral violence to our nature and the nature of dogs when we treat dogs as something other than dogs. If we treat dogs as less than dogs, that is being torture and utterly slave to our whims, and we do some violence to dogs when we treat dogs as more than dogs, if we treat them too anthropomorphically, if we have pet

cemeteries and all of this.

So we are in a certain respect responsible for dog happiness. We do a certain violence to our nature, although I'm not endorsing a law that would punish people who somehow did violence to their natures by sinning against dog happiness, but I think she's right in some way.

But with respect to human beings, what Ben was just talking about, the point that has been made and needs to be made again is we have no idea what a human brain would be like apart from a human body. It's unthinkable. The human brain and the human body are an undifferentiated whole, and it's the whole, right? The brain and body that make possible what is distinctive about human beings and what arguably has dignity because, in fact, at the end of the day, being human is an all or nothing affair. We can't imagine what it would be to be semi-human.

Human beings are the beings with language, who are as a result open to the truth about all things. Either you're human in a certain way or you're not.

And so from this point of view, the difference between a human being and a dolphin is infinitely greater than the difference between a dolphin and an ant. And so we know what it means to be human, a being with language and so all of the characteristics Ben was talking about. This is observable. It doesn't require really just faith really.

So if a human being had an animal body and nonetheless was a being with language open to the truth about all things, then that being would, in fact, be human. It wouldn't be a human giraffe or whatever or some combination word, but it would be a human being.

And so the idea of designing a being that's partly human and partly not is not really given to us. That designer point of view implies that you're not an animal at all, that you're standing outside natural life as Midgley points out, and so it's beyond our imagination even to conceive what the function of this designer being would be.

But if we could do it, here's something that we would know. The thing that we would create would be the most dangerous thing we could do to the environment imaginable because the truth of the matter is if it weren't for human beings, there would be no ecological crisis. Nature would be fine. If we were to disappear, we're the beings that can do war against nature or the technological beings, we're the beings who could kill for no good reason, dot, dot, dot, and so we have all of these adverse qualities which we have to try hard to keep under control.

Imagine what a being would be like that had a being with language and a body that was not fit for that. Imagine the discontent of this being. Imagine the perversity of this being. This being would wreck havoc on nature. This would be the ultimate ecological catastrophe.

So we shouldn't do this, but fortunately, as Ben points out, we can't do this.

CHAIRMAN KASS: I want to shift the gears slightly. The conversation has been sort of up here at a very high, talking about mixing organisms that would run around and also talking about, I think quite rightly, to try to give some sense of what are the principles or the grounds of the disquiet and the importance of trying to articulate some notion of human dignity or the species integrity or their relation.

But I'd like to spend the rest of the time on the concrete activities on which the science is now proposing to proceed, which is not to produce things that run around, but is to use the possibility of creating certain kinds of Chimeric organisms at early stage of development for the purpose of understanding certain things about development or transplanting, say, human cells into the developing brains of mice to learn something about — and then you can fill this out.

I mean, this is, I think, where the practical subject is, and I don't know, Janet, whether it's appropriate to ask you for comment on this since I know that the academy has had testimony on sort of chimeras in relation to stem cell research.

Could you say something about how you as a scientist, and not necessarily speaking on behalf of that committee, but how you would begin to think about this question of limitations between what would be perfectly appropriate, what becomes worrisome, and where the boundaries would be in this kind of research?

DR. ROWLEY: Well, I'm hesitant to say too much. As Leon has indicated, and this is not secret, the National Academy of Sciences currently has a group that is preparing guidelines for the conduct of human embryonic stem cell research. These, of course, would be strictly voluntary, but it is hoped

that if there were a thoughtful set of guidelines available for people who are embarking on this research, it might help to both set the bases for individual institutions setting their own guidelines, and if the guidelines were acceptable to institutions, they could be accepted as a whole.

The issue of chimeras has been discussed. It is clearly, along of the very thorny issues as to what should and shouldn't be allowed. I think it's recognized by all members of the workshop that this is an area that science has to proceed very cautiously because some of these procedures are going to raise substantial concerns in the broader community in which we live.

