

# Center for American Progress



## **“CAN STATES OVERRIDE THE STEM CELL VETO: ADVANCING STEM CELL RESEARCH IN THE FACE OF FEDERAL INACTION.”**

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MR. JOHN PODESTA: Good morning. I am John Podesta and on behalf of the Center for American Progress I would like to welcome you all here to today's event on state and federal support for stem cell research.

Let me begin by thanking the panelists, who will join us after our two principal speakers, Dr. John Gearhart, Dr. Bernard Lo, and Dr. Dave Scadden for taking the time to be here today and to offer their invaluable insights and expertise on this issue. And I also want to thank my colleague, CAP senior fellow Jonathan Moreno, for his excellent work spearheading the Center's bioethics initiative and for putting this great panel together. As many of you know, Dr. Moreno co-chaired the National Academy's committee on guidelines for human embryonic stem cell research.

Before I introduce our keynote speakers this morning, Senator Tom Harkin and Governor Jim Doyle, I want to take a moment to talk briefly about why the Center for American Progress believes that advancing stem cell research is so critically important.

First of all, you would be hard pressed to find someone who hasn't personally felt the effects of what it means to have a life threatening, painful, or incurable disease. As we all know, further research into the uses and applications of stem cells may stand to significantly lessen, the agony of that experience. Further research could offer cures for the 250,000 Americans with spinal cord injuries, the nearly 1 million people with Parkinson's disease, the 400,000 with MS, the 4.5 million suffering from Alzheimer's disease, or the 20.8 million Americans with diabetes.

And the potential is real: in the last few years there has been great scientific progress. A researcher at Johns Hopkins University has used stem cells to create motor neurons that help paralyzed rats walk again and UCLA scientists have used embryonic stem cells to create mature T cells, which could possibly lead to a cure for AIDS.

In light of the scientific evidence and the enormous potential of the research, it's not surprising that a recent poll released by a bipartisan group of senators and the Coalition for the Advancement of Medical Research found that 72 percent of Americans favor the expansion of federally funded stem cell research. Americans recognize that finding cures to devastating illnesses like Alzheimer's, Parkinson's, juvenile diabetes, and others should be a priority. Promoting healthy families should be a government priority.

Sadly, our president and his policy agenda do not reflect that. His veto of the Stem Cell Research Enhancement Act was a devastating blow to millions of American families affected by the currently incurable and painful illnesses that this research could cure. In the light of this most recent political development, the burden of advancing support for stem cell research seems to have fallen squarely back on the states. To

address this, the Center is pleased to release today a report entitled “Too Much to Ask.” As you will see in this report, it is clear that while states, particularly Wisconsin, are doing groundbreaking work to advance stem cell research, we cannot rely on states alone to step in when the federal government fails to act. In the crucial race to cure deadly illnesses, we need a collaborative approach. We need the federal government back in the game.

To that end, we’re truly honored to be joined by two leading voices on this issue: Senator Tom Harkin of Iowa and Governor Jim Doyle of Wisconsin.

I want to introduce Senator Harkin first, who will offer his perspective from the federal level and then at the close of his remarks I’ll introduce Governor Doyle, who will discuss stem cell policy and research advances in Wisconsin. Before I get to the bios, though, I just want to personally thank them both for being here today. I want to thank them for their courage in taking on this tough issue, for putting our progressive values to work, and standing up for the health and welfare of millions of American families.

Senator Tom Harkin has been doing just that in the Congress row for 30 years. Tom has served our country as a Navy pilot, as an attorney with the Polk County Legal Aid Society. He went on to be elected to the United States Congress from Iowa’s 5<sup>th</sup> congressional district in 1974. He served in the House of Representatives for 10 years before winning elections to the U.S. Senate in 1984 and is currently serving his fourth term representing the people of the state of Iowa. I don’t think people who are ill in this country have a better advocate than Senator Tom Harkin. In the Senate, he’s been a tireless advocate for stem cell research. He brings a depth of knowledge about biotechnology to the table that few in Congress can match. He’s the author of The Americans with Disabilities Act. With Senator Arlen Specter he led the fight to double funding for the NIH over the five-year period between 1998 and 2003. We were glad to support that when I was in the White House. He has dedicated himself to increasing the NIH’s budget to propel us forward in the race towards cures of killer diseases like cancer, and most recently he co-sponsored the Stem Cell Research Enhancement Act again with Senator Arlen Specter leaving the Senate to pass the bill by a wide margin despite the president’s refusal to sign the law.

It’s a pleasure to have him here this morning and now, ladies and gentlemen, please join me in welcoming the honorable Senator Tom Harkin.

(Applause.)

SENATOR TOM HARKIN: John, thank you very much for the kind and overly generous introduction, and thank you all for being here. And let me at the outset just thank the Center for American Progress for highlighting and defining many issues for the American people in a progressive manner. It’s nice to have a progressive think-tank looking ahead and, as I said, defining the issues in a more progressive, people-based, humane manner than what we had in the past from other think-tanks and so I just want to also thank John Podesta and all of you who support the Center for your great work.

It's an honor to be here this morning with Jim Doyle, who has done such great work in Wisconsin. You're going to hear from him. He's one of our really great leaders in the whole issue of stem cell research and a lot of other things in Wisconsin, too, but especially on this issue he has been wonderful. And you're going to hear a great panel this morning with Dr. Scadden and Bernard Lo and of course John Gearhart; Gearhart and Thomson being the two that derived the stem cells initially; one at Johns Hopkins and one at Wisconsin, as a matter of fact, where Thomson is.

So, again, I just want to start by saying that next Wednesday, August the 9<sup>th</sup>, it will be five years – five years since president Bush announced – I remember I was in Iowa at the time. It was August the 9<sup>th</sup>. It was 2001. And if you think about that, it was prior to 9/11. The president has been in the office just a few months and he took to the television to announce his policy on stem cells, which we were eagerly awaiting. Our committee – Arlen Specter and I had 18 hearings on this issue. We have had – at that time, we'd only have maybe about eight or nine, and we expected the president to actually come out with a fairly robust kind of a program.

I was dismayed when he said that prior to 9 p.m. on August the 9<sup>th</sup> all the stem cell lines derived would be eligible for federal funding, all lines derived after that would not. Well, that was really a straightjacket – really a straightjacket put on biomedical research.

I have often wondered aloud and I have said it many times: why is it that stem cells – embryonic stem cells derived prior to 9 p.m. August the 9<sup>th</sup> 2001 are moral? Those derived after 9 p.m. are immoral. Why wasn't it 9:10 p.m., 9:30, maybe midnight – just totally arbitrary, totally arbitrary. And then for the president to somehow set himself up as the moral dictator in America to say “Well, before it, that's fine. After, it's not fine.” Well, even at that time we thought “Well, okay, maybe we can live with it.”

