04-01-027

HOUSE OF REPRESENTATIVES
COMMONWEALTH OF PENNSYLVANIA

* * * * * * * * * * *

House Bill 2128

* * * * * * * * * * *

House Judiciary SubCommittee
on Crime and Corrections

Main Capitol Building
Room 140, Majority Caucus Room
Harrisburg, Pennsylvania

Thursday, April 2, 1998 - 9:30 a.m.

--oOo--

BEFORE:

Honorable Jerry Birmelin, Majority Chairperson
Honorable Stephen Maitland
Honorable Al Masland
Honorable Harold James, Minority Chairperson
Honorable Kathy Manderino

ALSO PRESENT:

Honorable J. Scot Chadwick
Honorable Craig Dally
Honorable Thomas Caltagirone
Honorable Peter Daley
Honorable Tom Yewcic

KEY REPORTERS
1300 Garrison Drive, York, PA 17404
(717) 764-7801 Fax (717) 764-6367

1998-094

ALSO PRESENT:

Brian Preski, Esquire
Majority Chief Counsel

Judy Sedesse
Majority Administrative Assistant

James Mann
Majority Research Analyst

C O N T E N T S

CHAIRPERSON BIRMELIN: Good morning. Welcome to the House Judiciary Committee Subcommittee on Crime and Corrections hearing on House Bill 2128. The legislation that we have before us deals with the issue of human cloning.

Prime sponsor of the bill is Representative Tom Yewcic, and he's going to be our first testifier. He also has prepared for us an amendment that's -- the Committee hasn't actually voted on the bill yet.

It has not been considered, but I'm sure it will be introduced to the full Judiciary Committee meeting. Today's meeting is simply a public hearing. We have several people that are testifying today, and we're going to get started off by introducing the Members of the Judiciary Committee who are seated with me here at the desk.

And after Representative Yewcic is finished with his testimony, I've asked him to come and join us as an ex officio member of the Panel today.

So I'll start to my far left and ask Representative Manderino if she will introduce herself and also where she's from.

REPRESENTATIVE MANDERINO: Thank you. Good morning. Kathy Manderino, Philadelphia County.

MR. MANN: My name's James Mann, Majority Research Analyst for the Judiciary Committee.

REPRESENTATIVE CALTAGIRONE: Tom Caltagirone, Berks County, City of Reading.

REPRESENTATIVE DALLY: Representative Craig Dally, Monroe and Northampton Counties.

REPRESENTATIVE CHADWICK: Representative Scot Chadwick, Bradford and Susquehanna Counties.

REPRESENTATIVE MASLAND: Representative Al Masland, Cumberland and York Counties.

REPRESENTATIVE MAITLAND: Representative Steve Maitland, Adams County.

CHAIRPERSON BIRMELIN: There may be some other Members who will be coming in during the course of the meeting, and I'll try to do my best to recognize them and put them in the official record today.

So we're going to start off right away with just a few comments from Representative Yewcic. And could you tell us a little bit about why you introduced the bill, outlining and

something you're going to be introducing at a later time?

REPRESENTATIVE YEWCIC: I'm Representative Tom Yewcic, Cambria and Somerset Counties. When the cloning issue first came out, of course, there was a lot of public comment and concern about the issue.

And, of course, it concerned me. And the comment that I received across my district from my constituents was one of concern, this is something that no one really has any use for or why are we doing this?

And it really struck at the fundamental beliefs that a lot of my constituents are concerned about that we really shouldn't be playing God and that sort of attitude that exists out in my district.

Very briefly, the bill was introduced. But having read it and doing a lot of investigating and talking to various people, the intent of the bill is to ban cloning. The language in the bill states the cloning of an entire human being.

After looking at that words, the verbiage, it come to my attention that that may

cause a loophole, that some people may recognize a human being, a entire human being, as a full-grown baby. And it doesn't address the problem of an embryo.

What this language does in the amendment that I passed out, just to share with the Committee, tightens up that language and recognizes that a human being is something that happened at conception with the human embryo.

So we try and address that language in this amendment so that we don't have a situation where we're creating human embryos to experiment on and then killing them. And that's what we want to ban.

Also we recognize with this amendment that, you know, we're not concerned about or we do allow and promote, I suppose, cloning technology that deals with tissue and organs and molecules, DNA, and other type of technology that's used for research.

And I think that's important for our health and for our future. Therefore, briefly, that's basically what we're trying to do here. I think that the human cloning issue is an important issue.

It's a weighty issue because it has the profound moral and social and ethical problems or raises issues of those concerns that need to be addressed because it talks about our moral fiber in our society. And I think we need to take a position on this issue. So, Mr. Chairman, that's all I have to say. Thank you.

CHAIRPERSON BIRMELIN: Thank you, Mr. Yewcic. And why don't you come up and join all us on the Panel here and include you in the opportunity to ask questions? You may ask one quick question, Representative Manderino.

REPRESENTATIVE MANDERINO: Thank you, Mr. Chairman. Thanks Tom. I was trying to read a marked-up version based on the amendment that you distributed to us. But something that you said triggered a concern in my mind.

And I just want to ask you on the record to state what your intent is with this bill vis-a-vis any effect that it might have on fertility methods, infertility methods, in vitro fertilization or things like that.

REPRESENTATIVE YEWCIC: It doesn't address those issues. This only addresses the human cloning issues. Those issues are not

concerned with this bill or with this amendment. We're trying to zero in on experimentation on human embryos vis-a-vis cloning.

REPRESENTATIVE MANDERINO: Okay. So if that is the intent, and the only reason that I asked the question is because you said something about defining --

REPRESENTATIVE YEWCIC: Human life.

REPRESENTATIVE MANDERINO: -- human life at the moment of conception and concerns about any destruction of any fertilization after that, which I realize that's what you said.

But what you're saying is if the words of this -- and those words can have an effect, I think, on in vitro fertilization. I don't know yet whether -- how it's listed in the bill does or not, but that's not your intent?

REPRESENTATIVE YEWCIC: Correct.

REPRESENTATIVE MANDERINO: Thank you.

CHAIRPERSON BIRMELIN: You may now join us. Our next two testifiers are Jeff Davidson -- he's the Executive Director of the Pennsylvania Biotechnology Association -- and Peter Johnson, M.D,Executive Director of Pittsburgh Tissue Engineering Initiative

Incorporated, Center for Biotechnology and Bioengineering.

Gentlemen, if you would come forward. And I see you're testifying together. For the purposes of the Committee, would you identify yourselves?

MR. DAVIDSON: Good morning. My name is Jeff Davidson. I'm the Executive Director of the of the Pennsylvania Biotechnology Association.

DR. JOHNSON: I'm Peter Johnson, M.D. I'm the President of the Pittsburgh Tissue Engineering Initiative and a member of the boards of the Pennsylvania Biotechnology Association.

CHAIRPERSON BIRMELIN: We have written testimony from both of you. And, Mr. Davidson, since you're first in the alphabet and you're on top of the pile, why don't you begin first?

MR. DAVIDSON: Okay. I prefer to precede Peter rather than follow him. He's a tough act to follow. Chairman Gannon and Committee Members, it's a pleasure to give testimony on the behalf of the Pennsylvania Biotechnology Association before the Members of the House Judiciary Committee today.

We believe the work you do in creating a

sensible legal environment for the Commonwealth of Pennsylvania is very important. It is our pleasure to describe our perspective today and to work with you as an educational resource in future deliberations on this topic and on other topics relating to biotechnology and life science research.

The Pennsylvania Biotechnology Association represents the biotechnology communities of the Commonwealth of Pennsylvania. This community includes biotechnology companies, pharmaceutical and biopharmaceutical companies, research universities, and the organizations that provide service to these industries.

Pennsylvania can be proud of the fact that it is both home to the fourth largest concentration of biotechnology companies in the United States and home to the second largest concentration of pharmaceutical and biopharmaceutical companies.

Further, it is home to many of the world-leading universities and colleges providing important basic and applied research, teaching, and training of Tom's work force.

The strength of this community makes

Pennsylvania one of the leading states in the nation and one of the leading regions in the world. We believe this community will be an important part of the economy of this state as we move into the next millennium and the age of biology.

The Pennsylvania Biotechnology Association is strongly in favor of using cloning techniques and technologies to improve human health, to improve agriculture, and to continue to improve our ability to clean up the environment.

These uses have already led to the development of products that have been used to treat over 100 million patients and providing improved therapy for serious medical conditions. These are the ways that the members of the association are actively engaged in using recombinant DNA technology or cloning for short.

Members of the Pennsylvania Biotechnology Association are using recombinant DNA technology or somatic cell nuclear transfer techniques to clone human genes for biomedical research and do not support using these technologies to create entire human beings.

The Biotechnology Industry Organization is our partner on a national level and is the organization that represents the companies and universities active in biotechnology. We share with BIO many common views on the regulatory and legislative issues surrounding human cloning.

The Food and Drug Administration has publicly asserted that it currently has statutory authority to regulate human cloning. The FDA has authority over somatic cell and gene transfer or gene therapy products under the Public Health Service Act.

In addition to FDA regulation, members of the U.S. Congress introduced legislation to restrict human cloning. Legislation must be carefully created to avoid unintentionally prohibiting potentially useful research in biotechnology, biopharmaceutical and pharmaceutical industries.

In closing, I would like to emphasize we are committed as an industry to responsibly using the modern techniques of biotechnology and life science research to develop useful products for human health care, agriculture, and the environment.

We support the National Bioethic Advisory Commissions ban on the use of human cloning technology to create human clones. We believe that the U.S. Food and Drug Administration has jurisdiction to regulate the use of this technology.

We believe that appropriate federal legislation addressing human cloning can be drafted, and we urge you to support FDA jurisdiction over human cloning experiments.

We are quite willing to work with you to consider Pennsylvania legislation that will address this area without unduly impeding scientific research.

We also are pleased to provide you with copies of a glossary of biotechnology terms and an issue of our publication, Your World/Our World, which is my proposal in my testimony.

On behalf of the Pennsylvania Biotechnology Association, I would like to thank the Committee for their thoughtful consideration of the complexity of this issue. I am pleased to introduce Dr. Peter Johnson to provide additional testimony on behalf of Pennsylvania's biotechnology community.

Dr. Johnson is a member of the board of directors of the Pennsylvania Biotechnology Association and is the founder and President of the Pittsburgh Tissue Engineering Initiative.

DR. JOHNSON: Chairman Gannon and Committee Members, thank you.

CHAIRPERSON BIRMELIN: Let me correct that. I'm not Chairman Gannon. I'm Representative Birmelin, Chairman of the Subcommittee. And Chairman Gannon's not with us today.

DR. JOHNSON: It's with the same degree of respect that I address you, sir.

CHAIRPERSON BIRMELIN: You're off to a good start.

DR. JOHNSON: Thank you for providing this opportunity to present testimony to the Senate Judiciary Committee today. We have just heard testimony from the -- the House Judiciary Committee.

You've just heard testimony from Mr. Jeff Davidson that illustrates the position of the Pennsylvania Biotechnology Association with respect to the cloning of human beings.

I've been asked to provide additional perspective, especially as regards to the words cloning and the implications of cloning for human health. In its simplest interpretation, the word clone means to copy.

For example, when a scientist makes a copy of a fragment of DNA known as a gene, this technique is known as quote, cloning, end quote, despite the fact that only a gene is being copied, small fragment of DNA.

Similarly, when cells are placed in a nourishing broth so that they will divide, this is also known as cloning. Apropos to our discussion today, when a nucleus from an adult cell is placed within an egg to recreate an entire human being, this is also known, perhaps regrettably by the same term, cloning.

Since legislation designed to prevent the replication of an entire human being is being considered but since there is no desire to restrict the medically important methods by which genes, cells, or tissues are copied, it is very important that we define how the word cloning is used in any such legislation.

The language in the present bill appears

to do this well since it specifies that the only act being prohibited is the transfer of a nucleus from an adult cell to an egg cell for the purpose of generating a whole human being.