We realize that the greatest areas of concern — and that clearly is reflected in the paper from Cynthia Cohen and her colleagues, is the area of the brain and mixing human and animal neurons and also any experiments that would allow human gametes to be produced by or mingled with gametes of animals.

So those are really the two most serious concerns, and the provision is made that any experiments that would be proposed in these areas would be reviewed very, very carefully by committees at the institution, and actually it's proposed that there be a special committee that would be developed at individual institutions, particularly those having a very active program in human embryonic stem cells, such that this would be a committee composed of individuals who were knowledgeable in the area, as well as ethicists and the public.

So the point is that individual research in this area is going to be scrutinized from the standpoint of is it necessary. Are we going to learn something important? Is there another way to do it that would not involve the use of human embryonic stem cells or stem cells differentiated down the neuronal pathway, and that slow is better in this particular regard, at least as regards to research that involves either neurons or the potential for gamete mixing.

CHAIRMAN KASS: Not to press too much further on this, and it may be premature to day more, but you've identified certain areas of greater caution, neuronal and things having to do with gametes. You set, therefore, a certain higher bar of scientific necessity before one considers these matters.

But then with respect to the ethical judgments, these are then to be left to the individual IRBs to sort through, or are there certain kinds of provisional, for the time being guidelines that one would say — because, I mean, Cynthia Cohen's paper, it's also partly — you know, it should be more of this. I don't have the — it's a similar kind of quantitative rather than qualitative kinds of boundaries, leaving room for judgment as to what is too much and the like.

Is that the general spirit of the inquiry?

DR. ROWLEY: I think that's the general spirit right now, in part because we are so ignorant, and there is the balance between in a rapidly moving field that is changing so constantly. To be very precise means either that you allow things that you ought not to or you prevent things that would turn out to have some merit.

So at this stage at least it is left to each individual IRB to consider and try to come to the best judgment that that particular group comes to. You are absolutely correct, and we say this specifically in the report, at least in its current state. It's still under review and will be modified, but the report does say we're setting a much higher bar than is normally set for research by a standard IRB.

So that's stated explicitly early on in the report, and I think that to some extent it's going to be quantitative. All of us are aware of the concern that we're going to have a human brain in a mouse with a person saying, "Let me out." And that clearly is not a state that we want to get into.

At the same time, there are individuals who feel that we could learn a great deal by having human neurons within the brains of experimental animals, and these would depend on the different experiments, in trying to see how those neurons may function or may respond to certain drugs, to certain hormones, to certain growth factors.

What would normal cells do in the brain of a mouse that has amyloid deposits? Might it change the level, the position, et cetera?

So there are experiments that do have to take place in living tissue, distinct from at least some of the papers here saying that everything can be done *in vitro*. That's absolutely not the case. You really have to have the interaction of living cells in the environment because there is so much that we don't understand about the communication between cells, which is extraordinarily important in governing the behavior of those cells.

They respond to signals outside, and most of those signals are unknown to us at the present time. So they think this is a balance, and I think we've tried in our considerations to recognize the concerns and to try to set fairly conservative limits at least in the beginning on how we think this research should proceed.

CHAIRMAN KASS: Gil.

PROF. MEILAENDER: Yes, just a question of clarification on this. In the paper from Cohen and the others, the three guidelines that are given.

CHAIRMAN KASS: Page 30.

PROF. MEILAENDER: On page 30. The third of them is about dissociated stem cells having to be used, and this may just be ignorance on my part, but would you characterize that as a quantitative rather than a qualitative guideline?

I would have thought that that was — whatever exactly those terms mean, that was closer to a qualitative than a quantitative guideline, unlike, say, the Guideline No. 1 about limiting the number of cells to the smallest number, but maybe I'm just misunderstanding something.

CHAIRMAN KASS: No, I take your point. Yeah, I think that is, if I understand it, as written, that looks to be different. It seems to say that for the time being one should not use anything other than the introduction of dissociated separate cells rather than integrated tissues, not that the transfer integrated tissues is necessarily going to integrate into the new host, which is a point that Ben, I think, has already made powerfully.

PROF. MEILAENDER: Right, but it would be a little stronger, these guidelines, what everyone thinks of the whole argument and so forth, is a little stronger than just recommending some quantitative restrictions. That was just what I was trying to get clear on.