I contacted a lot of scientists and people in the NIH and well, you know, we had about 78 lines at that time. They thought maybe that might be enough. We don't know. Well, here's what we found out. Much has changed in five years. Today, only 21 of those lines are available, not enough to reflect the genetic diversity that we need. After five years, the lines are becoming less and less stable. As one scientist said, the lines are getting sick themselves. More importantly, all 21 of those lines that we didn't know at the beginning, we now know – were propagated in a medium of mouse feeder cells, so they are all contaminated. And so it's highly unlikely that they would ever be used in any kind of human therapies.

So in five years the president's comments have been overtaken by events, but the president refuses to adapt to new facts and new circumstances and new science. Unfortunately, this is typical of President Bush's decision-making in so many policy areas. His position is inflexible, illogical, and uninformed.

Prior to vetoing HR-810, he refused to listen to other points of view including the pleas of former First Lady Nancy Reagan. Republican supporters of the bill requested an opportunity to just talk to the president and they were turned down. He simply insisted on staying the course. That's the end of the discussion. As I said, uninformed.

The problem is that five years later the president's course is not a way forward, it's a dead end. Virtually every reputable scientist in this country believes in the promise of embryonic stem cell research to cure and treat diseases. Shouldn't our top scientists be studying these new stem cell lines instead of being limited to the 21 that are contaminated, probably will never be used for any kind of human therapies? As I have said many times, after all we don't insist that our astronomers and scientists who are again under federal funding – we don't insist that they use 19<sup>th</sup> century telescopes to study the heavens. We don't insist that geologists use a tape measure to measure the earth any longer. So why should we insist that our scientists use old, outmoded things to study embryonic stem cells?

And let's be clear: nothing would have been more pro-life – if we want to get into that discussion – than signing HR-810, which is the bill the president vetoed, into law. We all know people, friends, family members with spinal cord injuries, ALS, Parkinson's, juvenile diabetes. What could be more pro-life than using the scientific tools that God has given us to help heal them?

And I want to emphasize: we carefully crafted HR 810 to impose strict ethical standards on embryonic stem cell research. HR 810 would not allow federal funding to be used to create or destroy human embryos. The only embryos we are talking about are already those that are slated for destruction. And it's right here in the bill and I quote it: "Prior to the consideration of embryo donation and through consultation with the individual seeking fertility treatment, it was determined that the embryos would never be implanted in a woman and would otherwise be discarded." So the only ones we are talking about are those that are left over in *in vitro* fertilization clinics that are destined to be destroyed – about 400,000 that we know of, currently sitting frozen in the storage.

As long as the donors provide informed, written consent, as long as no money changes hands – that's in there, too, so you can't force someone to do it because you're getting paid – and as long as they are going to be discarded. Now, again, if you are a donor now of embryos – let's say you're going through *in vitro* fertilization right now – you have had successful implantation, you've had one or two or three children, how many children you want. You have some left over. You only have one choice, you only have one choice: discard them, and they are being discarded every day.

What if you would like – what if you as a donor would like to have those embryos used for this life giving research, to be used by federal scientists? That choice is not open to you. That's what was in this bill. We provided that choice to people, to use those for life enhancing research. So with his veto the president is insisting that he knows better than the majority of the American people. We all know what the poll shows. Probably over 70 percent of the American people in poll after poll say that they are for this. He

said he knows better than scores of Nobel laureates. He knows better than every director of the National Institute of Health. We wrote a letter, Specter and I – Senator Specter and I wrote a letter. Eighteen directors wrote back and said “Yes, we need to do this.” Even Dr. Batty, who was the head of our stem cell team at NIH basically said the same thing. I give them high marks for their courage to come out and say things which are not politically correct in the administration’s environment.

And so it was one arrogant stroke of his pen, the president stops the bill and he stopped the hopes of millions of Americans. Well, some might claim that we don’t need this because the federal government already funds human embryonic stem cell research. Well, that may be technically true. I mentioned we had the 21 lines that some were investigating, but right now the NIH budget is \$28 billion this year. Well, if you’re keeping track it’s \$27.5 billion. Out of that, \$38 million were spent on embryonic stem cell research. That’s .7 percent for what almost all the scientists say may be the most promising area of biomedical research in our lifetimes.

And why is the funding so low? One reason is that the president’s restrictions are stifling interest of our researchers. They’re not applying for federal grants and it’s no wonder. If you are a scientist and you’re trying to break new ground in this field, would you want to confine your research to one of the 21 outdated, contaminated lines that somehow meets the president’s approval? Or would you rather work on one of the hundreds of new lines that were derived after August the 9<sup>th</sup>, 2001, and are therefore ineligible for NIH support? And where do you find those lines? Well, in some private institutions, some state institutions, and overseas – and we are losing a lot of our scientists overseas right now. I can’t verify this, but I was told the other day that Singapore – that huge, huge nation of Singapore actually is spending more money on embryonic stem cell research and has more people involved in it than the United States of America. That has to tell you something.

So while NIH sits on the sidelines, states like Wisconsin and Jim Doyle and California are trying to fill the void, and I applaud Jim for devoting precious state dollars to this effort. But we can have a Jim Doyle in every state and we’d still need leadership from the federal government. Only NIH can provide the oversight needed to ensure that this research conforms to the same strict ethical guidelines across the country. Without federal leadership we’ll end up with a patchwork quilt of regulation and research and progress towards cures and treatments.

But fortunately, the president’s veto is not the final word and we’re not going away. Science is on our side. There is an election in November. We need to know what every candidate stands in embryonic stem cell research because we intend to reintroduce this bill in the next Congress. I have already talked to Senator Specter and on day one when we come back we are going to reintroduce it and we hope to have all 63 – I don’t know if they’re all going to be back or not, but we’re going to have a lot of co-sponsors of our bill when we introduce it. And I would just say forthrightly that we are going to bring this up as early as we can next year and I hope that people all over America will talk about this in the election coming up.

I mean it in this way: that we know the bulk of the American people want this. Sixty-three senators voted for it in a bipartisan manner. The House voted for it in a bipartisan manner. Maybe we didn't have the two-thirds to override a veto, but a vast majority are for this, and so it seems to me that the American people need to, need to think about this when going to the election this November. You know, whose side are you on? Are you on the side of science, on the side of ethical research, on the side of cures, on the side of the most promising research that we have seen in our lifetimes? Or are you on the side with a president that has closed his mind on this issue, is uninformed on this issue, has taken a strict ideological approach on this issue? And I think we're going to see a lot of people in the elections this November take the position that if they are elected, they will join with Republicans like Arlen Specter, Orrin Hatch, and Gordon Smith, and Democrats like Harkin and Reed and others, that if the president does veto one more time, we'll override the veto.

That's going to be the issue in the November elections and I believe that we are going to have more people in the next Congress willing to stand up to the president and get this passed, and I believe we will prevail.

Thank you.

(Applause.)