However, I would just like to add the importance as you go forward as legislators to think of the word cloning and its potential broad-based implications to obstruct otherwise good progress in science and always use it in the most appropriate form.

While the prospect of replicating whole cells is repulsive to many, the need for the replication of parts of ourselves is quite acute, accepted, and even anxiously awaited.

As you know, many disease conditions require treatment using human tissues. The approximately half of our annual health care outlay is extended toward tissue-based therapies.

Such examples include the use of veins for coronary bypass, skin grafts for burns and the like. The most obvious is the treatment of organ failure through the transplantation of organs from other individuals.

In addition, reconstructive surgery after tissue loss is commonly performed. In this

case, we harvest tissues from one part of the individual and transfer them to other parts of the same individual.

Examples, as I said, include skin grafting for burn patients and bone transfers such as the movement of the fibula bone from the leg to the jaw for reconstruction after cancer surgery. This is all something known as tissue-based therapy.

A new science known as tissue engineering has made great progress in the growth of human tissues, but not whole humans outside the body. Examples include the growth of skin, cartilage, and bone promised for the eventual growth of whole organs, but not humans.

Tissue engineering can be thought of as organized cellular cloning whose creative conclusion is a tissue, but not an entire human. It is important that as legislation is drafted to protect society from the cloning of whole humans we do not inadvertently prevent the engineering of human tissues.

This would thwart our best chances to solve the organ shortage problem in transplantation, for example, as well as to be

able to avoid mutilating tissue harvest in reconstructive surgery.

Parenthetically, as a reconstructive surgeon and when I hear the words "moral fiber," I think that the care of the sick is one of the greatest aspects of the moral fiber of our society.

What we're attempting to do through tissue engineering is to enhance the quality of life, care for the sick in a way that does not require us to use the parts from other people or to use the parts from ourselves, but rather to use our skills to create components of ourselves to be used in therapy, something that completely bypasses the development of an embryo which is going to be very valuable to our society.

Whether there should be any research performed in which nuclear transfer technology is used to support drug development, et cetera, but not the creation of whole humans will require the significant input of many members of society.

It is, of course, important that all relevant voices be heard and that a careful judgment be made regarding the legislative avenues that shall best be pursued.

It is with respect to the fact that this Committee is pursuing this process that I submit this brief testimony to you today.

CHAIRPERSON BIRMELIN: I want to thank you gentlemen for your testimony. If you would, I'd appreciate it if you'd sit for some questions. I would ask the Members of the Panel as we're meeting this morning to keep in mind two things:

No. 1, we want to keep those who are testifying within their half-hour limits as scheduled, which means that your questions should be to the point.

They should not be repeating those questions that were asked by previous Members of the Panel which would require you to pay attention to what the other Members are asking as they go through their question time and that you would try to stick to this topic.

This is one that is ripe, shall we say, for tangents. We could go off into all sorts of other issues. And as we do question these gentlemen, those who follow them, I would appreciate the Members' attention to the fact that we are having this hearing on this

particular bill with this particular subject.

All that having been said, if I feel that we're straying and we are getting off the point, I will politely try to guide you back onto the flight path. And at this point, I will turn to my Democratic Chairman of this Committee, Representative Caltagirone, for any questions he might have.

REPRESENTATIVE CALTAGIRONE: Thank you, Mr. Chairman. I'm just curious -- either one of you can answer this question: Any of the universities, pharmaceutical firms, corporations that you deal with that are a part of your association, do they have any operations or satellite facilities or campuses in any foreign countries that you know of?

The reason why I ask that -- I'll be very to the point. It's all well and good for the State of Pennsylvania or maybe even the Congress of the United States to pass legislation prohibiting this kind of activity.

But outside of our borders, even outside the borders of the state does not necessarily mean that we cannot control what goes on in either other states or it's a national act or

outside of this country.

And I do believe that there are pharmaceutical firms and other corporations that deal in this type of area that operate outside the boundaries of the United States; is that not true?

MR. DAVIDSON: Yes, that is true. Actually, there are research operations kind of around the globe as it were and some other research centers of the world. I would just note that to the best of our knowledge, the distribution of that research does not change the character of that research.

So we really think that principally the research being done in the United States is very similar to that that might be done in another part of the world and that, generally, it seems that is trying to cure currently untreatable forms of disease.

And so we think most of the research around the world has that same intent and goal even though it's spread around in different regions.

REPRESENTATIVE CALTAGIRONE: The point that I'm making is that if, in fact, one of the

subsidiaries or branch campuses or whatever in another part of the world would get into this kind of activity, what's the Association's position going to be, especially if it affects this Commonwealth with legislation if it does become law?

I know we can't affect what goes on outside our boundaries. However, we can certainly affect if there's relationships with different types of organizations with those overseas. Doctor.

DR. JOHNSON: You know, this is a very good question because on the one hand, I'm thinking that you ask -- the question you asked was, Do your universities or industries have branch campuses or essentially affiliations in other places?

And the answer to that is, certainly, yes, whether they be formal or informal. The Internet allows us as researchers to essentially work with anyone in the world now and see them, talk to them, literally beyond I'm talking to a South African in the morning before you go to work and be doing work together.

So it brings up this whole moral fiber

question to the Commonwealth which is, you know, where are we going to make our stand with respect to cloning? I think that the organization of PBA -- I'm speaking as a board member of the PBA, not as its Executive Director.

I think that the board of the PBA has to look to the laws that you construct and take its policy from those, but to help you in the process of legislation.

And I guess my first take on this problem would be to encourage a communion of thinking to create the best way to decide where the moral fiber is going to be and then to restrict, say, cloning products or something like that, you know, where a whole human, not the word cloning in its many other meanings, but a whole human product like an organ -- a human farm that was used just to harvest organs, that you would then restrict something like that from being part of the Commonwealth's industrial practice. That's just my quick take on the question.

REPRESENTATIVE CALTAGIRONE: The point that I was dealing with, this specific legislation, the importation of organs from other countries around the world, a farm where they

could harvest those organs and then import them into Pennsylvania and in the medical community for their use is a very good possibility.

DR. JOHNSON: In a sense -- you know about the Chinese executions; you've probably heard about them. In a virtual way, this kind of a thing already exists. And we need to make -- we in the Commonwealth need to make decisions.

I guess my sense of things is the legislative bodies and those of us who are responsible for -- lets you know what the state of the art is and biotechnology are just now getting close enough together so we can make very intelligent decisions.

If nothing else comes from this, I certainly would like to commit my time to help with that process; and I think the PBA would as well.

MR. DAVIDSON: I would just -- I mean, the thought of -- some of the thoughts that are raised today are alarming in the sense of being alarming to our members or to members of the research community.

And I think principally the concerns are

probably twofold. One, we're at the early stages of using this technology. As you know, a sheep has been cloned and no humans have been cloned.

And so this technology is a very, very new -- and it certainly has not been used in humans. And so this is a good time to consider what our options are. But it's not a -- we don't need to be in a race to judgment, I think.

Secondly, I think the community of scientists and of biotechnology practitioners is fairly unified along the view that the use of this technology to create human clones is not something, frankly, that we are interested in doing as researchers or as corporations.

And so we do support the moratorium that the President's proposed. We do support the community development of responsible standards. And so I think that point was made.

DR. JOHNSON: I'm here as someone who is committed to the concept of tissue engineering. We know that now human skin is being grown as a product. It's a product in Canada. Within a month or two, it's probably going to be a product in the U.S.

Human cartilage will be -- is being

grown and being used as a product on a test basis. Virtually every other organ is now in the attempts to grow -- to be grown. There's a consortium developing with researchers in Toronto and around the world to consider a human heart and tissue engineering program.

I think that the best way to avoid the problems of whole human farms for organs, in other words, plucked organs from whole human organs is to focus instead on tissue engineering where you don't go through the embryo phase which causes so much political difficulty and moral difficulty, but instead focus upon the building of only those things that we're now -- that we're even now taking those transplanted organs from others with great difficulty.

REPRESENTATIVE CALTAGIRONE: Thank you, gentlemen. Thank you, Mr. Chairman.

CHAIRPERSON BIRMELIN: Representative Yewcic.

REPRESENTATIVE YEWCIC: Yes. Very briefly. Both of you had similar terminology in stating -- using the words, "generating a whole human being." Can you define that? Is that a whole human being? Is that a newborn baby? Or

is that the fetal aspect?

DR. JOHNSON: I think that I'm very sensitive to your presentation and to the political and moral groups that are assembled here.

I think you -- when we talk about whole human cloning, we're talking about the nuclear transfer technology taking an adult nucleus and putting it into an egg.

I think when that happens you're in that process of considering a whole human. Now, there are guidelines from the NIH that govern some of the initial activities within the first number of days after that embryo is formed and some accepted national guidelines that are out there now that violates the opinion or the moral opinion of some members of societies.

I'm aware of that. And I think that that's where the debate lies but it lies at that level. It doesn't lie at this whole baby level that you address. I think that we're all thinking at that early stage.

REPRESENTATIVE YEWCIC: My intent is to address it at that level on when a embryo is created. We recently passed a fetal homicide

rule to recognize as life.

My wife's sitting over here. And when she conceived, I considered that as my children in her womb. And that's, more or less, I want to go that far, I think, in my presentation.

DR. JOHNSON: And to respond as a doctor to you, if there's a -- we know that in in vitro fertilization, for example, there are many embryos created and not all are chosen.

If there is the possibility that knowledge gained from that stage of the embryo without allowing a whole human to -- without a whole human to mature and develop outside the womb, there's knowledge to be gained.

As a doctor and someone who has to take care of horrible diseases, if you could -- if you could rectify some of those diseases with that knowledge, then I think that's not something that we want to push aside quickly and completely simply because we have a sense that life has been created and is therefore a complete life, particularly in light of the in vitro fertilization issue. But I think it's an open debate still.

REPRESENTATIVE YEWCIC: Thank you.

Thank you, Mr. Chairman.

CHAIRPERSON BIRMELIN: Representative Dally.

REPRESENTATIVE DALLY: Thank you, Mr. Chairman. I have one question for Mr. Davidson. In your prepared testimony, you indicate that your Association believes that the FDA has jurisdiction to regulate.

Do you look at that at -- do you look at that as being exclusive jurisdiction, or is there room for the states to be involved in this?

MR. DAVIDSON: That's a good question. And, certainly, there are areas where the FDA does have jurisdiction and states have additional laws as well. Our thought I think at this point is probably threefold.

Again, this technology has been improving in humans; so we're dealing with a matter of time. Secondly, no one's really actively pursuing and engaging in.

Third, we really think that most of the regulatory apparatus that is in place in this country is to provide protections for patients and for people involved in clinical trials; and clinical research is managed by the Food and Drug

Administration.

And in general, that's a very careful and thoughtful process that provides good protection for those involved in the research, good demonstrations of safety and efficacy.

That allows then our society as a whole to have protections in place, and we think that's very important. Whether additional laws would be necessary, I think it's probably a bit early to really say.

REPRESENTATIVE DALLY: Um, the other question that I had was for Dr. Johnson or Mr. Davidson, whoever wishes to answer. In terms of this legislation, Dr. Johnson, as you mentioned in your testimony that it's important that legislation is drafted to protect the society from the cloning of whole humans, we do not inadvertently prevent the engineering of human tissues.

In review of this legislation, do you think that this legislation serves that purpose?

DR. JOHNSON: The legislation as I originally read it before I came today seems to. The addendum that I saw today where the words "human cloning" are being used in

replacement -- I haven't had a chance to really look through it and think through it that way.

But I just -- I would want to be careful. Remember, I talked earlier about the fact that the word "cloning" can be generalized to mean so many things.

If the word "human cloning" somehow overlaps tissue cloning or cell cloning for purposes other than the creation of a whole embryo, I would be concerned. So I think that's why I'm trying to emphasize language and the meaning so much.

REPRESENTATIVE DALLY: And my final question, not to go too far afield of the legislation but since we have the expertise here, the issue of genetic engineering I think dovetails into this issue of cloning.