CHAIRMAN KASS: There was a hand. Bill.

DR. HURLBUT: I want to underscore what Janet has said about this scientific significance offered by these possibilities. I think that we should take that very seriously and recognize it because of the conservation of biology across phylogeny. You get useful systems that can be in some ways compared or studied with parts of human capacities, even partial trajectories of human development in animal models could teach us a great deal without in any way violating the integrity of human moral standing that we would want to assign to a natural human being.

But I would also like to add another element of caution. Janet has, I think, rightly identified the danger implicit in early mixing of ES cells, and can develop very much into human characteristics.

I think we also have to be attentive to this concern with regard to later what I sometimes call the architectural changes. It is possible using certain technologies to transplant whole modules of developing portions of the embryo from one species to another. This has been done by Le Dourian and Balabon, where they actually transplanted a portion of the developing brain, early neurologic system at that stage, and got the crowing capacities of a quail put into a chick.

And so he actually transplanted a unit of behavior. Just to draw that a little farther, I think we should also be careful to not do that with elements of human form. In other words, it isn't just a matter of cognition that we're concerned about. The categories of our world, the conceptual categories that organize our world provide an intelligible world to us. These are not to be taken lightly.

The way we understand our world is by the separations within the world. For very serious purposes we might mix those, but I think we should be careful not just to see that as a matter of inner psychological or cognitive functions, but we need to preserve the human form, the dignity of the human form.

So I would say as at least an additional principle that we've been discussing, that later stage transplantation of human embryonic stem cell derived tissues, cells or organs, or any other way of deriving these things would be allowable until they manifest evocation of defining human dimensions of function or form also. No unique human neurological capacities, but also no human faces, larynx, hands, or genitals, no characteristic body plans, postures, gaits should be produced by such a project.

Now, in order to prove something is too human-like even if we didn't assign it full human moral

meaning, and certainly we don't want any of those kinds of elements of animals placed onto the human form either, no tails or antlers, for example.

I say that jokingly, because we wouldn't do it, but we need to take seriously the notions of where our natural boundaries sustain our understandable world, our intelligible world.

So it isn't just a matter of function. It also involves a matter of preserving human dignity by preserving the uniqueness of human form.

CHAIRMAN KASS: Diana.

DR. SCHAUB: Yes, can I ask Bill a question about that?

CHAIRMAN KASS: Yes.

DR. SCHAUB: I thought that some of that had already been done. I thought I read something about, you know, a human ear on the back of a mouse, and I also wondered what it would mean for these possibilities that were distributed yesterday about growing human kidneys within animals and then being able to transplant them.

I mean, what counts as form? Is the form the human kidney or the respect in the way that the — if one of our ears is worthy of respect.

DR. HURLBUT: You know, that's a terrific question. This morning earlier when we were talking about altered nuclear transfer, I was thinking about how we're uncomfortable with anything that's growing and seems to be alive. Is it a being?

I personally feel a certain queasiness about factories growing kidneys, but nonetheless, I would think that it has such a good possibility if we could do it, I think we probably ought to.

But growing human organs inside of animals, if we could do it, does not strike me as the same as growing human forms in animals. I mean, if you had a sheep with a human face or an animal that had human hands of a very identifiable sort, I think you'd be doing something that would involve violence.

The mouse with a human ear, I think everybody kind of understood they put a — isn't the way they did that, they put a form and the tissue grew around it? It wasn't really a human ear exactly.

I agree there was a weirdness to it, but I'm talking about something a little bit more serious than that, I think.

DR. SCHAUB: But why would the hand be different than the kidney?

DR. HURLBUT: Because the kidney does not evoke for us the natural moral sentiments that preserve the intelligibility of our world. It's a functional agent, an internal organ. I think our external manifestations — let me extend this to robots, too.

I don't think we should produce robots that are so indistinguishable from human beings that they confuse our categories. That I think is actually a serious issue, and so it doesn't even have to be biological. I think we have to preserve the meaning of the human form. And that's largely a visual phenomena.

The very word "species" is related to the word "to look" and the appearance of a thing. And I think we have to take these species separations seriously.