MR. PODESTA: Thank you, Senator, for your remarks and thank you for your work. I have had the pleasure of working with Tom Harkin for probably almost 30 years and I have to say that when you're in a fight, there's nobody that you'd rather have with you in the fight than Tom Harkin, and I know we're going to prevail. It may take a while, it may take some work, and it may take those votes that you described and the clarity of the position that you described, but we're going to prevail.

Now, it's my pleasure to introduce Governor Jim Doyle of Wisconsin. Since taking office in 2003, Governor Doyle has committed himself to moving Wisconsin forward, whether through reducing the largest deficit in Wisconsin history, expanding financial aid and educational opportunities for Wisconsin students, or investing in biotechnology. In just a few years' time, he has also demonstrated an incredible dedication to finding cures to devastating illnesses, while in the process enhancing Wisconsin's economy.

For instance, when the Wisconsin state legislature passed a bill that would criminalize stem cell research, Governor Doyle not only vetoed it, he fought back in a big way. He vastly expanded the state's investment in stem cell research and launched a \$750 million initiative to invest in research and biotechnology – a public-private initiative.

We're truly honored to have him here this morning, and with that, ladies and gentlemen, please join me in welcoming the honorable Governor Jim Doyle.

(Applause.)

GOVERNOR JIM DOYLE: John, thank you very much for the kind introduction and I want to thank the Center for American Progress for many things, but certainly for the work that it has done on this issue, an important one and very important in the state of Wisconsin and I know across the country, and we thank you for your work. And I am honored to be here with Senator Harkin, who has been one of the great champions of medical research for many years, but has really been the person on the national level who has stepped forward to push stem cell research. And in a state like Wisconsin that is as committed the stem cell research, we are very thankful for the efforts that Senator Harkin has made. In many ways, he's kind of like a third senator in the state of Wisconsin given the number of times he visits us, but we are thankful for all that he has done.

And I am pleased to be here with so many other friends, and particularly with those who are actually out there doing the work. It is an important issue for the people of Wisconsin and across the country. And in the wake of the president's veto, we are now engaged in a very important national conversation. Now that the president has made his veto and his friends in the House have upheld it, we need to ask ourselves, what is the future of stem cell research? And I will talk about that in a minute, but before I do, I think it's important to talk about some real people and I want to talk about a couple of great Wisconsin moms who really to me sum up what this debate is all about.

I meet a lot of families, as you can imagine, who have members that are suffering from illnesses for which they see stem cell research as the potential cure. And I recently met Pam Fleisher in Stevens Point, Wisconsin. She has a wonderful teenage son, Forrest, and he has been living with juvenile diabetes. She told me, as many of these parents do, about all of the sleepless nights that she has had and going in every two hours to check to see how he is doing and all the time she's spent worrying about his health, testing his blood sugar, making sure that he is all right. And she summed it up by saying "I don't know a single mother in this state who wouldn't give her own life to save her child. I would gladly sacrifice myself for even a chance to have a cure for my son." As a mother, Pam told me she just simply cannot understand why any politician would say that a few cells, smaller than the head of a pin, are more important than her teenage son. And I can't understand that either.

The second mom I would like to talk about is my own mother, who passed away recently after a 30-year battle with Parkinson's. She was a wonderful woman in many different ways. Elected to the Wisconsin legislature in 1948, she didn't have – we didn't have any Democrats in Wisconsin in those days and they had put her name on the ballot just to fill out the ballot and that was the year that Harry Truman pulled off the big upset and somehow she got elected and there were three of us who had been born within the last four years. And her first words out of her mouth were an election – and at her death some of this was reprinted and it was wonderful – the first words out of her mouth were, "What am I going to tell my mother?" (Laughter.) But she was a wonderful woman and

my family is incredibly thankful for the scientific research that had gone on on Parkinson's that allowed my mother to live for 30 years with Parkinson's.

For those people of her generation who were diagnosed with Parkinson's just two years before she was, their end was a very, very difficult and quick one. But because of enormously effective medical research and prescription drugs, she spent much of her remaining 30 years relatively healthy, and we are thankful for that. And the thought that we would subject other people to what I saw her have to go through and not search for the cures is unthinkable to me. And the thought that we would cut off scientific research that has benefited us for so many years now as we move forward to even a potential cure for this illness is the unthinkable as well.

The next breakthrough may well come from stem cell research and I understand that it's too late for my mother, but I cannot understand why anyone would block that progress because of a very narrow political ideology. It is too bad that this issue has become partisan, but it has. The repercussions are enormous and it's time for all of us to make our voices heard to engage in and to win the political fight over this research.

I'm often asked about whether I think it's appropriate that there should be a political issue. And I say "Of course not." In fact, let's understand where the politics of this are coming from. If there weren't people trying to use the political machinery to stop this research, it would be going on. The status quo is that the research would be progressing and those that have chosen to make it political are the ones who are trying to stop it. I think we all wish this is not a political issue at all – that the scientists were at work doing their research, that NIH was looking at grant applications and deciding where money should go and where the research is most promising, and that this was just not political. But there are those who have brought this into the political arena now to try to stop it and that's why it is so important that we speak out.

When I speak about this issue, I speak not as the governor of any old state: I speak as the governor of the State of Wisconsin, the birthplace of stem cell research where we have the best and brightest researchers who are among those leading the world. Just eight years ago, the University of Wisconsin medicine researcher Dr. Jamie Thomson and his team became the first to successfully isolate and cultivate an embryonic stem cell line. This was a proud, proud moment for Wisconsin, but we didn't stop there. In 2001, a Wisconsin team developed a way to cultivate stem cells into primitive blood cells that later would become red and white blood cells and platelets. Three months later, another team from our state found a way to produce neural cells moving us a step closer to the day when we'll find treatments or cures to diseases like Alzheimer's and Parkinson's.

Last October, Wisconsin's Y cell was selected as the nation's first and only national stem cell bank by the National Institutes of Health. And just this year, Wisconsin researchers announced a new method of deriving stem cell lines without using any animal cells that might contaminate them.

Wisconsin has been at the center of stem cell research, but it has been just the beginning. I have set an ambitious goal for the state of Wisconsin to capture 10 percent of the stem cell industry by 2015 and to that end I have launched the \$750 million public and private investment strategy to maintain our leadership in the fields of biotechnology and stem cell research, including a major new research center – public-private center: the Wisconsin Institutes for Discovery.

The institutes with public and private investment of nearly \$400 million will bring together leading biologists, biochemists, engineers, computer scientists, medical researchers, and those from other disciplines as well in an interdisciplinary environment to foster collaboration and innovation. And it will also offer space to entrepreneurs and emerging businesses that will convert these discoveries into the jobs of tomorrow. As part of this effort, we have invested an additional \$170 million in two other new multidisciplinary research facilities. And I have signed an executive order directing our Wisconsin Department of Commerce to aggressively develop the stem cell industry in Wisconsin.