And there's been reports in the various media about the use of genetic engineering to choose the sex of the child, the eye color of a child, the hair color of a child. And you see that as a prevalent practice, something we should be concerned with as Legislators?

DR. JOHNSON: I think you should be concerned to be aware of how that is moving

forward. I mean, that really becomes a moral fiber question. And that means that you have to have intense debate and really understand what's happening, which means we are responsible to you to make sure that we give you the information you need to make your decisions.

MR. DAVIDSON: I think I can just add a little bit to that as well. If you look at the way that our corporations are funded, we principally ask for money from the public, in essence, to underwrite our research. And, generally, the public is very focused on curing important societal problems.

And so if you look at a corporation, it's much more likely to be studying how do we solve problems associated with Alzheimer's because that's a massive societal problem where hundreds of thousands of patients are suffering, where the quality of life is drastically impaired by Alzheimer's.

And so, generally, the market pushes us to be doing the kinds of things that we think as a society are the most important, pressing problems.

I think many of us find that a child

with blue eyes or brown eyes is probably not such a pressing problem that we're going to invest 250 million of our own dollars in developing technologies around that and defining it.

And so we think in general the biotechnology pharmaceutical communities focused on solving some of the more pressing problems. If a hundred years ago, a hundred years from now we had solved all of the pressing health problems of our society, at that point, we might find that, well, what else can we do with this technology?

At that point, I think we'll be in a much different place.

REPRESENTATIVE DALLY: Thank you, gentlemen.

CHAIRPERSON BIRMELIN: Representative Manderino.

REPRESENTATIVE MANDERINO: Thank you, Mr. Chairman. With the amendment that was handed out this morning, the definition of human cloning is proposed as follows:

As used in this section, the term "human cloning" means the practice of creating or attempting to create a human embryo by

transferring the nucleus from a human somatic cell from whatever source into an egg cell from which the nucleus passed to initiate the development of a human organism.

Given that definition, if you were able to follow, is there anything that we are doing today in the field of biotechnology or that is on the perceivable forefront that would be impacted and particularly prohibited by this definition?

DR. JOHNSON: Yes.

REPRESENTATIVE MANDERINO: And could you elaborate?

DR. JOHNSON: Yes. What would be prohibited would be the generation of knowledge that we really have only the slightest grip on right now.

It would be the generation of knowledge about how a cell begins the process of unfolding and translating its genetic information into the preparation to become an entire organism.

We've never been able to harness that knowledge before. And it's only now with the transfer technology that it would become impossible to do that on a scale that's broad enough to be able to harness technology, to be

able to do enough experiments to do it.

Um, now, as I say, I realize that that's knowledge that's gained at some price and we're here to sort of determine what that price will be and we don't know what the impact of that knowledge may be.

It may allow us to pattern whole lines of cells to treat disease because we'll be able to identify it probably at the earliest stage.

REPRESENTATIVE MANDERINO: You indicated that the original definition you reviewed you were more comfortable with, I guess it's fair to say. What is it about what I just read that is particularly troubling in your field of biotechnology?

DR. JOHNSON: Only that -- only -- with these kinds of issues, I like to take some time to let them sort through and only because I haven't had that time to let them sort through.

CHAIRPERSON BIRMELIN: Representative Chadwick.

REPRESENTATIVE CHADWICK: Thank you, Mr. Chairman. I must confess when I came to this hearing I thought we pretty well had this locked down how this legislation was going to permit

tissue and organ work which is very important, which we should do.

I thought it was going to absolutely prohibit cloning of a whole human being which is something we should do. And I, frankly, didn't expect to have to stay very long.

But in sitting here, one of the pieces of material that was provided to us was Charles Krauthammer's essay in the January 19 edition of Time Magazine. I don't know if you two gentlemen have seen it or not. If you have not, I would like the staff to make it available to you two; but I found it very disturbing.

And one of the things it points out is that laboratories at the University of Texas and the University of Bath have successfully cloned headless mice and headless tadpoles and a biologist at Princeton University -- which is a very fine university -- named Lee Silver told the London Sunday Times that it would be almost certainly possible to produce human bodies without a forebrain.

And he says that, quote, these human bodies without any semblance of consciousness

would not be considered persons and thus it would be perfectly legal to keep them alive as a future source of organs.

And I find that very disturbing. And reading the bill with the amendment, I'm not sure we've gotten to where we need to be with this language to make sure that we can't do that and that we have some work to do.

That being said, the question I have for you gentlemen is, where should we draw the line? Should we allow the cloning of parts of humans, whether it be an arm or leg or just individual organs? There's a tough line to be drawn here someplace. And I would like to know what you think, where you think that line should be?

DR. JOHNSON: This is one I actually have a pretty well-formed answer to. If you think about it, what's happening in these experiments is that they're using the human body as a bioreactor for organs. When we talk about a bioreactor, we're really talking about an incubator that grows organs.

And there actually are designed devices called bioreactors that are used to grow tissues, and incubators are one subset of them. I think

if you're using the human body, if you're harnessing the human body to be the final reactor for multiple organs, that's really where you draw the line.

If you create a mechanical bioreactor that grows an organ like an incubator that's specialized to provide flow and temperature control and the other things that allow you to engineer tissue, it's distinctly different because you don't even have the potential to have a soul hooked into that machine.

In this case, you know, one of the first things that happened to me in labor and delivery in medical school was to deliver an encephalic child, a child without a forebrain.

And you don't feel like that's not a person when you deliver it. You know it's not going to survive, but you don't feel like it's not a person. So I think it's the use of the human body as a bioreactor that disturbs me the most.

REPRESENTATIVE CHADWICK: Thank you, Mr. Chairman. I'll honor your request to limit my questions.

CHAIRPERSON BIRMELIN: Thank you.

Representative Maitland?

REPRESENTATIVE MAITLAND: (No audible response.)

CHAIRPERSON BIRMELIN: Representative Masland?

REPRESENTATIVE MASLAND: (No audible response.)

CHAIRPERSON BIRMELIN: And we've also been joined by Representative Daley from Washington County. Do you have any questions --

REPRESENTATIVE DALEY: Yeah. Thank you, Mr. Speaker. To follow up on Representative Chadwick's question or at least his statement, he said it is a distinction -- in law school, someone once said it's a distinction without a ton of difference.

I really don't know how you could differentiate from growing a heart when you don't grow other organs. I think that's the problem. I also basically feel that there's a problem -- you know, somehow this reminds me, I guess, historically if we could have gone back maybe 55, 60 years ago when Oppenheimer, Professor Oppenheimer was discussing where are we going to go with nuclear reaction and nuclear

fission.

And I think we're at the precipice of that type of hearing here, not only here, but throughout this nation. I mean, something could be happening here very good and very positive for all human existence.

However, something could be happening very, very destructive too. And that's one of the questions I have. I think that's where Scot Chadwick was coming from. I think there needs to be a distinction of what's going on here.

If it's tissue regeneration or tissue engineering, how do you separate that from actually growing a heart or a limb or something else? I don't know.

DR. JOHNSON: Maybe I can clarify this a little bit. When we talk about nuclear transfer technology to grow an entire embryo, we're talking about a cell whose history is essentially being reset to zero.

But just like us as we grow and differentiate into our different professions and appearances and so on, cells do that in our bodies. When you have cells, for example, in the muscles of your body and you take some of those

cells out and you try to grow them, they grow into muscle cells.

They don't grow into hearts, and they don't grow into the heart as a muscle; they don't grow into brains; they don't grow into toenails. It's the fact that cells differentiate and generally do not go back. That is what we leverage when we do tissue engineering.

So we're essentially protected from creating whole organisms if you're engineering tissues using somatic or tissue-based cells but not putting them back into an egg so that you can reset it back to zero. I think that's where your distinction's going to lie.

MR. DAVIDSON: And I think to answer that and I'll add, very modestly admit, we would agree that the language here is difficult to craft so that you're prohibiting what would generally be desirable to prohibit without prohibiting those things that are generally considered to be desirable.

So we would agree with you that it's fairly difficult and the drafting of the legislation must be done pretty carefully so that we get the results that we want out of it.

Now, perhaps, and this is what you do do routinely is crafting good legislation carefully. As a community of biotechnologists and pharmaceutical companies and universities, we generally are not that involved in exactly which word might be preferred.

And so I think this is an area where we would agree with you that it's important to craft carefully and there are distinctions that are somewhat hard to draw. And that's why we would like to work with you in the future to make sure that the legislation that's drafted is achieving this desired --

REPRESENTATIVE DALEY: I can't remember in the 16 years that I've been here that this process generated good legislation. It's always a compromise of 253 different ideas.

And I'm -- the concern that I have is that the intent that's going to come out of this legislation has to be so clear and so specific and so pristine that we all understand exactly where it's going and what its impact is on the next generation of Pennsylvanians in America. Thank you, Mr. Chairman.

CHAIRPERSON BIRMELIN: Thank you,

Mr. Daley and Mr. Davidson and Dr. Johnson. We want to thank you for your testimony. We on the Panel want to agree that it's been very enlightening and probably a little bit over our heads yet.

But I'm going to hang on to your testimony and all of the information that we have today because I think it's a subject that is just beginning to involve us as Legislators.

And contrary to what Representative Daley said, I think we often craft a fine piece of legislation here. Not always. But we do want to thank you for coming here, and we appreciate your testimony.

DR. JOHNSON: We'd be pleased to help or even identify others to help.

CHAIRPERSON BIRMELIN: And I would appreciate it if you would, if you have not already, spend some time with Representative Yewcic, second to my left, who is the prime sponsor of this bill who I think would appreciate input from you folks. Thank you very much.

The next person scheduled to testify is Michael Geer, Executive Director of the Pennsylvania Family Institute. And I would

ask that his testimony be distributed to all you folks. Michael, welcome to the Judiciary Subcommittee on Crime and Corrections. And when you're ready, you may begin your testimony.

MR. GEER: Thank you very much. Good afternoon, Mr. Chairman and Members of the Committee. I am Michael Geer, President of the Pennsylvania Family Institute, a statewide nonprofit research and education organization based in Harrisburg that focuses on policies and cultural trends that impact families, much like when a factory or shopping center is built an environmental impact study is required.

We at the Pennsylvania Family Institute analyze policies and social trends that impact the most basic building block of our society, the family.

The subject of today's hearing, human cloning, strikes right at the heart of family, what family truly is, what it means to be part of a family, and the role the family plays in the nurturing and development of human beings.

The Pennsylvania Family Institute stands squarely against human cloning and strongly supports its ban. As we come to the end of

twentieth century and, indeed, the end of the millennium, I think it is useful to take a brief look at the years gone by in this century in which we saw exponential leaps in science and technology.

Today we take for granted many things our grandparents could only have dreamed about thanks to science and technology. But through this century, we have also learned many lessons both practical and moral about the limits of science and technology and the willingness of mankind to use this science in dangerous and evil ways.

Unfortunately, we have to relearn them again and again. Early in this century, technology made bold proclamations about a ship that was so amazingly designed and built that not even God could sink it. The cost of that Titanic arrogance was more than 1500 lives.

But we also learned that human lives should not be offered up on an alter of technological arrogance and showmanship, and so now even the most modern ships are equipped with sufficient life boats to save every life on board.

There were some other terrible lessons learned in this century here in America. Most significant but little talked about lesson is on America's involvement and leadership in the eugenics movement in the early 1900s.

The word eugenics was coined by English scientist Francis Galton who took the word eugenics from a Greek, Greek root meaning -- Greek root meaning good in birth or noble in heredity.

He intended it to denote the science of improving human stock by giving the more suitable races or strains of blood a better chance of prevailing speedily over the less suitable.

His ideas caught on here in America. And by 1915, three years after the Titanic disaster, this was recorded in the news, this is a news report:

Mrs. E.H. Harriman's gigantic eugenics enterprise at Cold Springs Harbor, Long Island, to ascertain what is the matter with the human race launched a campaign today for the sterilization of 15 million Americans.