CHAIRMAN KASS: Could I? I think we should wind up and go to public session fairly soon, in fact, in a couple of minutes.

But I want to come back to these currently proposed developmental studies rather than producing things that are sort of visible grotesque and strange and raise those kinds of questions.

And I'm sorry Charles isn't here because Charles had a kind of intuition about what it means to be creating what he there called certain monsters or creating teratomas. And I suppose for people who don't think an early embryo is much of anything — and Alfonso's comment, I think, prepared the ground for this — something which is not much of anything into which you incorporate an animal cell doesn't seem to be grotesque or weird if you sort of guarantee that you're not going to sort of face it grown up.

And similarly, since we probably rightly or wrongly care less for mice than we do for ourselves, putting a few human stem cells into a mouse blastocyst, especially if you think it's not going anywhere, one could sort of say, "Well, that's not really very much of anything either."

But leaving aside the vexed question of what really is the ontology and moral standing of the earliest stages of life, whether human or animal, and even allowing that this research could be beneficial, are there no people here who have some sense that we're engaged in something strange and weird, even going in the direction of a few human cells into the animal?

Now, Janet in her comment says we have to proceed cautiously because — and I listened pretty carefully — it was not necessarily because the people proposing to do these experiments themselves had qualms, but that the public at large wouldn't somehow understand this or would be nervous about it.

We are not altogether immune from being members of the public at large, and the question is: is there some kind of — leaving aside the gross things that we've been talking about, but just staying with this very it looks like modest research, I mean, do people like Charles or Dan or Paul or Peter who have expressed some kinds of disquiet over creating teratomas or teratoma-like things which are not organisms had any kind of disquiet about creating these kinds of mixed species? And is that disquiet articulable in some way? And does it make any sense?

I think if we could have a minute or two on that, that I think is the practical question that we face at the moment and worth some attention.

Ben, do you want to say at least something?

DR. CARSON: Yeah, just briefly. I think it's very important as a Council that we make sure that we distinguish between using human or animal parts across species, such as, you know, insulin, heart valves, things of that nature, and mixing the genetic material that has, you know, proliferative capacity.

I mean, there's a huge difference between those two things. We need to make sure that the public understands that we are distinguishing between those two things.

CHAIRMAN KASS: Well, thank you.

And I think in our last report we were very clear about that, and I think as the conversation proceeded, we should absolutely be clear about that.

Gil, do you want to have a comment?

PROF. MEILAENDER: I was just going to say, I mean, I think what gives one pause, even if it doesn't finally lead you to object to say the sort of thing that this paper we read talks about, is that the sense that we are on our way to thinking about the human being as much a collection of interchangeable parts or species as just collections of interchangeable parts.

Now, I realize that once you start to press that, you can ask questions about organ transplantation and so forth, too. Here we're thinking mainly about much lower levels of organization, but it's sort of the unity and integrity of the human person that's really the issue there.

Yeah, I mean, I think that it's the sense that having set foot on that path, it's not clear where there would be an exit ramp that is troubling in a way.

And that is actually why I asked the question about whether that one guideline was qualitative. I mean, I'd be more interested in qualitative than quantitative guidelines because that would suggest that there was some ability still to make important distinctions.

CHAIRMAN KASS: Last comment. Alfonso and then we should stop.

DR. HURLBUT: I completely agree with that, Gil, but that's why we have to do the hard moral work of defining what we're trying to protect because otherwise we're going to close off great human goods with scientific investigation.

You didn't say we would close it off, but it seems to me that we need to figure out what is it. What combination of fundamental moral principle and natural moral sentiments, those things which we're trying to preserve, what analysis can help us define this?

That's why this whole arena with developmental biology requires that somebody do that hard work

of figuring out what is the locus of human moral standing and human dignity. It's not a simple matter. It's the challenge of our era.

CHAIRMAN KASS: But it seems to me Diana's paper was very, very useful because she didn't simply want to allow us to rest with the concern about the human, and that there is a certain posture with respect to the natural world, and at least raised the question beginning with the geep.

And I don't think — I mean, there are, in fact, people interested in proposing legislation that might seek to stop the creation of chimeras in which animal cells are added to human embryos rather than the reverse. There are people worried about that.