Given all of this progress, both on the science and the commercial front, you would think that Wisconsin would be the very last place where people would want to shut down stem cell research. You think that, but you'd be wrong. And in many ways at times I think maybe it's the first place people want to shut it down, because if they figure they can do it in Wisconsin, maybe they can do it anywhere. While Wisconsin is the birthplace of stem cell, it also lies at the ideological fault line in the battle over this research. Last year, our legislature sent me a bill that would have criminalized some of the most promising scientific techniques used by stem cell researchers. Not only would it have outlawed research, it would have been a signal to every researcher in the state of Wisconsin that they'd better look for – they ought to take some of these offers that are coming to them every single day from someplace else. Well, I vetoed that bill.

And in April, the assembly of our lower house passed legislation that would have prevented any company that does stem cell research from applying for state research and development tax credits. Fortunately, we were able to stop that bill in our state senate.

Today, the Center for American Progress is releasing a report which shows that Wisconsin is one of the very small group of states that is funding the progress of stem cell research. In fact, it shows that the bulk of state funding is coming from Wisconsin and California. Shutting down research in Wisconsin would be a major setback, but the fact is, if we are truly committed to finding cures for diseases, we can't rely on Wisconsin and California and the other states who are moving in this direction to go it alone. Without the resources of the federal government, the research will fall farther and farther behind.

The report shows that even aggressive financial commitments by states can't come close to matching the federal government, and the federal government under the Bush policy clearly is not doing its part in the funding of stem cell research. Of the \$600 million in federal funding for stem cell research, less than a third is devoted to embryonic

stem cell research, which would show such great promise. The amount of federal research funding for embryonic stem cells is tiny compared to what is spent on other diseases. And as the scientists keep telling me, the research into embryonic stem cells is enormous in just what we are learning about the basic science of cells and its application will reach to areas that we do not even know today. To me, it is the classic Washington, D.C., story these days of misplaced priorities and missed opportunities, and the president's veto only makes it worse. It means that researchers in Wisconsin and across the country will not have the funding they need. It means that they'll have to waste money building duplicate labs to do research that Washington won't fund.

We do this in Wisconsin. We have established a private, not for profit that raises private funds for stem cell research. And researchers have to go from one lab to another lab to do work that should have been done in a single lab. It also means that over time, as the federal dollars fade, the researchers are going to go other places in the world and that means, tragically, that potential new treatments will take longer to develop. How many years will cures be delayed because of special interest politics? And how many more sleepless nights for these families? How many more finger pricks for the mothers of children who have juvenile diabetes and how many more lives will be lost before Washington gets the message? From a mom like Pam Fleisher in Stevens Point, Wisconsin, who wants her son to have a normal life, it cannot come soon enough.

All of us who hold compassion for those who battle illness and all of us who believe in the promise of tomorrow need to bring our will for progress into the political arena. We are going to win this battle through practical politics.

We cannot afford to lose this battle. I think we all understand what direction history is going in here. It is a question of how slowly are we going to advance or how rapidly are we going to move forward for the cure of illnesses. Let's not turn back the clock on stem cell research. Let's move forward and always let hope and good science be our guide.

Thank you very much. Thank you.

(Applause.)

MR. PODESTA: I want to thank you, Governor, for your vision, for your leadership, for your courage, and for your tenacity. That was terrific. Thank you, Governor.

Now we're going to take – we're not taking a break, but I'm going to bring our panelists up and we're going to move on to the other part of our presentation here. If Dr. Lo, Dr. Gearhart, and Dr. Scadden would join Dr. Moreno at the table and I'm going to make one last introduction of our senior fellow, Jonathan Moreno, but as we do that, let me just thank one more time Senator Harkin and Governor Doyle for their great leadership on this issue, so please join me in thanking them.

(Applause.)

MR. PODESTA: Now, let me introduce my colleague, senior fellow Jonathan Moreno, who will moderate this morning's panel. Jonathan's work and research in this area is truly impressive.

Currently, Jonathan is the Emily Davie and Joseph Kornfeld Professor of Biomedical Ethics and Director of Center for Biomedical Ethics at the University of Virginia. He served as the co-chair of the National Academy's Committee that produced guidelines on human embryonic stem cell research. Since its publication, these guidelines have received widespread support from professional associations, state stem cell initiatives, and major research universities and they're actually being adopted, as I just learned, around the world.

Additionally, as I mentioned before, Jonathan currently directs the Progressive Bioethics Initiative which the Center launched almost a year ago. That initiative seeks to promote the idea that scientific development can continue within an ethical framework without needlessly restricting scientific progress or ignoring the value of scientific fact. To date, the initiative has published reports and articles and held numerous events in an effort to promote rational discussion about how our progressive values can help shape scientific innovation. I'm proud of the work that the Center has done in taking on this issue and much of that is due to Jonathan's stellar leadership of the Progressive Bioethics Initiative.

So with that, it's my pleasure to turn the floor over to Jonathan to formally introduce our panel and moderate today's discussion. Thanks.

DR. JONATHAN MORENO: Thank you, John. Let me welcome you again to the Center for American Progress. One of the most unfortunate and misleading statements that has repeatedly been made about this debate is that it is a question of ethics versus science. I am a philosopher, not a scientist or a physician. I have been working in medical schools for 27 years and I often say that I learned more about medical ethics and the ethics of basic science research from scientists and physicians than I learn from the great philosophers.

This is a worldwide phenomenon. It's not only the case here that important physicians and scientists like the distinguished members of our panel are working on these questions and engage in disciplining themselves, in developing their own professional guidance for the way that this work should go forward. I got off the plane last night from Beijing – I hope you are impressed that I got here at least physically – where I spent several days participating in training with 20 scientists in a laboratory at Peking University who are doing embryonic stem cell research.

The training was about the requirements established by the National Academy of Science report that John mentioned that was published last year and the Chinese guidelines that are virtually identical to our National Academy's guidelines. My point is

that in China, as here, the scientists are interested in the same issues: the moral status of the embryo, issues of foreign consent, issues of the donation of sperm and egg, informed consent, intellectual property. I learned that there is no inheritance tax in China. That should make some of us want to move there. So I kept hearing the phrase “China rising.” China is rising in science and technology as well as in other areas and there too, again, the important scientists and their students are working at the same issues and are worried about scientific self-regulation just as we are.

Our three panelists today are all distinguished physicians and scientists and the one thing that I have learned about doctors and researchers is that they are not trained to talk policy. Now, the journalists in the room I’m sure it had the experience of calling a scientist trying to do an interview and they don’t – you know, they don’t talk policy; they talk nuance and science. And they are not often temperamentally comfortable with talking about these difficult policy questions. Our three panelists are all people who have made a special effort to immerse themselves in the policy issues without which, frankly, the public debate would be far poorer and far less rich. Both at the federal level and the state level, this is a bipartisan effort to explain to the American people what the issues are. I think it’s an effort that is succeeding and it’s very important that we have the people that are actually doing the work to help us understand why it’s so important.