Coincident with this amazing statement comes the exclusive announcement through the

international news service of the plans of the Eugenics Society which will have at its disposal the vast fortunes of Mrs. Harriman, the liberal financial assistance from J.D. Rockefeller and Andrew Carnegie and scientific aid from Alexander Graham Bell and the greatest host of scientists ever joined in the huge undertaking.

The committee estimates that it will be essential similarly to treat annually an increasing number as the population increases until 1980, 415,000 persons in the United States alone will be sterilized every year.

When that time arrives, there will have developed, the committee believes, a practically perfect manhood and womanhood. During that same time period, state fairs in Kansas and elsewhere held "fitter family" contests where families were judged for their breeding like pigs or cattle.

We didn't escape it here in Pennsylvania. At a sesquicentennial celebration in Philadelphia, the American Eugenics Society exhibit included a board, which like population counters of the later day revealed with flashing lights that, quote, every 15 seconds, $100 of your money went for the care of persons with

bad heredity; but every 48 seconds, a mentally deficient person was born in the United States; and that only every 7 1/2 minutes did the United States enjoy the birth of a high-grade person who would have the ability to do creative work and be fit for leadership.

An exhibit placard asked how long are we Americans to be so careful as to the pedigree of our pigs and chickens and cattle and then leave the ancestry of our children to chance for blind sentiment?

I present these news dispatches from history as a reminder that science can get away from us and that even the most brilliant minds and the greatest hosts of scientists can still lead us astray.

Unfortunately, America was not turned away from its eugenics mind-set until the horrors of Nazi Germany evidenced the natural extrapolation of these dangerous ideas.

We are not God, and we get in deep trouble when we try to play God. Now to cloning and the proposed ban here in the Commonwealth. As I stated earlier, The Pennsylvania Family Institute supports prohibiting cloning of all

human beings through somatic cell nuclear transfer.

On this point, the vast majority of Americans agree. In an ABC News poll released on Nightline last year, 87 percent of those polled said the cloning of human beings should be banned, 82 percent said cloning human beings would be morally wrong, and 98 percent said they personally would not choose to be cloned.

Beyond popular opinion is the question of whether human cloning is right or wrong. I believe it's wrong for several reasons: Humans as guinea pigs, cloning is not a routine process, few people realize that the successful creation of Dolly the cloned sheep came only after hundreds of failed attempts.

Before researchers Jerry Hall and Robert Stillman succeeded in cloning a human embryo in 1994, they created and destroyed numerous human embryos. Literally hundreds of human lives, human embryos will have to be brought in existence to overcome the technological hurdles of cloning a human embryo that grows in maturity, more likely the thousands or tens of thousands.

These embryos will not be treated as

intrinsically valuable human beings, which they truly are, but rather as things to be used to further the ends of science and the benefit of others.

To quote C. Ben Mitchell, Ph.D, The dignity of individual human lives both prescribes and proscribes how humans are to be treated. Human beings may not be used as means to our own ends. They may not be the subjects of experiments without their knowledge and permission.

We may not demean human beings by imposing upon them conditions they may not have consented to if allowed to make the decision for themselves. He goes on to say, These principles would make immoral most of the reasons which have been suggested as reasons to clone human beings.

Thus, human clones would not be suitable organ farms for those needing transplantable organs. Human clones would not be acceptable substitutes for children who died leaving their parents grief stricken.

Human clones, likewise, would be ethically unacceptable as candidates, as icons -- unacceptable candidates as icons in some

kind of narcissistic cult of self-worship.

Human cloning would be offensive to millions of Pennsylvanians who hold the view that all human life, whether embryo, fetus, infant or adult is created in the image of God and sacred. Let's look further.

Human cloning would have an inevitable deleterious effect on the formation of natural biological families and would, thus, contribute to the breakdown of the traditional family.

Francis Beckwith, a philosophy and law professor at Trinity International University in California says this: Imagine if an infertile couple were to produce a clone of the male partner in order to have a child.

The clone would technically be the father's twin and, therefore, a brother and not the father's son because sons are the product of the union of a man's genetic code with a woman's. And what if this couple were to clone another child, but this time it is the female partner's clone?

Technically, this would be the sister-in-law of the father's twin. The bottom line, the distinctions between parent, child,

sister and brother which ground our notion of family life are at risk of becoming unraveled further if cloning is treated as just another exercise in reproductive rights.

Second, it is not needed to address the problem of infertility. While infertility is a pressing problem for thousands of couples, there are numerous treatments and techniques available to remedy this problem.

Because of its profoundly unnatural quality of cloning, it is simply unrealistic to expect cloning to solve the infertility problem. In addition, cloning held in this sense profoundly changes the nature of child rearing and adoption of naturally born children.

And the problem of infertility is largely behavioral. A little reported fact of the infertility problem is that more than 75 percent of all couples having trouble having children have sexually transmitted diseases.

It makes no sense to promote a grossly unnatural alternative to infertility when in many cases the solution is overwhelmingly behavioral. Human cloning for the production of spare parts is wrong.

While Dolly the sheep made headlines, it was not widely reported as we heard this morning that researchers in Texas and England had through genetic manipulation successfully cloned headless mice and tadpoles.

The ominous significance of this process is that some day headless or brainless humans would be cloned for the purpose of providing organs for transplant and other spare parts.

And I will say that when I heard the previous testifiers mention whole human beings, I thought that perhaps these headless or brainless humans would not fit their definition of a whole human being. And so that's a problem with that.

This idea of headless -- producing headless or brainless human beings for providing organs is not a farfetched idea, again, as we heard the Representative say. Princeton biologist, Lee Silver, told the London Sunday Times, it would be almost certainly possible to produce human bodies without a forebrain.

These human bodies without any semblance of consciousness would not be considered persons, and thus it would be perfectly legal to keep

them alive as a future source of organs.

But honestly, I think there are people in state hospitals in Pennsylvania who have little or no semblance of consciousness themselves and we consider it unethical and immoral to go in there and harvest organs from them. The specter of this possibility alone argues for the ban on human cloning in my view.

This ban and the amended House Bill 2128 would not prohibit the cloning of human tissues or cells that are not embryos for beneficial medical research or research involving cloning of plants or animals.

It would simply put into law the respect for all human life that civilized society requires. I am not surprised that there remain those in science who balk at any ban on human cloning and others who want a free hand to experiment with cloned human embryos they then will kill.

As George Annas pointed out in 1989, ethics is generally taken seriously by physicians and scientists only when it either fosters their agenda or does not interfere with it.

If it cautions a slower pace or more

deliberate consideration of science's darker side, it is dismissed as fearful of the future, anti-intellectual, or simply uninformed.

And I think our experience in this century and past centuries says that scientists should not be leading this debate. The experience of the twentieth century tells us that science that is uninformed or unrestrained by moral and ethical guidelines adopted by and for society as a whole for its own good can be a dangerous thing.

The Pennsylvania Family Institute wholeheartedly supports a ban on human cloning here in the Commonwealth. I'll take any questions.

CHAIRPERSON BIRMELIN: Thank you, Mr. Geer. And as you are used to, we will ask you to sit for some more questions. Representative Maitland.

REPRESENTATIVE MAITLAND: (No audible response.)

CHAIRPERSON BIRMELIN: Representative Masland.

REPRESENTATIVE MASLAND: Just a brief comment because, you know, we have a lot of

people on the Panel. I agree with your position. I think that it is sad that we try to be like God or like the gods, whether it's Greek mythology or modern day Pennsylvania situations.

It is sad when we try to do that. But the question really comes down to who is going to lead the debate? I don't know that this is something that we can rely on Washington to address.

And I think Representative Yewcic for that reason developed this legislation and has introduced it here. So I don't know what your position is on that particular aspect as to whether this is something that you feel we should handle here in Pennsylvania or we should leave up to Congress?

MR. GEER: Well, interestingly, the debate continues in Congress. After Dolly was cloned and there was an uproar that Nightline -- those Nightline statistics I mentioned were -- that poll was taken the day after Dolly was announced.

President Clinton then quickly announced based, I think, on his sense of public opinion and perhaps other motivations that there should

be a ban on cloning.

But then what the White House seems to be proposing and what some Senators in Washington proposed is a weak proposal that would sunset it after a certain number of years that would allow human embryo research of cloned human beings.

So whether or not Washington is going to lead on this remains to be seen. I think that as elected representatives of the people of Pennsylvania that it is wise and right that you should move forward with this bill and enact the ban here in Pennsylvania.

REPRESENTATIVE MASLAND: Just one other comment. I wondered as I was listening to this testimony and looking at the bill where we would have been 30 years ago if this debate had taken place, or 50 years ago, what people would have been saying and where we will be 30 or 50 years from now?

We have gone a long way in terms of how we respect human life, human dignity. And whether it's the young, the old, it's a sad situation.

My concern, really, is if we don't address this now we will definitely be down the

proverbial slippery slope to a point where we don't really get fazed when we hear the word headless human beings; that's just taken for granted.

MR. GEER: I think in the testimony that we heard and in response to the questions of the previous testifiers they mentioned in a relative sense since we are currently in the case of in vitro fertilization destroying many human embryos for the choice of one that may help an infertile couple to, say, that that -- therefore, that we're already doing that which many of us would consider a wrong thing to do, therefore, should then allow the next step kind of creates that relativistic slippery slope that will create the question you're raising, which is, where we will be in 30 or 50 years? That's why we have to make a strong stand now.

REPRESENTATIVE MASLAND: Thank you. Thank you, Mr. Chairman.

CHAIRPERSON BIRMELIN: Representative Daley.

REPRESENTATIVE DALEY: One real quick question, Mr. Chairman. You stated that you wholeheartedly support the ban on human cloning.

What about the proposition of tissue generation and organ generation?

MR. GEER: Well, that remains to be seen. I think the language of this amended bill allows for tissue generation and things as long as it's not a human being, which is a creation of an embryo. And we are not the sum of our parts. My finger is not me; my heart is not me; my brain is not me.

So on that basis, I do not have as strong a position against research that would perhaps create, enable -- and I think this may already be being done and perhaps could be done more effectively through cloning of tissue, the creation, for example, of skin that could be used in a skin graft of a burn patient.

So I think there's a distinction between a human being and a finger or skin or something of that sort.

REPRESENTATIVE DALEY: Thank you, Mr. Chairman.

CHAIRPERSON BIRMELIN: Representative Yewcic.

REPRESENTATIVE YEWCIC: Thank you, Mr. Chairman. I wholeheartedly agree with your

testimony. It seems that once again science and technology is building the social conscience of our society. And you know that the question is really, you know, not so much should we do this, but should we even allow it to happen?

Most people, I think, would agree at least where I'm from that this is just something that goes against our nature of who we are as human beings and we just shouldn't even consider this. So if you want to respond to that.

MR. GEER: I talked a little bit about the history of America earlier in the eugenics movement because at that time as noted in Titanic, the building of Titanic was the sense that science could answer all problems and if we followed science's lead we could have created a perfect human race as was said by those people at the turn of the century.

And we only learned later the ominous repercussions of that kind of thought. I said when a nation puts forth those in science as the arbiters of morals and ethics, I think we are on very shaky ground.

REPRESENTATIVE YEWCIC: Thank you.

CHAIRPERSON BIRMELIN: Representative

Manderino.

REPRESENTATIVE MANDERINO: Thank you, Mr. Chairman. Most of the testimony that you've presented to us either by way of reference or by your footnotes, you gave us the source from which you got that information.

One fact that you stated in your testimony which is not sourced and which I would like to know the source because it's new information to me is the following: The problem with infertility is largely behavioral.

A little reported fact of the infertility problem is that 75 percent of all couples having trouble having children have sexually transmitted diseases.

MR. GEER: I'll be happy to provide that to you. Medical Institute for Sexual Health in Texas has done significant clinical research as well as statistical research indicating that because of the pervasive, epidemic spread of human papillomavirus, Chlamydia, and other sexually transmitted diseases that -- and scarring of the fallopian tubes and because of other problems that it, indeed, is the cause of an epidemic of infertility in our society.

Not only is it the prevalent cause of infertility, but it's caused -- the spread of sexually transmitted diseases has caused a huge increase in the number of infertile couples.