But Diana at least has raised the question: what does it actually mean to start down the road to producing these admittedly merely embryonic hybrids? Is it sufficient that we know that that they're not going to grow up to somehow make the moral question sort of disappear, or is there a certain posture toward either species integrity or what is somehow owed to the animals in our relation to them?

That may not be the moral question of greatest interest to Robby or to Alfonso, but it is, I think, part of what's a concern for, quote, unquote, creating monsters, meaning something simply the crossing between two different kinds.

I don't want to sweep that particular question away.

Frank and then Alfonso and then we'll stop.

PROF. FUKUYAMA: I would just like to point out that we eat all of these animals. So I'm not quite sure what interest of the animals we're protecting by this.

CHAIRMAN KASS: I think that's one question that leaving aside the alternative that rejects the eating of animals, there are respectful and disrespectful ways to treat the creatures who we exploit, and Diana.

DR. SCHAUB: Yeah, this is not an example of a chimera, but I think it says something to it. Yeah, we eat pork or some of us eat pork, but pigs should not be raised in a way that they gain weight at such a rate and to such an extent that they all become lame, and apparently for a while in the industry that's what was happening. You had just, you know, all of these lame animals.

So that, you know, pigs should enjoy a kind of pig happiness before the point at which we slaughter and eat them.

PROF. MEILAENDER: I just wanted to remind Frank that we would be remiss if we did not call to his attention that, you know, he could read the *Hungry Soul* and think about these matters.

(Laughter.)

PROF. MEILAENDER: Or read some of the reviews of the *Hungry Soul* that we produced back when the *Hungry Soul* was public.

CHAIRMAN KASS: Alfonso, the last word on this.

DR. GÓMEZ-LOBO: Yes. Just a question of conceptual clarification or for any other reason for my own mind. I think that from what I read about chimeras there's a sense in which there are no real chimeras, that there is an incorporation of something coming from a different species into the life of whatever organism that is.

In other words, the geep, strictly speaking, is a goat, is a goat. Now, this may prove to be useful in trying to draw boundary lines, and as Ben just said, for instance, just using pig valves clearly does not threaten the identity of the host.

So the real question is here what kinds of mixers are such that the identity of the host is being threatened.

But that brings us back, of course to the need to identify in humans what is that core.

SESSION 7: PUBLIC COMMENT

CHAIRMAN KASS: Thank you very much.

I think that should be it for this particular session. We have one person who has asked to speak in

the session for public comment, and I'd like to ask Council members if they can to simply remain seated as we are now and invite Father Thomas Berg of the Westchester Institute to offer his public comment.

Welcome, Father Berg.

FATHER BERG: Thank you very much, Dr. Kass.

The Council will be grateful that I have a plane to catch shortly which will require me to be brief and to the point. So I'll just read the statement that I've prepared.

I'm a Catholic priest and an ethicist, and I'm also the Director of the Westchester Institute, an ethics think tank located in Farmwood, New York, and which organizes scholarly forums twice annually here in Washington.

In what I'm about to say, while I speak only for myself, I would wager that my views are shared by not a few Catholic moralists.

It is safe to say that the Catholic community, by and large, would follow with great openness and interest the development of new technologies that would allow science to harness the therapeutic potential of embryonic stem cells by non-embryo destructive means were that possible, and by means that in no other way would be detrimental to the integrity and dignity of the human embryo.

I think it is also evident from the deliberations of this Council and from preliminary scholarly comments upon the proposals that all proposals are deserving, to use the language in the current draft of the white paper and I hope language to this effect would remain in the document, that all proposals are deserving of careful and serious consideration, further public discussion and, where ethically appropriate, a vigorous scientific exploration.

As a Catholic moralist, I heartily welcome the invitation to further this process of sustained moral scrutiny of each of the proposals, and I cannot stress enough that we are only at the beginning of that process, at least from my perspective.

As one step in that process, our institute has organized a private gathering of ethicists and scientists, moral theologians and philosophers at the end of April here in Washington to give particular attention to Bill Hurlbut's proposal, altered nuclear transfer, and I expect that in the context of that collegial dialogue there will also be some discussion of the other proposals.