I said a couple of minutes ago that I don’t think this is a question of ethics versus science, and I don’t think so because I think that science and medicine are callings that involve ameliorating human suffering, so that’s why I think this is such an important issue.

So I’m going to introduce very briefly our three speakers with their academic affiliations. Thankfully, in the age of Google our introducers don’t have to worry about much detail. Each of them is distinguished in his field. They come from three small colleges: Bernie Lo from the University of California of San Francisco, John Gearhart from Johns Hopkins University, and Dave Scadden from Harvard. Bernie Lo will start us off telling us what’s going on with respect of the situation in California. After each of our panelists has spoken, we will have a few minutes for give and take and then an opportunity for questions from the floor.

So it’s my pleasure to introduce my friend and colleague first, Bernie Lo.

Bernie?

(Applause.)

DR. BERNARD LO: Thanks very much. It’s a pleasure to be here. I wish I could have brought some San Francisco weather to you. It’s about 30 degrees cooler there than it is here.

In the elections of 2004, the California voters passed Prop 71 by a margin of 59 percent to 41 percent. That proposition authorized \$10 billion in public funding for stem

cell research over the next ten years. Priority is given to research that cannot be funded under current NIH guidelines. So the California voters stepped up to a plate and expressed their dissatisfaction with the federal policy and also put their money out for it.

Now, that money has been tied up unfortunately with lawsuits, but it's going through enough in the legal system so that just this week, our governor, Arnold Schwarzenegger, who is a Republican, authorized that \$150 million in state treasury money be loaned to the stem cell organization to jumpstart this research. In addition, a considerable amount of money has been raised from private donors (and since have?) loaned to the Stem Cell Institute.

In addition to actually getting the money in the pipeline to scientists, California very wisely I think thought that there needed to be a set of ethical regulations to ensure the voters that the stem cell research they were funding would be carried out under high scientific and ethical standards. I was asked to co-chair that panel and we have spent, I have spent a lot of my time during the past year trying to go into the intricacies of how you design the system of regulation that can assure the public that research is being carried out in a rigorous, thoughtful manner and yet not impose so much regulation that it stifles the research.

Yesterday, the governing board of the Californian Institute for Regenerative Medicine, which is dispersing this \$10 billion in funding, approved our final version of the regulations which now go to a state agency and are expected to have the force of law in California sometime this fall.

I'm not going to go into the details of what those regulations involve. I would be glad to talk with you later if you like, but I want to sort of step back for a minute and suggest three main themes that have come out of our work in California with regard to the policy issues that Jonathan's alluded to.

The first is to try and argue that what's in the states is tremendously important because that's where a lot of these issues are being hammered out and that's where the voters I think are going to be making up their minds. Secondly, I think how we think about stem cell research is inexorably linked to how we think about the role of government. And I think what California is trying to do offers a model of a positive role for government that's different than, I think, for example the role the federal government's taken. And thirdly, we've involved the public in forming these stem cell regulations in a way which was new, was difficult, but I think ultimately very productive and I'd like to sort of stress that as another sort of policy theme that they bears looking into.

With the passage of Prop 71, the ethical debate really changed in California. The issue was no longer should we do embryonic stem cell research, but the issue became how do we do it in a responsible manner? Governor Doyle alluded to the fact that the legislature also gets involved. And in California, we have had a number of bills introduced and passed through at least one house of the legislature that would have

actually contradicted many of the things that Prop 71 tried to do and which required a lot of attention. I got swept up in that because as we studied these bills many were scientifically inaccurate. They contained serious misunderstandings about the science, which I think needed to be corrected for this debate to go forward. They also were carried out without knowledge of the ethical standards that are evolving with the NAS panel that Jonathan co-chaired, but also the work that was going on by the California Institute of Regenerative Medicine Panel to develop legally binding regulations.

What I found when I was asked to speak in these debates was an absence of both a policy framework and strategic organization, so that one of the bills which passed unanimously in the California Senate had a number of provisions which would have set back stem cell research in terms of onerous oversight, restrictions on the ability of women to make choices about disposition of embryos, and restrictions on research institutions and physicians. And what we needed to do was to try to mobilize people to make them aware that these were issues that really were directed their core issues, so universities, research institutions, women's advocacy groups needed to be informed that the bill had been passed and if they looked at it more closely, it was actually detrimental to their interests although it's advertised as being in their interest.

So a lot of clear thinking was needed, but even more so there needed to be sort of a political organization and network. I found it very difficult. We found it very difficult to sort of contact the right people and organizations that we thought should be involved and it was really an uphill struggle.

What we were able to do, I think, was to show people that their interest really had to be conceived in much broader terms and so what we tried to do, for example, is get the research institutions and the universities to appreciate that they had to not just take into account how the bill was going to affect them, but also form alliances with other stakeholders. So that's the first issue: state battles and importance of addressing those and having policy analyses and strategic organizations.

The second issue I would like to throw out for you is a vision of government – that you heard the senator, you heard the governor articulate how if you talk to people about curing diseases that are devastating illnesses for which we currently have no good treatments. That's a common thread that I think everybody wants to support. I think we need to move from that to really include people who ordinarily in other issues are not in agreement. So one of the things we need to do in California is to bring together patient advocates, who have really been at the forefront of these issues, with the biotechnology companies, the research universities, and big pharma, who are going to be essential for taking scientific discoveries and turning them into drugs that would be available at the bedside in the clinic.

And many of the patient groups were very, very skeptical at first about whether this was going to be a windfall for large universities and for biotechnology firms – \$10 billion just sort of going to institutions. They need to understand how without those institutions doing what they are really good at, the research discoveries would just stay at

the bench and not be translated into therapies. That required a lot of discussion and a lot of education about how the patent system works, how the FDA approval process works – issues like that.

When one tries to write regulations, it's not just an arcane process, it's a very technical process. And as co-chair of the panel, it was really important for us to get the best thinking on specific issues: legal scholars, scientists – whatever. What we were able to do was to draw upon experts and to use their expertise – that we came in with the assumption that science has an objective base, that some things are true and some things are not, and that ideology can't be dismissed totally, but some things work and some things don't and what their ideology is doesn't change that. There's just a lot of inaccurate information about what's been shown scientifically. We've heard already just the number of stem cell lines, how useful they are. Claims are made that they are just not backed up when you go and talk to the scientists.

And I think one of the things that we were able to do is to say we need to find out what the facts are. Before we try and settle and issue, let's make sure we get the facts straight. Let's see what's been tried, what works, and what doesn't.