REPRESENTATIVE MANDERINO: Medical Institute for --

MR. GEER: Sexual Health.

REPRESENTATIVE MANDERINO: Sexual Health.

MR. GEER: By Dr. Joel McIlheney. And I will --

REPRESENTATIVE MANDERINO: Could you spell McIlheney?

MR. GEER: M-C, capitol I-L-H-A-N-E-Y, make it, E-N-E-Y. And I will send you all the statistics. I apologize for not footnoting it on there.

CHAIRPERSON BIRMELIN: Thank you, Mr. Geer. We appreciate your testimony.

MR. GEER: Thank you.

CHAIRPERSON BIRMELIN: Our next testifier is Gary Graham. He's a diabetes patient advocate, and Members should have his testimony before them as well. Welcome, Mr. Graham. And when you feel comfortable, you

may begin your testimony.

MR. GRAHAM: Good morning, Mr. Chairman and fellow Committee Members. I promise you I can't get that technical. I thank you for the opportunity to tell you what advances in medical research have meant to me personally.

I'm a native Pennsylvanian currently living in Dauphin County, and I'm a third-generation diabetic. I'm just one of the 1.1 million Pennsylvanians suffering from diabetes.

The most common types are Type 1 which is juvenile, and Type 2 which is Adult on-set. Adult on-set is the greater percentage of them simply because it takes in the people who are trying to control their diabetes with diet, those who take pills, and many of us who take insulin.

And as you know, high blood sugar levels can hurt different parts of the body resulting in nerve damage, kidney disease, eye damage, heart disease, tooth and gum disease, and infections that frequently lead to amputations.

A quick fact, an estimated 1.1 million children and adults in Pennsylvania have diabetes. It's incurable. Half of them don't

know they have it, which is probably the most discouraging part of it.

Diabetes is the third leading cause of death in Pennsylvania by disease, and more than 11,500 Pennsylvanians die each year. I was first diagnosed with Type 2 diabetes 12 years ago.

As an individual with Type 2 diabetes, my body may produce insulin and probably does; but it's unable to properly, which is -- use it properly, which is why I must give myself three insulin shots per day.

And even with those insulin shots, I was not able to keep control of my blood sugar. And recently, my doctor put me on a new FDA approved drug, which has dropped it 40 to 50 points on a daily basis.

And that's been extremely important, and that's really why I'm here. In some Type 2 diabetics, this new treatment may result in reduction or elimination of insulin or oral medications. But the most important thing is that you have better control of blood sugar.

Continued medical research is not the only quality-of-life issue for patients, but new drug therapies coupled with education, nutrition,

and life styles will dramatically reduce health care costs.

Currently, the direct and indirect costs of diabetes is 6.7 billion annually. If you're interested, it cost me $4700 a year, my insurance company and myself to be a diabetic.

In Pennsylvania, over 3800 amputations occur annually. Cost for hospitalization, 26,940. Of them, couple more than $40,000. Eighty percent of these amputations are diabetics.

In Pennsylvania, over a thousand new cases of end-stage renal disease related to diabetics is diagnosed each year. Cost per hospitalization, $38,700. Sixty percent of these people are diabetics.

In Pennsylvania, there are 937 new cases of diabetes-related blindness. Seventy percent of the blind in Pennsylvania are diabetics. It's my hope and prayer -- and I know you share my feelings -- that continued genetic research, that it enhances the quality of life, reduces more expensive hospital stays and invasive procedures, will some day lead us to a more effective treatment and, perhaps, even cures for diseases

like diabetes and cystic fibrosis and AIDS and Alzheimer's and ALS and cancer and many other things.

The thing that I would ask you is that as you review this legislation such as House Bill 2128 and probably the bills that will come after it, that the language be carefully crafted so that there's not any unintended negative impact on the future of biomedical research. This is one of those things that has happened to me. And I thank you very much for the opportunity to share it.

CHAIRPERSON BIRMELIN: Thank you, Mr. Graham, for coming and for your testimony. Sort of as a parenthetical statement, I will tell you that I'm also a Type 2 diabetic, but not to the extent that you are, thankfully.

But I understand and appreciate what your concern is. And at this time, I will turn the -- this portion of our testimony over to the Panel and ask them if they have any questions. Representative Dally?

REPRESENTATIVE DALLY: No.

CHAIRPERSON BIRMELIN: Representative Caltagirone?

REPRESENTATIVE CALTAGIRONE: (No audible response.)

CHAIRPERSON BIRMELIN: Representative Manderino?

REPRESENTATIVE MANDERINO: (No audible response.)

CHAIRPERSON BIRMELIN: Representative Yewcic?

REPRESENTATIVE YEWCIC: (No audible response.)

CHAIRPERSON BIRMELIN: Representative Maitland?

REPRESENTATIVE MAITLAND: (No audible response.)

CHAIRPERSON BIRMELIN: Nobody has any questions for you. You must have done a very good job of presenting your testimony

MR.GRAHAM: Either that or I didn't tell you what you wanted to know.

CHAIRPERSON BIRMELIN: We're not looking for people telling us what we want to know. We're interested in having them tell us what we don't know.

MR. GRAHAM: Thank you, sir.

CHAIRPERSON BIRMELIN: Thank you for

coming. Our next testifier is Richard Doerflinger. He's the Associate Director of Policy Development with the National Conference of Catholic Bishops. Mr. Doerflinger, you may proceed when you feel ready to. You may begin your testimony.

MR. DOERFLINGER: Thank you. I'm from Washington, and I've been an advisor to the Catholic Bishops of the United States at the congressional level on this. I'm representing today the interests of the Pennsylvania Catholic Conference which are identical to the interests of the National Conference.

You have my prepared text and appendices, and I ask those be submitted in the record. I'd like to begin, though, by commenting on some past testimony here, which if you're like me, it must have been very confusing.

We had -- we had the phrase "whole human being." And I share Mr. Chadwick's concern earlier that this could allow for some horrendous things involving headless and brainless humans.

We also had the phrase "whole human being" distinguished from human embryo. It was said at one point that researchers want to be

able to study how an embryo turns into a whole human being, which seems to be something that happens later and yet everyone seems to be agreed that we don't want to be cloning whole human beings.

Now, something that is not as widely appreciated as it needs to be is that there is no such thing as the act of cloning a whole human being, if by whole human being you mean fully developed person with arms and legs and so on.

There's only one kind of cloning of human beings, and it happens at the cellular level. It makes an embryo. It makes the same kind of embryo ultimately that fertilization makes to many peoples' astonishment.

But it's still the same kind of creature, the same kind of organism of the species Homo sapiens to quote current Pennsylvania law against harmful experimentation on fertilized embryos.

What happens, what this legislation needs to be very careful about if it's going to ban human cloning, what is it you're trying to ban? If you want to ban cloning, you have to ban it at the outset.

You have to ban the use of that cloning technique to create this new human organism known as a human embryo so that it cannot be subjected to lethal experimentation, picked apart for its tissues and cells and so on.

And in doing so, you'd be conforming this law as Mr. Yewcic now proposes to do, you'd be conforming this law to the way that current Pennsylvania laws treats all other embryos because current Pennsylvania law treats as a Class-3 felony any nontherapeutic experiments on an embryo produced by sexual reproduction or in vitro fertilization.

I think this answered the gentleman's question earlier about what effect this has on IVF. IVF is already governed by a law treating harmful experimentation on the embryo as a felony.

All we want to do now that it has become apparent that not only fertilization but also somatic cell nuclear transfer can produce this embryo is to apply that same protection to human life as created this new and bizarre way.

And, in fact, the need is even greater here because this technique is so bizarre, so

divorced from human relationships, human sexuality, from ordinary parent/child relationships that it involves the complete laboratory manufacture of a new human life that has no parents in the ordinary sense, no advocates, no protectors, no one who anyone would have to go and get informed consent from in order to do the harmful experimentation that some people want to do.

That means that embryo is even more defenseless than any other in the Commonwealth of Pennsylvania and especially needs your protection.

I have here something that I would be interested in passing around because it's particularly revealing, a diagram which -- I don't know if there's anybody who can pass it around -- but this is something that was passed around during the congressional debates by biotechnology companies, by those who disagree with me on this issue.

In fact, this was first shown to me by Senator Kennedy when he was trying to persuade us of the reasonableness of his position allowing cloning of human embryos for destructive

experimentation. I was able to show him that it shows exactly the opposite.

It shows three arrows, one coming from sex between man and woman, one coming from in vitro fertilization, one coming from somatic cell nuclear transfer, and they all point to the same place being that that chart calls early embryonic cells that any ordinary person would call a new human life, a new human embryo that that embryo if you just leave it alone and let it develop turns into a new human being.

If you cut it apart for its tissues, then it becomes specialized cells. If you cut any of us apart for our organs, we become specialized cells.

What some biotechnology people want to do -- and I'm not sure that the Pennsylvania biotech companies want to do it because I found their testimony, frankly, rather self-contradictory.

On one hand, they said they did not want to be creating human embryos, and on the other hand, they seemed to be denying that. The National Biotechnology Association wants the go-ahead to be creating these human embryos by

cloning but then destroying them for their tissues and cells.

Now, that means that under the guise of banning cloning, what you'd actually be banning is live birth; you'd be banning survival. You'd be allowing unlimited cloning of human embryos for experimental purposes and then bringing a felony conviction against someone if he fails to destroy or throw away that embryo.

Now, to us that's the equivalent of state-coerced abortion. You don't want to be banning cloning by doing that. I mean, we don't even want to be allowing it, much less having the state coercing the destruction of embryos especially when it's a felony to do that same thing to any other embryo and those embryos would be distinguishable from the others by the biotechnology company's own chart.

I want to say something about medical research. I'm very upset at the way in which this issue has been handled in the Congress, and I hope it doesn't go the same way here.

Because the way in which legislation was at least temporarily deferred in the U.S. Senate was by biotechnology companies making enormously

exaggerated claims for the medical benefits of human cloning on embryos and in fact whipping up a great many disease groups that are well-meaning and legitimate into believing that the only way to cure any of their diseases is to make and break human embryos.

Even the scientists that support the moral position of those companies have said that those benefits, if they are any, are conjectural. New England Journal of Medicine said that the other day.

The National Bioethics Advisory Commission said that those benefits are farfetched. And it suggested on its own initiative three different ways to get those same medical benefits without creating and destroying human embryos.

The amendments that we very strongly support now offered by Representative Yewcic, in fact, for the first time give explicit approval and permission to use cloning technology to produce tissues, organs, animals, genes, recombinant DNA research they talked about.

All it forbids is creating that cell known as the human embryo, which in every other

circumstance is already protected from destructive experimentation by the Commonwealth of Pennsylvania.

I do not think that the national government is -- the Congress is very clear on this issue, frankly. I think that I always like to see the states with the great laboratories to do legislation.

I think Pennsylvania has been a bell ringer in the protection of human life before and it has that opportunity to do so again, to show the rest of the states and to show Congress the way to protect human life while still protecting legitimate medical research that does not take human life. Thank you.

CHAIRPERSON BIRMELIN: Representative Manderino.

REPRESENTATIVE MANDERINO: May I pass?

CHAIRPERSON BIRMELIN: Representative Caltagirone.

REPRESENTATIVE CALTAGIRONE: (No audible response.)

CHAIRPERSON BIRMELIN: Representative Dally.

REPRESENTATIVE DALLY: You mentioned

that the previous testifiers from the Pennsylvania Biotechnology Association presented testimony you felt was contradictory. Could you just expand on that?

MR. DOERFLINGER: Yes, I can. I was taking notes. Mr. Johnson testified that he'd be concerned if the ban overlaps with any cloning of cells or tissues that does not involve creating, quote, a whole embryo.

There I completely agree with him. That's where the legislation makes the distinction between the new human embryo versus these other cells and so it cannot possibly develop as a human organism.

But then when he was asked if there was any problem with the bill that simply said you can use this for anything except creating a human embryo, he had problems because that would ban the gaining of knowledge in how an embryo eventually develops into a whole organism.