Our objective is to give the proposal a fair hearing and to sustain the kind of interdisciplinary dialogue that will be necessary for moralists, most of us non-scientists, to obtain the information we need to begin and carry on a process of moral discernment with regard to the licitness of ANT.

As a Catholic moralist, I need the proponents of ANT to provide me with a body of scientific data which can constitute a basis of information sufficient for me to arrive at moral certainty that the entity created by ANT would not be a severely disabled embryo, indeed, would not be an embryo at all, nor could have the potential to become an embryo.

I am convinced that such scientific data can only be assembled through the further exploration of this theory in animal models. Obviously, we would never endorse at this point laboratory experiments with ANT involving the use of altered human nuclei and ova.

Lacking such a body of scientific data, we are simply not in a position at this moment to arrive at a definitive ethical judgment on ANT. I believe that the majority of us are eager to get our hands on that body of scientific information that will enable us to move toward a moral judgment on ANT and to get that ensemble of information in the fastest way possible.

Not only should we commence as soon as possible with the animal experimentation phase of ANT. We should pursue federal funding to do so.

Thank you very much.

CHAIRMAN KASS: Thank you very much.

Robby.

PROF. GEORGE: Yes, just a quick point since Father Berg in his presentation mentioned the therapeutic potential of embryonic or embryonic type stem cells, and having in mind what you said, Leon, when we were discussing this about the way a report could be misinterpreted or things can be

read into the report and read out of it, I just wanted to say that I think it would be a bad thing if anyone in reporting on our deliberations about this suggested that our willingness or the willingness of people like myself to do everything we can to try to find what we consider to be ethically sound sources of pluripotent stem cells, it would be a mistake to suggest that that means that we have come to accept what I believe is the hyping of the therapeutic potential of such cells.

I believe that it remains speculative what the therapeutic potential is. I certainly hope that there is great potential there. I'm not convinced that there is, but nevertheless, I believe that we should go forward in trying to find ways to obtain these cells and permit the research to go forward without the destruction of embryos.

CHAIRMAN KASS: Thank you.

I think the point is well taken. I'm fairly sure that the document as currently written is sober on that point.

PROF. GEORGE: Yes. The document is absolutely fine. I just make the point because we can't always count on people who are reporting on the document to read it as carefully as they should.

CHAIRMAN KASS: Well, one of the things one learns in this business is you cannot control what other people make of what you've done. The best you do is you put it as carefully as you can and hope for the best, but we'll do our best.

Thank you all for your attendance. Thanks to members of the public. The meeting is adjourned.

(Whereupon, at 11:57 a.m., the meeting in the above-entitled matter was concluded.)

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LEON R. KASS, M.D., PH.D

COUNCIL MEMBER



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 numerous articles and books include: *Toward a More Natural Science: Biology and Human Affairs* (1984); *The Hungry Soul: Eating and the Perfecting of Our Nature* (1994); *The Ethics of Human Cloning* (1998, with James Q. Wilson); *Wing to Wing, Oar to Oar: Readings on Courting and Marrying* (2000, with Amy A. Kass); *Life, Liberty, and the Defense of Dignity: The Challenge for Bioethics* (2002); and *The Beginning of Wisdom: Reading Genesis* (2003).

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.

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BENJAMIN S. CARSON SR., M.D.

COUNCIL MEMBER



Benjamin Solomon Carson Sr. is the Director of Pediatric Neurosurgery at the Johns Hopkins Medical Institutions, a position he has held since 1984. He is a professor of neurosurgery, oncology, plastic surgery, and pediatrics.

In 1987, he gained world-wide recognition as the principal surgeon in the 22-hour separation of the Binder Siamese twins from Germany. This was the first time occipital craniopagus twins had been separated with both surviving. In 1997, Dr. Carson was the primary surgeon in the team of South African and Zambian surgeons who separated type-2 vertical craniopagus twins (joined at the top of the head) in a 28-hour operation. It represents the first time such complexly joined Siamese twins have been separated with both remaining neurologically normal.

He is noted for his use of cerebral hemispherectomy to control intractable seizures as well as for his work in craniofacial reconstructive surgery, achondroplasia (human dwarfism), and pediatric neuro-oncology (brain tumors).