The other thing that was important to us was to carve out a vision of what regulation should be. When you think about regulations, most of the time you think about some bureaucrat in an office making life difficult for people who are trying to do good things, and there's some truth there. But in fact regulations are also important, particularly on such a complicated, controversial issue of stem cell research, to assure the public that informed consent really is informed and we went I think beyond the NIS report in sort of saying, how can we really assure that the women and the donors of materials for stem cell research are informed about what they're doing? We also took very seriously claims that – concerns about the physical well-being of women who volunteered to give oocytes for research. Not necessarily embryonic stems – different types of research. And we put a lot of provision into trying to protect them from the physical risks of oocytes retrieval.

At the same time, we didn't want our regulations to be burdensome. We tried to state what the goal to be achieved by the regulation was and then leave discretion to the person being regulated as to how to achieve that goal. Stem cell research is quickly moving. We didn't think we could tell people how to do it because that was going to change over the next six months, year, and two years. We thought that degree of flexibility was important into allowing the research to proceed in a timely manner.

The third issue I want to mention is public participation. Prop 71 just would not have passed without the hard work and the inspiration of people who were either suffering from serious illnesses or have family members and have formed advocacy groups. We thought it was important not just to have them supporting the ballot measure, but to make them part of the oversight process and the grants-giving process, so patient advocates are on the governing board of the California Institute of Regenerative

Medicine, they were richly represented on my subcommittee, and that was an important thing to do for a number of reasons I would suggest to you.

First, they have a real vision, they have a lot of energy, and they have a perspective that's important. Secondly, again, I think it helps them see that they needed to work with people who originally they originally frankly mistrusted. Now, I mentioned sort of the mistrust between, for example, some advocates and biotechnology and pharmaceutical companies. It was also important – and I think that this has been shown in other fields as well – that advocates can develop expertise. They can learn the science. They can learn about FDA regulations. They can learn about the regulatory process and become real contributors. It was also important for us – California has policies regarding how you issue regulations that require public response to comments on draft regulations. Lots of times that public press comment period is pro forma. People send something in that's predictable and then it's just written up in a formal response.

Our committee went beyond that. We held public meetings to help California to try and listen to what citizens were concerned about. And when people made a comment, we didn't just write it down and sort of claim a response somewhere, we tried to talk to them. Our goal was to listen to them, to show them that we understood what their concerns are. We didn't always agree with these comments, but then we said – we tried to explain why we didn't agree and that process of engagement, which I think is really different – and we were told this over and over again as the process evolved – engaging with the public in an intellectual meaningful way I think it's very useful. I think it really built support for the regulations we proposed and frankly it have us better regulations. People came up with ideas and rather than having the response, “My Gosh, we spent so much time on that. You must be wrong,” we had to listen, we had to try and explain why we disagreed. And a number of times we said “You know, we don't agree with all this, but this idea you have is really good and let's try and incorporate it.” And I think, again, as a model of how to be inclusive on very controversial issues. It worked for us and it may work elsewhere.

So in summary, let me just say the stem cell issue is often viewed as a very divisive and controversial issue. I think if we are able to move beyond this big hump of should we do it all, there are a whole lot of issues that the public really is concerned about. How do we do it well? And to address that question, we need to articulate a vision of what the common good is, what kind of society are we, what kind of a government do we want, how can we have an effective government that uses expertise that respects the scientific facts that have been peer reviewed, and finally how can we have a government as responsive to the concerns and needs of people?

Thanks very much.

(Applause.)

DR. MORENO: Thank you.

Dr. Gearhart?

DR. JOHN GEARHART: Well, I'm here I think to add a scientific perspective to some of the issues of the embryonic stem cell research, but I would tell you, as someone who leads a very large effort in this, it's difficult to get sometimes through the policy. It impacts on virtually everything you do during the day.

So I hope you will permit me to comment a little bit on policy, at least from the science side or a scientist's side and I will do that in a few moments, but I think we all have to appreciate that it's very rare that any advance in science could have such a great impact on many aspects of our society. If you think of where the stem cell arguments are, whether it's in science itself – I mean, stem cell biologists argue among ourselves as to what are the best sources and how do we prove this, how do we demonstrate that, and how good is this claim. There's no uniform position on this other than to say all areas of stem cell research should be pursued unfettered. The economics, the ethics, the medicine – I mean, when's it going to get into clinic – it goes on and on, okay, and it impacts on all of us.

At the very first congressional meeting or congressional hearing before one of Senator Harkin's committees, Harold Varmus, who was the director of the NIH at the time that these so-called discoveries were made and the other issue is, come on, stem cells have been around a long time and they just don't appreciate the history that goes with it and the little bit of advances that are made at one point and then everything breaks loose. But anyway, he hailed the isolation of stem cells or the embryonic stem cells as one of the greatest achievements of the 20<sup>th</sup>-century science that brings medical research to the edge of a new frontier that is extraordinarily promising.

And if you think about it, for the first time we had in the laboratory cells in the dish that – although as you sit there and look at yourself you have about 100 trillion cells that are sometimes functioning in concert, okay? Most of the time it seems they are going in other directions – 100 trillion. But of those 100 trillion cells, there are only 220 different types of cells. That's the number of different types of cells that comprise your body. Now you have a cell in a laboratory that can form all of those in a dish. That's really the – I mean, when you get to the gist of it, that's it. And if we could only learn how to work with these cells, how to grow them, how to specialize them into any of the 220 different cell types, we could perhaps use this as a resource to effect some therapies. That's where the hope is. That's where the science is.

And I think that everything we've done since then – in the laboratory since the Varmus's comments only bear out, I think, his comments. But unfortunately the national policy in this area has prevented really the unfettered study of this work and really has caused delays.

Now, the major charge that I had today was to say after Bush's veto of HR-810, where do we go from here particularly as a scientist? But before I do that and tell you where I think we're going, I have to comment briefly on the president's veto message. I

hope you read it. I hope you read what he sent to Congress in response with the veto of HR-810. How does this impact on the scientist? Well, upfront in this he continues to imply that scientific research is at odds with the ideals of a decent and humane society. That's written in there. This plays on the perception that scientists are more interested in science than society and that scientists are less moral.

This is completely wrong. I hope you understand that. I mean, I think I'm a pretty good guy. I think everything we're doing is ethical and moral. I am confident of that and some of my colleagues as well. (Laughter.)

Several years ago, the president had stated that those who pursue this work are traveling without a moral compass and his chairman at that time at the Bioethics Council said that we would be well rid of these scientists. Now, think that the impact of this of the trainees, of people coming into the laboratory, the scientific community itself. You know, if you have the chief person in your country making these comments about you – I mean, we have these major discussions in the laboratory dealing with that. And furthermore, we get into this issue that is it any wonder that the president's spokesperson said the president considered the use of these embryos to be murder. Remember, this happened in the last several weeks and therefore the scientists pursuing this work are murderers.

From our side, you don't take it trivially in any manner. Anyway, this was corrected or slightly corrected in the past week. This imagery and what not continuously coming up I think from this administration certainly, we find appalling.