Now, that's -- first of all, it seems to me internally inconsistent. And it's inconsistent with current Pennsylvania law because current Pennsylvania law defines an unborn child as an individual organism.

It is already an organism of the human -- of the species Homo sapiens from fertilization until live birth and then proceeds to make it a Class-3 felony to doing a nontherapeutical medical procedure experiment on that organism.

So I think if you were to take his view of allowing a free fire zone, if you will, for some stage of embryonic development during which you can do nontherapeutic or destructive experiments you'd be in contradiction with the way Pennsylvania law treats all other human embryos.

See, I think there's been a confusion about this because people think that cloning is such a bizarre technique and so demeaning that the creature that results from it somehow must be a subhuman class of human being.

But that's the amazing thing. Dolly is just as much a sheep as any other sheep. A human created this way would be as much a human as any other. It's the technique itself that's demeaning.

And unfortunately, because it is such a dehumanized process divorced from loving

relationships, sexuality and so on, plus it's a matter of mere manufacture, it does invite people, it tempts people to then treat the product as something less than human.

But it's not. Cloning is wrong. Not because the cloned individual is not human or doesn't have human dignity, it's wrong because these embryos do have the same human dignity as the rest of us and deserve better. They deserve to be treated better.

REPRESENTATIVE DALLY: And it's your opinion then that this legislation as amended addresses the concerns of the Catholic Conference?

MR. DOERFLINGER: Yes. The language of the amendments are similar to clarifications that are in some of the federal bills, including the federal bill that's passed the House Science Committee offered by Congressman Hilliard, who is the only research scientist in Congress.

The disclaimer about distinguishing between the creating of embryos and the creating of cells, tissues, and organs and genes that can allow the legitimate research to continue.

If I can just add because I forgot to

say it earlier, the other thing I thought was very interesting from the earlier testimony is that Pennsylvania was cited as one of the leading states in the nation and one of the leading regions in the world for medical biotechnology advances.

It has become that leading state in the nation with the ban on nontherapeutic and harmful experiments on human embryos. If you pass this bill, Pennsylvania will still be the leading state in the nation, the leading region in the world because there aren't any medical benefits that can be done in other ways.

One of the fact sheets in the appendix of my testimony was nine different alternatives to some of the things that embryo cloning has been suggested for.

REPRESENTATIVE DALLY: Thank you very much.

CHAIRPERSON BIRMELIN: We've been joined by Representative James who is my counterpart as the Chairman of the Subcommittee on Crimes and Corrections. Representative James, do you have any questions?

REPRESENTATIVE JAMES: No questions.

CHAIRPERSON BIRMELIN: Representative Masland.

REPRESENTATIVE MASLAND: No questions.

CHAIRPERSON BIRMELIN: Representative Maitland.

REPRESENTATIVE MAITLAND: Yes. And I'm going to digress just slightly. Your opposition to the cloning that we've discussed today centers around creation of a human embryo. What would your position be on the inserting of human genes into other species to enhance genetic research; for example, to make the kidney of a pig compatible with a human's transplantation?

MR. DOERFLINGER: It's a different issue, but it's certainly an interesting and complicated one. What's being done right now is things like genetically engineering, say, a cow at the embryonic stage or later so that it can -- its milk can produce a protein that is particularly needed by human premature babies so that then those babies could be given this cow's milk and it's as good as their own mother's milk for providing that special protein.

Catholic Church doesn't have any principle objection to that. We feel that's

similar to other kinds of therapies where individual traits and individual cells and tissues are transplanted.

We don't have a principle objection even to some of the transplantation that's been done where, for example, a human patient received a baboon heart. We raised questions about whether some of those patients really get informed consent and know how experimental this is, that it might not really help them because there are times when people get used as research subjects and they don't understand that this may not help them as individuals.

But it raises some interesting questions for all of us because the question arises that at what point do you cross the line from simply engineering individual traits all the way to making some kind of animal/human hybrid that is a member of neither species but is some kind of new thing that we have to question the human dignity of.

I have grave concerns about that. I don't think anyone is seriously proposing it at this point, but it's another issue of concern here.

REPRESENTATIVE MAITLAND: Thank you. Thank you, Mr. Chairman.

CHAIRPERSON BIRMELIN: Representative Yewcic.

REPRESENTATIVE YEWCIC: I just want to say thank you for your testimony and I agree wholeheartedly with you and I appreciate your input on this issue because I think it strikes at the heart of who we are as a people, basically, from my perspective and the people who have commented to me from my district and are -- quite frankly, from across the country people are looking at various legislation to see that, in effect, we do ban cloning of human beings at the embryonic stage, hopefully.

And I have a lot of correspondence coming in on this issue, and it's a tribute to me. And I appreciate your position, and I look forward to working with you and others like you in getting this bill passed in amended form into law that we can continue being the No. 1 state protecting human life. Thank you.

MR. DOERFLINGER: Thank you. If I could just comment, I don't want to be entirely negative on the national. One of the earlier

witnesses said, Well, there are national guidelines on this coming from the NIH.

And I want to clarify that because the NIH did propose guidelines in embryo research. Those were rejected by President Clinton part way and then entirely rejected by the U.S. Congress.

The current national guidelines -- now there's no federal law that bans private embryo research. That's considered a state matter, and you've done a good job on that.

But the federal government usually sets policies on these things initially by deciding what can be federally funded, what can be done at the National Institute of Health.

This bill does not go beyond the restrictions that are now in the federal funding. The current national guidelines on embryo research are that no creation of embryos for research purposes and no harmful experimentation may be done on a new human embryo from the one-celled stage on, whether it's produced by fertilization or cloning.

We added the words about cloning, about using a somatic cell just this year in order to cope with the new situation created by Dolly. So

the national guidelines are in agreement with what Mr. Yewcic wants to do with this bill.

CHAIRPERSON BIRMELIN: We want to thank you, Mr. Doerflinger, for your testimony. I appreciate the fact that you've come here before us and answered these questions, and perhaps we'll hear from you again. And thank you for your involvement in this issue as well.

MR. DOERFLINGER: Thank you, sir.

CHAIRPERSON BIRMELIN: I'm going to ask the Members if they would please stay in their seats for about two or three minutes. We need to set up a slide projector. Our next testifier is going to be showing us some slides.

And it will be very instructive, I think; and this will involve a few minutes of setting up for that. So we're going to just temporarily be at ease. Thank you.

Our next testifier is Mary K. Howett, Professor of Microbiology Department, Hershey Medical Center, not so far down the road from here, and part of Pennsylvania State University College of Medicine.

Dr. Howett, we want to thank you for coming here this morning. I noticed in the

handout that you've given us you've given us a glossary of biotechnology terms relative to human cloning and according to, I guess, along with a slide presentation, we're going to get a primer on this issue of cloning. And I'm assuming that your testimony apart from the glossary is not in print?

DR. HOWETT: That's correct.

CHAIRPERSON BIRMELIN: So we will pay rapt attention to what you have to say. And if you would afterwards when you're done with the presentation sit and answer some questions, we'd appreciate that as well. So you may begin.

DR. HOWETT: Okay. Well, thank you very much and thank you for inviting me here today. I am primarily a researcher over at the medical center. My laboratory is involved in research to study the molecular relationship between virus infections and cancer development.

And I have a Ph.D. degree in molecular biology. And I use techniques of recombinant DNA cloning, recombinant DNA biotechnology in my laboratory. One of the other hats that I wear is that I am a member of the Pennsylvania Bar Association Committee.

It is an interdisciplinary committee on medical and health related issues. And I have served sort of in that capacity as an itinerant scientist and really see my role as an educational one to try to present you with some of the technical details of what we are talking about today and to take and answer your questions in terms of distinguishing some of these very highly complex distinctions between different types of cloning.

So my basic goal in my talk today is going to be to try to make it perfectly clear to you the three different distinctions that we mean when we talk, first of all, about DNA or recombinant DNA cloning and molecular biology techniques associated with that.

Secondly, what we mean when we refer to twinning experiments for separation of human or other animal embryos for production of more than one genetically identical organism.

And this is a type of cloning, but it is distinguished from what was done in the third scenario with the Dolly type of cloning where we use an adult cell to actually reproduce an adult organism, now as a new embryo, and then as a new

born animal. So that's my goal today.

And in that regard, I've brought some very simplistic diagrammatic slides which I'd like to go through. So you all are familiar with the concept that within the human body all of the organs are composed of cells, cells being the very basic unit of human life and of all living life.

And we have what we call specialized cells that perform specialized function. So in an embryo, whether it is a single cell embryo or then two, four, eight, sixteen cell embryo, at those very early stages when we refer to all of the cells in the embryo as being totipotent.

And that means that in a two-cell or a four-cell or an eight-cell embryo every single cell in the embryo could be separated and would have the capability of developing into an entire organism.

Later in development, both in the embryo and then in the adult, we have specialized cells such as liver cells, skin cells. And those cells are no longer in a traditional sense totipotent.

They have been assigned their task in the body. A liver cell knows that it is a liver

cell. It does not perform the function of a skin cell even though it contains the same amount of DNA. So that's what we mean by a specialized cell.

Now, when we talk about cells in general, there are two broad categories that we talk about. We talk about prokaryotic cells. Prokaryotic cells are cells that do not have nuclei; and they essentially constitute all of bacterial species.

We also talk about eukaryotic cells. Eukaryotic cells are cells that do have nuclei, these ovoid bodies in the center of the cell. That's the nucleus, and that black body here is the nucleus.

I've shown you here two very different types of cells, the human nerve cell and the human liver cell, just to show you that they can have very different appearances even though they're both cells.

And in the nucleus of these cells, we find the DNA or the genetic material of the cells which is represented here by these red strands in the nucleus. This green area in the cell is referred to as the cytoplasm.

And it's basically all of the other structural components of the cell outside of the DNA and inside of nucleus. This is just a light microscopic picture of cells in human skin that we can grow in plastic dishes in the laboratory.

And this is just to show you that one of these tiles here is a single human cell. And inside of this single human cell, this large ovoid body is the nucleus. This darker body is something that we call the nucleolus.

But it is this large ovoid body that contains the DNA. Now we can grow both bacterial cells and eukaryotic cells in the laboratory, and we grow them mainly in either glass or plastic vessels. We grow bacterial cells on agar plates.

I'm sure many of you have seen in basic high school biology labs agar plates or gelatin plates that have bacterial colonies growing on them, or we can grow them in liquid culture. And we use these bacterial cells for generation of gene products and for generation of recombinant DNA.

And that's why I'm telling you about them today because I want you to understand that we can introduce genes or DNA from normal animals

or normal plants into bacteria and we can reproduce them to very high copy number inside of bacteria which we grow in these cultures.

We can also take tissues out of organisms be it animals or plants, in this case, human liver. We can break the cells from the human liver apart, and we can also grow these liver cells in culture.

And normally we grow them by attaching them to the surface of the plastic. So those skin cells that I just showed you were actually growing on the surface of the plastic.

And, for example, in the case of human skin cells, you can then harvest those cells up off the plastic and you can use them for grafts for burn patients. You can take them back out of the culture, put them back on the patient.

Now, this is the basic structure of eukaryotic cells. We have the nucleus which has the DNA inside. In the cytoplasm, we have a number of other factory machinery parts of the cell that carry out the functions of the cell.

One of the things that we have in the cytoplasm are these small red bodies. They're called mitochondria. And the mitochondria also

have DNA in them. And that becomes important in the aspect of genetic identity.

And I will tell you that because of the mitochondria Dolly is not a true clone because Dolly has the DNA in the nucleus from the donated cell of the biological sister or biological mother of Dolly.

That is the nucleus that was put into that embryo. But the cytoplasm of Dolly still contains the original mitochondrial DNA from the original donor of the egg.

So while it is a 99.9 percent clone, it is not an absolutely pure clone. Now, DNA as you know is the genetic code. This is a chemical representation of the DNA strands.

That's a ladder. This is the famous double helix. These letters down the center of double helix represent the code of the DNA. And there are only four chemicals that are involved in the letters.