Dr. Carson is a recipient of numerous honors and awards including more than 20 honorary doctorate degrees. He is a member of the American Academy of Achievement, the Horatio Alger Society of Distinguished Americans, the Alpha Omega Alpha Honor Medical Society, and many other prestigious organizations. He sits on many boards including the Board of Directors of Kellogg Company, Costco Wholesale Corporation, Yale Corporation (the governing body of Yale University), and America's Promise.

He is the president and co-founder of the Carson Scholars Fund which recognizes young people of all backgrounds for exceptional academic and humanitarian accomplishments.

He is the author of *Gifted Hands*, *THINK BIG*, and *The Big Picture*.

Dr. Carson has been married to Candy Carson for twenty-five years and has three sons.

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REBECCA DRESSER, J.D., M.S.

COUNCIL MEMBER



Rebecca Dresser, J.D., M.S. Daniel Noyes Kirby Professor of Law, Washington University School of Law, and Professor of Ethics in Medicine, Washington University School of Medicine. Professor Dresser has written extensively on bioethical issues, and she serves on the editorial board of *IRB: Ethics and Human Research*. Her book, *When Science Offers Salvation: Patient Advocacy and Research Ethics*, was published in 2001. She is also a co-author of *The Human Use of Animals: Case Studies in Ethical Choice* (1998) and *Law and Bioethics: Cases, Materials and Problems* (2003).

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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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FRANCIS FUKUYAMA, PH.D.

COUNCIL MEMBER



Francis Fukuyama is Bernard L. Schwartz Professor of International Political Economy at the Paul H. Nitze School of Advanced International Studies of Johns Hopkins University.

Dr. Fukuyama's book, *The End of History and the Last Man*, was published by Free Press in 1992 and has appeared in more than twenty foreign editions. It made the bestseller lists in the United States, France, Japan, and Chile, and has been awarded the *Los Angeles Times*' Book Critics Award in the Current Interest category, as well as the Premio Capri for the Italian edition. He is also the author of *Trust: The Social Virtues and the Creation of Prosperity* (1995); *The Great Disruption: Human Nature and the Reconstitution of Social Order* (1999); and *Our Posthuman Future: Consequences of the Biotechnology Revolution* (2002). His most recent book, *State-Building: Governance and World Order in the 21st Century*, was published by Cornell University Press in the spring of 2004.

Dr. Fukuyama has written widely on issues relating to questions concerning democratization and international political economy. He has, in recent years, focused on the role of culture and social capital in modern economic life, and on the social consequences of technological change.

Francis Fukuyama was born in Chicago on October 27, 1952. He received his B.A. from Cornell University in classics, and his Ph.D. in political science from Harvard. He was a member of the Political Science Department of the RAND Corporation from 1979-1980, then again from 1983-89, and from 1995-96. In 1981-82 and in 1989, he was a member of the Policy Planning Staff of the US Department of State, the first time as a regular member specializing in Middle East affairs, and then as Deputy Director for European political-military affairs. In 1981-82 he was also a member of the US delegation to the Egyptian-Israeli talks on Palestinian autonomy. From 1996-2000 he was Omer L. and Nancy Hirst Professor of Public Policy at the School of Public Policy at George Mason University.

Dr. Fukuyama is a member of the President's Council on Bioethics. He holds an honorary doctorate from Connecticut College and Doane College, and is a member of advisory boards for the National Endowment for Democracy (NED), *The National Interest*, the *Journal of Democracy*, and The New America Foundation. As an NED board member, he is responsible for oversight of the Endowment's Middle East programs. He is a member of the American Political Science Association, the Council on Foreign Relations, the Pacific Council on International Policy, and the Global Business Network. He is married to Laura Holmgren and has three children.

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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.

He is the author of *Making Men Moral: Civil Liberties and Public Morality* (1993) and *In Defense of Natural Law* (1999), and editor of *Natural Law Theory: Contemporary Essays* (1992), *The Autonomy of Law: Essays on Legal Positivism* (1996), and *Natural Law, Liberalism, and Morality* (1996), all published by Oxford University Press. He is also editor of *Great Cases in Constitutional Law* (2000) and co-editor of *Constitutional Politics: Essays on Constitution Making, Maintenance, and Change* (2001), from Princeton University Press, and *The Clash of Orthodoxies* (2002), published by ISI Books. He is co-author of *Embryo: A Defense of Human Life* (2008, Doubleday) and *Body-Self Dualism in Contemporary Ethics and Politics* (2008, Cambridge University Press).