The last thing I would make is I think the president continues to demonstrate that he's on the wrong side of history with respect to stem cell research and you can see this worldwide.

All right, now to the meat of this, right, after my soap box. What is the status of the embryonic stem cell research currently? Well, first, what is the goal of human embryonic stem cell research? We talk really about basic science issues, we talk about bringing cells into the clinic to provide some type of cell based intervention for a large number of devastating illnesses. Well, if you think about it, the real goal that we're after – and this is the nub of it – is that we want to be able to instruct our own cells. We want to be able to tell our cells what we want them to do. It's a real basic science effort, but if you learn how to do that, you're going to be able to tell cells in your body how to repair, how to rebuild. This is really where we are going with this work. Whether or not we actually generate a number of cells that are going to be used directly in a therapy or whether we are going to use the information out of the cells to affect therapies remains to be seen, but this is the issue. We want to know more about instructing our own cells.

These challenges, both scientifically and medically, are enormous as you can imagine and it's going to take the efforts of teams of scientists – and a number of the major medical institutions have put these teams together in institutes. We have that at Hopkins – of bringing together basic scientists, clinical scientists, radiologists,

physiologists, on and on and on to work together to take these cells from the bench through translational medicine into the clinic. This is what it's going to take. It's a very expensive proposition. But it's going to be years before this clinical application, and so this circumspection has to be – I mean, it's not a retreat from promise, but it's a reality. It's going to take a while.

What is the progress? This is where the excitement is. I think this is what keeps us going when we go to the laboratory every day and talk to your faculties and students and see the progress.

First of all, how do you assess where we are? This is a fairly new field. Well, you do it through publications; you do it through – for example, the International Society for Stem Cell Research that met recently in Toronto, presentations of unpublished work. We look at our own research efforts and we begin to really get a sense of where this field is and where it's going. And I am going to speak globally about it, not just where is going in the U.S. First, we see in the past couple of years well over 100 publications dealing with the identification of a new cell type being grown and isolated in culture from these cells. In other words, of the 220, you know, we've already – we're hitting dopaminergic neurons or motor neurons or insulin-producing cells, but there's hundreds of other cell types out there and we have seen a number of publications over this period saying we can find these cells in the culture and we can isolate them and we can do studies on them. This is important that we were able to do it.

The whole issue of understanding what we call stems. I know this sounds like a weird term, but for the lack of a better term I think it conjures up an image here. We want to know what it is about the stem cell that makes it a stem cell so unique from all these other trillions of cells that are in your body. It's the molecular definition that we're after here. Once we determine this, we may very well easily convert any of your cells to a stem cell – patient specific. We may be able to induce these changes within your body as well. Interested in this property – we're interested in taking cells in a dish now that can form 220 different cell types and instructing them to form only one cell type if you need a certain type of cardiac cell or neuron. And we've made wonderful progress in this area. We're not there yet on many tissue types, but work on motor neurons, dopaminergic neurons, heart tissue. I think it's going really well from the standpoint of growing these things and with reproducible procedures, large numbers of these are going to take for grafting.

We can show that these cells are the real thing. They're the same that's in your body and you're always concerned that you're growing it in the dish and there may be something abnormal about it, but all the parameters that we can show for many of these say "This is what's in your body." That's encouraging, I think, if you want to put it back. There are now a number of studies involved in grafting these cells into various animal models, the so-called proof of principle, and these are encouraging. Where we have taken motor neurons, dopaminergic neurons, cardiac tissue and grafted them into animal models of congestive heart failure, on and on and on, and showing that indeed these cells are functioning and there's a positive outcome to this.

There's danger in this. The danger is that when we publish this kind of work or we show rats walking again after they've lost motor neuron function, the public thinks it's ready for the clinic. I hope you can appreciate there's a lot to do here downstream. We're interested in safety issues. You put these cells into an already existing organ or structure. Are they safe? Are they going to continue to function? These are difficult questions. When we first went to the FDA with our results, we were so happy about the outcomes to this that we were saying, well, we're putting in 200,000 cells, we want to know what every one of those cells has done and what it's doing. What this did – I mean, and it's a good question – we have to get those answers. It made the radiologists rich. These are the people who are imaging these cells trying to find out where they are going and how are they functioning, all of that. Development of a new technology to see single cells within an animal – it's amazing stuff. This is all sort of a result of the stem cell work. Anyway, I think what has been going on here has been remarkable and, yes, the U.S. is involved in this work in case you're interested, okay?

What about the future list of embryonic stem cell research? Well, as Yogi Berra said, "The future ain't what it used to be" nor I might add, what it could be for many Americans suffering with debilitating diseases with our current policy. If this work had been funded robustly, we would be I think much further along in our goals and I just can't predict where we are going to be in the U.S. I think it's still a matter of concern, but clearly there are many investigators throughout the world now who are pursuing this and so I have no – you know, I have no concern that this work won't go forward, but obviously there is some kind of proprietary issue here and where the U.S. should be in all of this.

I believe that someday that we're going to look back on this period and wonder how we ever rejected or impeded a pathway towards knowledge so imbued with life-saving technology, but it's going to happen. We're going to wonder why we go through all of this.

Anyway, a few comments if I may on research funding. In his veto remarks, the president asserted that, "my policy has allowed us to explore the potential of embryonic stem cells and it had allowed America to continue to lead the world in this area." I want to say, crap, but you can't. (Laughter.) I mean, it's just not true and I think you've got to appreciate this. There is no objective way of measuring this and coming to this conclusion. It is really because if we are number one – if we are, it's simply because the private side has picked us up and has supported us and only certain groups of us to be honest with you, in the amount of money. The private side has rallied and Hopkins has received substantial support; several other institutions have. We founded an institute at Hopkins where we brought together all these people. We think the future is going to be still good.

There has been an argument made by opponents of stem cell research that with these gifts there is no need for public money to support it. We have enough. This is a very expensive proposition and that's just baloney. There's also an op-ed piece that's

floating around published in a number of papers over the last few weeks that states “The vast majority of medical and scientific breakthroughs in this country’s history have been accomplished by the private sector.” This simply isn’t true. We don’t have time to get into that, but it is not true. Okay? It’s really the academic side of things which has trained scientists that have really contributed in this work.

I don’t want to leave the impression that since the NIH has not been involved as completely as it should that worked we’re without oversight and regulation. You’ve heard that we do have it.

The last comment I want to make is that there are significant new players in the field and I want to comment on what’s happened to the state of Maryland, where we’ve had the privilege of working with a number of legislators – Sandy Rosenberg, Paula Hollinger, Mike Bush, Pete Hammond – a very powerful advocacy group led by Susan O’Brian who is here, who really brought this state into focus and it’s those people we have to thank for now having additional monies that we can put to this effort. So the states are important, but it’s not going to last forever, so we still need this national leadership and funding from that source.

So thank you for your time.

(Applause.)