And what is important, therefore, is not the chemicals per se, but the sequence of the chemicals. So we read the DNA just the way you read a sentence, just the way we only have 26 letters in our alphabet but we can combine them

into millions of words.

It's the same thing with the four bases of the DNA. We only have four bases in the alphabetic DNA; but we can combine them into millions of different sequences, linear arrays that constitute the genes.

The linear array of the DNA inside of the normal cell is copied into something that we call the RNA. The RNA is the substance which is more or less the mirror image of the DNA. And the RNA carries the message from the DNA out of the nucleus into the cytoplasm of the cell.

And it is the code within the RNA, again, as a linear array which is responsible for transferring the information to make the protein. All right.

The RNA represented here in blue goes out into the cytoplasm. It goes to a structure called the ribosome which is in yellow here. And the ribosome reads then, by chemical machinery it reads the code on the RNA; and the consequence of that reading activity is the production of the protein.

And the proteins are the actual building blocks of the cell. They are the things that do

all the structural functions of the cell and they are the things that do all the biochemical activities of the cell.

So if you metabolize sugar, if you respire oxygen, if you make fat, all of those mechanisms that happen inside of your cell are done by proteins, by enzymes that are made.

So the dogma, the central dogma in biology is that DNA makes the code, the code is transferred to the message in the RNA, and the message in the RNA is transferred to the protein.

All right. Now, one of the important distinctions that needs to be considered when writing legislation about cloning is that we now have an ability in our laboratories to clone genes.

Now, in the normal human cell, there are at least 100,000 genes. And one popular scenario that was presented in the Jurassic Park movie is that somehow you could take the DNA that was all broken up and put all these genes back together and you could now recreate an organism.

In fact, that is not possible. We're talking about an array of linear sequences that once they are broken, they cannot be reassembled.

We not only do not have the mechanical ability to reassemble them, we wouldn't know how to put them back together.

Now, we can isolate, however, a single piece of DNA, either a whole gene or a piece of a gene. And we can replicate that DNA as a cloned DNA through the construction of recombinant DNA molecules.

And we do that by use of small DNA molecules called plasmids. Plasmids are small, self-replicating bacterial DNA molecules; and they are normally found in bacterial cells.

And so inside of a normal bacterial cell, you have a chromosome which is the main DNA and then you have these small other DNAs which are self-replicating. And the bacteria in nature use these plasmids for antibiotic defense. That's one of their main functions in the bacterial.

But we have found ways to actually insert genes into the plasmids and to grow the plasmids. And we use that as a main source of cloned DNA. So this is just a pictorial representation of the chromosome of the bacteria and the plasmids growing inside.

And you can have hundreds of copies of these plasmids inside of a single bacterial cell. And so it's a way of generating very large amounts of DNA and then subsequently generating very large amounts of product from a single piece of DNA.

So this is currently used both for pharmaceutical manufacturing; it's used for vaccine development. The hepatitis B virus vaccine which is being used worldwide consists of a small piece of DNA that has been inserted in this plasmid.

It makes a single, tiny piece of the hepatitis B virus protein. And we can make very large quantities of this protein very cheaply. And that's what's been used as the vaccine, so this is a very valuable technique.

One of the major issues with the withdrawal of the federal legislation on the cloning ban was that as it was written, it interfered with this process.

So this is a very important distinction, I feel. When you consider writing legislation that wordily bans human cloning, that it must be drafted in such a way that this process is not

interfered with.

Now, the use of recombinant DNA technology is not without ethical implications because in part this technique is also used for gene therapy; and we'll talk a little bit about that in a moment.

This is just a schematic diagram of what we do. We take the very long human DNA, the foreign DNA, we cut out the piece that we want, we insert it into the plasmid, and we replicate it in the bacteria.

If we have such a plasmid and it is making something that we like, something that could be used for human therapy, it's possible to now take the plasmid out of the bacteria, purify the DNA, take that same DNA and insert it into a white blood cell and culture, and then put the white blood cell back into a patient.

And this is the exact experiment that has been done with the boy in the bubble syndrome. It's called adenosine deaminase deficiency, adenosine deaminase deficiency.

These are children who are born; they are lacking in a particular protein called adenosine deaminase. They are globally

immunodeficient because they cannot make this protein.

The gene for this protein has been cloned. It has been inserted into a plasmid. Blood has been drawn from these children. The white blood cells in the blood have been grown in culture, the plasmid has been reintroduced in the white blood cells, and the white blood cells have been given back to the children.

There are a handful now of these children who have been treated in such a way. They're in clinical trials at the MIH Clinical Center, and these children are making adenosine deaminase.

And they are currently undergoing tests to test their immune function. So this type of an approach of gene therapy replacement of something that is missing is clearly of benefit for human therapy.

Now, clearly, we cross the line here ethically when we begin to talk about what traits should be corrected, who makes the decisions about what traits should be corrected, are we only talking about medical issues here, are we talking about cosmetic issues? And that's

another issue for another bill.

But from the perspective of allowing recombinant DNA cloning, I would urge you that this is a very beneficial technique and even though it in and of itself should be ethically regulated, it should not be banned.

So the types of recombinant DNA technology that I've been talking about can be used for many, many different approaches. We can use this approach to isolate single genes and just look at basic aspects of life and basic aspects of disease because we can now identify and look at single genes in a test tube; we can define what their function is; we can look at single abnormal genes in a test tube; we can find out what function is missing compared to the normal gene; we can define the basis of disease; we can use cloned genes to do genetic testing to determine if people are carrying genes to determine if newborns are affected by certain genes; we can use cloned plasmid DNAs to develop new drugs by making very large quantities of proteins from these cloned gene products.

As I just discussed, we can replace deficient genes; we can add proteins back to

living cells, to living organisms and fix them through gene therapy; we can use cloned genes to identify individuals.

We now have a enormous effort which is being mounted by the United States Foreign Services. They're going to have DNA libraries stored on every soldier, every enlisted man. And so we will never again have an unknown soldier as long as we can recover any portion of the deceased because we can use DNA for identification.

And then, of course, not so much a subject for human cloning, but we can use cloned DNA products for a whole host of agricultural improvements. Now, I want to switch at this point and discuss the distinction between this type of cloning, molecular cloning, and organism cloning.

So you all know that in normal fertilization you have a sperm and an egg which are united and make a fertilized embryo. What you need to appreciate is that this is the step by which biodiversity is generated.

In a normal nucleus, in a normal cell, you have two copies of every chromosome. When

the sperm and the egg are generated in the father and the mother, the sperm and the egg are what we call haploid cells. They only have one copy of every human chromosome.

And so when fertilization occurs, you become biodiversities by virtue of the fact that you receive half of your chromosomes from each parent. That's not true for a clone.

So one of the major biological drawbacks of cloning is the absence of biological diversity. By doing cloning, we are basically stopping the clock on evolution because each time we go through this selection, mixing of the chromosomes and selection of the embryo, we are basically going through the basic process of selecting the most biologically desirable traits.

Plus on a population basis, we have retention of those chromosomes that are most desirable and deletion of those genes which are least desirable.

It doesn't happen in every case, but over many generations of humans and over thousands and millions of births, there is a slow but steady selection which results in biodiversity.

Now, remember in the beginning of my talk I talked about when you go from the fertilized embryo to the two-cell, the four-cell, the eight-cell stage here, that each one of these cells is totipotent.

Each one of these cells can be divided, and that's shown here as a single cell. You could take this eight-cell embryo, you could separate it mechanically into eight single cells, you could introduce each of those eight single cells into a foster mother and if they all implanted properly, you would have as a result eight births of genetically identical individuals.

They would be twins. Even though they were gestated in eight separate uteri, they would be twins. Now, what is the purpose of this approach? This approach has been used for more than ten years already for agricultural breeding purposes.

One of the main places, for example, that it has been used is in the generation of genetically desirable cattle. They've always had great selectivity in selection of male cattle because you can have one male donor fertilize

many females.

But they have not been previously able to very selectively breed the females because one female could only produce one or at most two embryos. So now they've used this technique agriculturally to very much improve breeding selectivity in agricultural animals.

They've also used this technique of twinning to create some very select experimental animals. The one I'm most familiar with is that it has been done with rhesus monkeys.

And basically they have produced genetically identical rhesus monkeys in order to use them in medical experiments where they have genetically identical individuals.

So the concept of twin generation is a type of cloning which is distinct from that which is what's used to create Dolly. Now, we talked briefly about the concept of introducing DNA which has been generated through recombinant DNA technology into embryos.

All right. And that's a method called transgenic technology. And what we do is we take the eight-cell embryo; we take a single cell from that embryo. It is microinjected under the

microscope with recombinant DNA.

The cell then can be put back into a foster mother and the foster mother then can produce offspring which will carry that trait. All right.

So this is a possible method for genetic therapy in humans. It's a possible method for genetic alteration of livestock. It's a possible method for introduction of human genes into nonhuman cells.

There are some reasons why you would want to do that; for example, the kidney example that you mentioned previously. People are attempting to introduce human histocompatibility antigens into pig kidneys so that there is less ability to be rejected when those kidneys are transplanted into humans.

There are at least three commercial companies who are engaged in this type of technology with porcine organs, pig organs, to humanize the organs for use in human transplantation.

All right. And then in my last slide, I'll just explain to you briefly what was done in the case of Dolly. In the case of Dolly, it was

not a twinning experiment, but it was a generation of a fertilized embryo from a normal adult cell.

So what was done was cells were placed in culture. An egg had its normal nucleus removed. It was surgically removed from the inside of the egg. The cells that were in culture -- I believe they were from breast tissue -- they were then taken and nuclei were taken out of those breast cells that had been grown in culture.

And those nuclei were placed inside of this enucleated egg, and then that hybrid was then implanted. All right. And as a consequence, one sheep, this clone sheep was produced. Now, I want to finish by saying that first of all you should remember that with Dolly more than 300 hybrid embryos were made.

Of those, only a very small number, less than 50, were actually implanted. Of the 50 that were implanted, probably only 20 actually produced a pregnancy in the sheep. And the result of all of that effort was only the birth of one sheep.

So we are talking about something that

at this point in time is technically possible assuming that Dr. Woollett is correct. But we are not talking about something that somebody could just go out at the local K-Mart mall and start doing.

We're talking about something which is very technically demanding. It has a extremely low efficiency of success. And while it raises the specter of possibility, it is not something which is about to imminently happen in the human population. So I think I'll end there. And I'd be glad to take your questions on any of those. Thank you.

CHAIRPERSON BIRMELIN: Representative Yewcic.

REPRESENTATIVE YEWCIC: Just one brief question. You said that was imminently happening in the case of Dolly, how it's not going to imminently happen in humans.

DR. HOWETT: In other words, it has not currently happened in humans.

REPRESENTATIVE YEWCIC: But we're pointing in that direction.

DR. HOWETT: Well, there are people who are saying they're working in that direction, but

whether they actually have the capability to do that or not -- I mean, the case that was most prominently featured in the newspaper was this fellow who basically announced that he was going to do this for profit. He was going to set up a clinic to clone humans and help infertile couples produce offspring by this technique.

Now, first of all I would say that this gentleman has a Ph.D. in physics, so I doubt that he's highly familiar with the techniques of embryo cloning.

And he may have very good entrepreneurial motives, but I don't think he has the skills to do this because normally he could hire individuals to do this.

The second thing I would say is that currently in good clinics with in vitro fertilization the success rate is about 20 to 40 percent.

So there are numerous individuals who even by standard techniques using a normal human egg, a normal human sperm, and implanting an in vitro-fertilized embryo only manage to get pregnant one out of two times or one out of three times.

In the case of Dolly, you're talking about a success rate far below 1 percent. So while the specter of this happening is certainly there, assuming that the sheep experiments are correct, I don't think that we are going to read in the legitimate press that humans will be born by cloning any time in the near future.

REPRESENTATIVE YEWCIC: Thank you. Thank you, Mr. Chairman.

CHAIRPERSON BIRMELIN: Representative Caltagirone.