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.

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**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.

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WILLIAM B. HURLBUT, M.D.

COUNCIL MEMBER



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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CHARLES KRAUTHAMMER, M.D.

COUNCIL MEMBER



Charles Krauthammer, M.D., Syndicated columnist. Dr. Krauthammer, a board-certified psychiatrist who received his medical degree from Harvard Medical School and practiced psychiatry at Massachusetts General Hospital for several years, writes a nationally syndicated editorial page column for The Washington Post Writers Group. He won the 1987 Pulitzer Prize for distinguished commentary. For 20 years, he has written articles on several bioethical topics, including human experimentation, stem cell research, cloning, euthanasia, and assisted suicide.

Dr. Krauthammer was a recipient of the Inaugural (2003) Bradley Prize, awarded by the Lynde and Harry Bradley Foundation, as well as the recipient of the 2004 Irving Kristol Award, given by the American Enterprise Institute.

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PETER A. LAWLER, PH.D.

COUNCIL MEMBER



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.

Lawler has published more than 125 scholarly articles, chapters, and reviews. His writings have appeared in such scholarly journals as the *Review of Politics*, *Government and Opposition*, *The South Atlantic Quarterly*, *The International Philosophical Quarterly*, *American Political Science Review*, *Journal of Politics*, *Gravitas*, *Interpretation: A Journal of Political Philosophy*, *Polity*, *Modern Age*, *Public Integrity*, *The Intercollegiate Review*, *Presidential Studies Quarterly*, *The Public Interest*, *Perspectives on Political Science*, *First Things*, *The Good Society*, *The New Atlantis*, and *Society*. He is also published in more popular magazines such as *The Weekly Standard*, *Current*, *The Claremont Review of Books*, *The University Bookman*, *The American Enterprise*, *Crisis*, *The National Review*, and *National Review Online*.

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, conservationism, 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.

Dr. Lawler recently edited a book on Tocqueville and American political life today and the fifth edition of *American Political Rhetoric*. He wrote an introduction to the new Sheed and Ward edition of John Courtney Murray's *We Hold These Truths*, and book chapters on religion and the American founding, Locke and American greatness, Flannery O'Connor, and *Casablanca*.

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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.

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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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JANET D. ROWLEY, M.D., D.Sc.



COUNCIL MEMBER

Janet D. Rowley, M.D., D.Sc. Blum-Riese Distinguished Service Professor of Medicine, Molecular Genetics and Cell Biology, and Human Genetics, Pritzker School of Medicine, University of Chicago. Dr. Rowley is internationally renowned for her studies of chromosome abnormalities in human leukemia and lymphoma. She is the recipient of the National Medal of Science (1999) and the Albert Lasker Clinical Medicine Research Prize (1998), the most distinguished American honor for clinical medical research.

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MICHAEL J. SANDEL, D.PHIL.

COUNCIL MEMBER



Michael J. Sandel, D.Phil., Professor of Government, Harvard University. Professor Sandel, who was a Rhodes Scholar, teaches contemporary political philosophy and the history of political thought. Sandel's books include *Democracy's Discontent: America In Search of a Public Philosophy* (1996) and *Liberalism and the Limits of Justice* (1982). He has received fellowships from the Ford Foundation, the American Council of Learned Societies, and the National Endowment for the Humanities.

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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*.

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JAMES Q. WILSON, PH.D.

COUNCIL MEMBER



James Q. Wilson, Ph.D. The James A. Collins Professor of Management and Public Policy Emeritus at the University of California Los Angeles and a lecturer at Pepperdine University. Professor Wilson, one of the nation's most respected political scientists, has written extensively on human nature and ethics. His publications include *The Moral Sense* (1997) and *Moral Judgment: Does the Abuse Excuse Threaten Our Legal System?* (1998). He has received numerous awards and honors, including the Presidential Medal of Freedom.

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