REPRESENTATIVE CALTAGIRONE: Doctor, your laboratory, do you do embryonic testing now --

DR. HOWETT: No, I do not.

REPRESENTATIVE CALTAGIRONE: Is any done in Pennsylvania to the best of your knowledge in any of the laboratories, research centers?

DR. HOWETT: Yes, it is. There are two main techniques that are used for genetic testing. They -- they are done -- one technique is amniocentesis which is normally done at 16 weeks of gestation.

Amniocentesis basically involves removing amniotic fluid from the uterus. It does

genetic testing on cells which are shed from the surface of the embryo. And there is no manipulation of the embryo, no direct puncture or wounding of the embryo involved in the sampling procedure.

However, obviously it is the basis for some people to make abortion decisions based on the results of that test. An amniocentesis also carries approximately a half percent increased risk of spontaneous abortion.

At 16 weeks, a normal rate of spontaneous abortion for all pregnancies is 3 percent. And in all women undergoing amniocentesis, it's 3 percent. The second technique that is used for genetic testing is something called chorionic villus biopsy.

This is normally performed at eight weeks of gestation. And it actually involves sampling of one of the embryonic membranes. It does not, per se, involve removing tissue directly from the embryo.

But those cells are also used as the subject of genetic tests. Now, at eight weeks of gestation, the overall rate of spontaneous abortion for all pregnancies is much higher.

It's about 30 percent or 20 percent. So it's been much harder to determine if chorionic villus biopsy actually has some risk to the embryo.

What is known is that a number of patients who have had -- nationwide who have had chorionic villus biopsy have subsequently delivered children who have had digit deficits, missing fingers or missing toes.

The mechanism of that is not clear. So I think some people are much less favorable of this procedure. As far as I know, there is no testing currently being done on very early embryos.

It is possible, let's say, for an eight-cell embryo to have a single cell removed, a genetic test performed on that, and the single cell and the remaining seven cells used for in vitro fertilization. I am not aware of any routine clinical procedures in Pennsylvania by which that's being performed.

REPRESENTATIVE CALTAGIRONE: Since you mentioned it on the abortions that are, in fact, performed, then do you know if there are any research facilities in this state or in any of the states as a matter of fact that use any parts

of those organs of the aborted fetus for any medical purposes?

DR. HOWETT: Yes.

REPRESENTATIVE CALTAGIRONE: Would you please tell us what those purposes are?

DR. HOWETT: To my knowledge, the main thing that people do for tissues from aborted fetuses is the use of those tissues for growth of cells in culture. And those cells are usually used for either basic molecular biology studies, sometimes they're used to study substrates for infection, sometimes they're used to study basic anatomy, ultrastructure of those cells.

But those samples, there are very strict regulations already regulating the transfer of those tissues. First of all, the experimentor, the person who is actually procuring the tissues for experimental use can have no knowledge or contact at all with the individual receiving the abortion.

The abortion is performed totally independently of the procurement of those tissues. The experimentor then has to make a separate arrangement with the clinic or a facility that's involved in either spontaneous

abortion procurement or elective abortion procurement.

And there has to be an arrangement of transfer of those tissues to the laboratory, and that must be an anonymous transfer so that the person receiving the tissues has no idea of the source of them.

REPRESENTATIVE CALTAGIRONE: Do you know if any of the organs of the aborted fetuses are used for any medical or research purposes?

DR. HOWETT: Do you mean transferred back into humans?

REPRESENTATIVE CALTAGIRONE: No. You know, we're talking about growing tissues and --

DR. HOWETT: Yes. Well, when I say procurement of tissues, I mean procurement of organs.

REPRESENTATIVE CALTAGIRONE: -- organs that are utilized. It is possible then to utilize those same organs that have been harvested from a fetus that has been aborted either willingly or unwillingly, whatever the case may be, and then use those organs possibly to developing the nuclear technology that is now available? Is that possible?

DR. HOWETT: Well, it depends on the procedure that is performed on the pregnant woman. Most elective abortions that are done in the first trimester do not harvest an intact fetus because they're vacuum abortions and the result is the disruption of the organs.

Now, it's still possible that the cells are still living, and it is still possible to harvest the cells. So, for example, one of the things that individuals have discussed is the concept of using fetal nerve cell transplants in Parkinsons Disease or in other neurological disorders. You could theoretically harvest nerve cells. You could use them for implantation.

REPRESENTATIVE CALTAGIRONE: Is it being done?

DR. HOWETT: It's not routinely being done.

REPRESENTATIVE CALTAGIRONE: To the best of your knowledge, is it being done in this state or anywhere else?

DR. HOWETT: I believe that there are one or two clinics in Europe that are, for example, using the technique I just described. It is certainly not a routine technique.

REPRESENTATIVE CALTAGIRONE: Since you're educating us on the medical side of this issue, can you reproduce a liver or lung or any other organ from the cells that you're taking out from an individual? How far away are we?

DR. HOWETT: Right. It's a complicated question because when the embryo develops into an adult or into a child, into a newborn, at that point in development, every single organ contains specialized cells with specialized function.

Some of those cells are harder to grow than others. And when you grow them, some of them will maintain their specialized functions; and some of them will not. So, for example, it is possible to take skin either from an adult or from an embryo, and it's possible to grow skin in culture.

And you can then take the skin up out of the culture, the skin cells, and you can take them up and you can put them back on as a skin graft and they will make skin. But you are limited in that technique. It has to be the skin from the same person. If it's not, they'll reject it.

So that's a common technique which is

currently used for burn patients. It's possible to in the case of liver, all right, everybody's liver is a certain size depending on their body. If I open your chest and I take out part of your liver, it will grow back and it will grow back to exactly the same size.

If you have a destroyed liver and you need a liver transplant and I transplant a liver into you from a 6-year-old child who is killed in a car accident, that liver will grow back and it will grow to be the size of your liver.

So there is some intrinsic program in the cells that says, okay, for this size person, we need this size liver. Okay. But there are other cells in the body that we don't have any idea at all how to grow them or how to make them replace themselves.

So, for example, if you are injured and you sever your spinal cord, we have no idea how to put those cells back into the spinal cord and how to make them cross over that injury. We just don't know. So it's a complicated question based on what tissues you're talking about.

REPRESENTATIVE CALTAGIRONE: One final question. Genetic makeup of the people

who -- the organs that you're growing in animals, what you said about they've been experimenting with pigs, let's say, and take some of your genetic code and then put it into a pig and then there are certain organs that you can then harvest from that pig and put those organs, let's say, a organ back into you if there's something wrong with one of your organs, correct?

DR. HOWETT: That's the intent.

REPRESENTATIVE CALTAGIRONE: I'm just curious about this. Is there any -- I'm just curious about this -- I guess it's too early to tell what effects, long-term effects that that may have.

Let's say you then have a baby with this new organ that has been grown in an animal, and what type of effect, if any, that might have potentially on the future genetic makeup of that child or children?

DR. HOWETT: All right. There are two issues in that regard: One is genetic and the other one is infectious disease. When a child is born at gestation, all of the sperm cells that that will form the sperms and the eggs of that child, be it male or female, are already present.

And the genetic makeup of those cells could not be altered by the transplantation of a pig or baboon organ into your body. So from a genetic aspect, there will be no effect on the genetics of the child.

One concern that has been raised in the scientific literature, however, is that foreign species such as monkeys or pigs may harbor infectious organisms that we don't even know about yet and that by undergoing the process of xenotransplantation, the harvesting of an animal organ and placing it in a human body, we may actually favor the outcropping of those infectious diseases. It's a separate concern, but it's not a genetic concern.

REPRESENTATIVE CALTAGIRONE: Thank you, Doctor. Thank you, Mr. Chairman.

CHAIRPERSON BIRMELIN: Representative Dally.

REPRESENTATIVE DALLY: Thank you, Mr. Chairman. Dr. Howett, thank you for that presentation. It was very informative. The 20 year cloning by 8 division, aside from the ethical considerations, are there restrictions on that type of research as far as humans are

concerned?

DR. HOWETT: There are currently restrictions on the use of embryos, at least in federally funded -- human embryos -- at least in federally funded research. That, however, does not preclude private individuals or companies from engaging in such activities if they wish to use their own dollars rather than NIH dollars.

REPRESENTATIVE DALLY: Are you aware of any of those activities?

DR. HOWETT: No, I'm not. And I'm not aware of any intentional twinning for the purposes of in vitro fertilization either. What is normally done in in vitro fertilization is that more than one egg is implanted. But those are genetically distinct individuals. It's done in order to increase the rate of success.

REPRESENTATIVE DALLY: My other question dealt with molecular cloning. In the gene therapy that you've discussed, that would also be involved in therapies to address genetically transmitted diseases like cystic fibrosis?

DR. HOWETT: Yes.

REPRESENTATIVE DALLY: Would that therapy also be utilized to determine the sex of

a newborn or hair color or eye color?

DR. HOWETT: It could be.

REPRESENTATIVE DALLY: Thank you.

CHAIRPERSON BIRMELIN: Representative Manderino.

REPRESENTATIVE MANDERINO: Thank you. Just one question that I asked earlier. If you could respond to -- and I'll read it again -- the definition of human cloning that we're considering?

And I think based on your presentation, what I've heard before, nothing we're doing now fits this yet -- although, if I'm mistaken on that, please correct me -- what do you foresee on the forefront that might fit this definition?

Because I can't think in these abstract terms. The definition of the term "human cloning" means the practice of creating or attempting to create a human being by transferring the nucleus from a human somatic cell from whatever source into an egg cell from which the nucleus has been removed to initiate development of a human organism.

DR. HOWETT: That's correct. That's a correct definition. It would cover the creation

of human clones via the Dolly technique. It would not cover twinning.

REPRESENTATIVE MANDERINO: And it would not cover the gene therapy kinds of stuff we talked about?

DR. HOWETT: Correct. I read the bill, and I have to say that I think that it was not interfering with the ability to do recombinant DNA technology. So in that regard, I was approving of the way it is written.

REPRESENTATIVE MANDERINO: Okay. And you read it with the amendment that was distributed today or prior to the amendment?

DR. HOWETT: No, I didn't see that.

REPRESENTATIVE MANDERINO: Because I read you the words as they were edited by the amendment we got today. But you're saying where what I read, you still think --

DR. HOWETT: I agree with that definition, yes.

REPRESENTATIVE MANDERINO: Okay. Thank you.

CHAIRPERSON BIRMELIN: Thank you, Doctor Howett, for your testimony.

DR. HOWETT: You're welcome. Thank you

for your time.

CHAIRPERSON BIRMELIN: And your Cloning-101 course. We appreciate it.

DR. HOWETT: That's what we call it too.

CHAIRPERSON BIRMELIN: And I will admit that not all of it was absorbed in my brain, but I want to thank you for coming in and sharing with us your testimony.

DR. HOWETT: Well, you're welcome. And if any of you have further questions, I'd be glad to answer them.

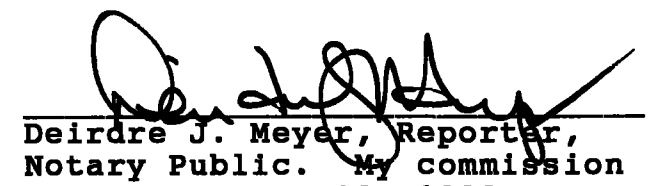
CHAIRPERSON BIRMELIN: Thank you. I'm sure you're a person of great experience that we can count on. This meeting is now adjourned.

(At or about 11:54 p.m., the deposition was concluded.)

C E R T I F I C A T E

I, Deirdre J. Meyer, Reporter, Notary Public, duly commissioned and qualified in and for the County of Lancaster, Commonwealth of Pennsylvania, hereby certify that the foregoing is a true and accurate transcript of my stenotype notes taken by me and subsequently reduced to computer printout under my supervision, and that this copy is a correct record of the same.

This certification does not apply to any reproduction of the same by any means unless under my direct control and/or supervision.



Deirdre J. Meyer, Reporter, Notary Public. My commission expires August 10, 1998.