DR. MORENO: Thank you, John.

Dr. Scadden?

DR. DAVE SCADDEN: Thank you very much and thank you to the Center for the work that they’ve done and for the leadership they’ve shown. I’d like to speak to you from two perspectives: one, as a physician, and as a physician who is a hematologist oncologist as well as a scientists and my scientific emphasis is largely on adult stem cells.

As a physician I work in an area where the fruits of stem cell research have been progressively more evident as a life-saving technology and I think it’s worth reflecting back on the early days of that type of stem cell research and what is regarded now as essentially an ethically, if you will, non-contentious area. But at the time when it was being first tested, it was being done at a time where there was also organ transplant and it was regarded as ethically very ambiguous. The idea of creating people that were essentially chimeras – that they would have contents of another individual – was something very troubling for many and a great concern both from the perspective of the moral dimension as well as the scientific, and yet today we see people regularly who have had their lives completely transformed and indeed have had their lives saved by this effort being able to move forward in a careful and a very thoughtful manner, but in a way that is allowed to develop the full potential.

I think it's reasonable to regard that type of approach as one that may be the same for the use of embryonic stem cells. Now, we don't know that, but we know that it took 25 years for adult stem cell work to really find its way into meaningful clinical use and we are still in the very, very early days of embryonic stem cell research and we can only use the guides that we have and if adult stem cells teach us anything, it is that we should move forward carefully, but with all due dispatch, to try to achieve what has been accomplished with adult stem cells.

Now, the second is that as an adult stem cell biologist, for me the notion of working on adult stem cells absent the perspective of embryonic stem cells is one that I find a remarkably impairing one. That is, in general we all learn by virtue of comparing and contrasting. In fact, we see by virtue of context and perspective. And if you remove the ability to see things in the context and in the contrast that are provided by other views that we really not just reduce the aesthetic dimension of sight, but actually are encumbered by the restrictions that that imposes upon us. And similarly, to view adult stem cells without the additional benefit of being able to understand what is the most fundamental stem cell – the embryonic stem cell – would be to really be trying to view things with a very compromised vision.

And so while we don't know whether or not embryonic stem cells will ever be used in the clinic the way adult stem cells are now, what we do know is that adult stem self therapies will be bettered by the study of embryonic stem cells.

The issue of the funding that we were talking about today, where the federal government has decided to opt out of further support for embryonic stem cell research, at least as it applies to the new lines that are available, and why is it that state and private funding is not sufficient? Well, I would say that these states that have taken a leadership position in this and there are a number of – you heard from Governor Doyle, who's been a spectacular leader in his state. Maryland has taken a lead, as has California. I must say Massachusetts – while the other states have given both love and money, we're the control group where our legislature has decided that love should be sufficient. (Laughter.) But one of the issues that we have to think about is that while we've been able to achieve some money within the Harvard system because of leadership of our president, former president, because of the leadership and generosity of our alumni, but I don't think institutions like Harvard or Hopkins or the institutions of California or Wisconsin have the monopoly on good ideas or great talent.

And one of the things that I am very concerned about is that young people don't decide that they are going to be stem cell biologists by being born that way. They do it because they see the excitement of the research by coming in contact with it during the course, usually, of their undergraduate education. And if that doesn't include some contact with people who are doing this work in the rest of the 40-plus states that you don't have support for this kind of research, then that actually constricts the talent pool that would go into this field and that I think is an enormous cost. It's a cost that we can't measure, but it's one that we know other nations are recognizing and saying that we have basically decided to impair our own ability to make great contributions in this area.

The second point I'd say is that this is a field that we know is not going to result in new embryonic therapies tomorrow. While there are ongoing efforts that involve the clinic now, that really the full flower of this research will take years if not decades to achieve, and the current ability to do that is dependant on a very durable source of funding. In research, generally, any funding that comes from the private sector is very short. Foundations are happy to provide money for a project that lasts on the order of two to perhaps five years. They very rarely support things that are on the order of a decade.

In general, there isn't this kind of support from the commercial sector either. This takes a real effort by the federal government and while California has a ten-year plan in place, I think for the most part most states do not have the capacity to do this. I know in my own state, we worry about plugging holes in tunnels and it may not be that states can continue to be provided a high level of funding. I'd also say that state policies about science don't give great comfort in terms of thinking about a long-term view. And just this week, as you know, in the state of Kansas, the notion that evolution was something that was an important part to be taught in biology was considered a fairytale on Monday, but was considered a credible piece of biology come Thursday, so I think there are vicissitudes of approach to science at a state level that we could hope the federal government would be at least somewhat inured to.

The third point about why state or private funding is not sufficient is the breadth of work and the settings in which this research must take place; that while it is possible to develop small compartmentalized zones where we can do this research, that you can distinguish from the other places of research that the federal government has supported. This takes an enormous amount of attention. Within our own institution, we have been able to isolate certain compartments. Those compartments have taken the work of an enormous number of people, with literally hundreds of hours of attention to it and the concern that if you are a scientist who works in this area that you're basically walking around with a target on your back means that you also have someone from the accounting office who is following you or at least paying enough attention that everything you work with is marked with either a green or red sticker so that you know that you are in the process of using something that is acceptable or not acceptable to analyze these cells.

And I'll say that while the work of analysis is currently still at a relatively primitive level in embryonic stem cells, as we start to get more sophisticated in the science and actually accomplish the directed differentiation that Dr. Gearhart mentioned, we require instruments that are enormously expensive that are on the order of \$500,000 to a \$1 million each. To recreate that and buy new instruments is an extreme impediment and burden on the scientific enterprise. It really is something that has a very real impact and I can tell you, at our own center we have people using methods of analysis that we haven't used in 10 years simply because the instruments that we usually use are ones that have federal money associated with them.

I will also say that this issue of facilities and infrastructure is not just a place. It has a lot to do with the kinds of, if you will, the guideline and regulation infrastructure

that also goes with federally funded research. I know, for example, as a clinical scientist that if we decide that we would like to do a clinical study that will involve a new therapy in people, that we can involve investigators from California, from Texas, from whatever state in the union, and we will all be using the same guidelines. So we can move very quickly to testing something in an individual center to essentially a multi-center and across-the-nation type of investigation.

In the absence of federal guidelines, each center is now developing its own approach. And while the National Academy of Sciences has done an enormous favor to the scientific community and to us all as a society in providing these very carefully thought out guidelines, which we have to thank John enormously for them, that these still represent guidelines that are variably interpreted. Within Harvard we have different interpretations in the different institutions and that does change to some extent the ability we have to just exchange the ideas and the way that we're moving forward with the research.

And then I'll say finally this – one of the issues about having state funding only is that it's very difficult to think back on any major scientific breakthrough that has been funded by state money only. I don't discredit the contribution that the states can make and that private corporations can make, but I think, as John has pointed out, virtually all of that is touched in some way and is usually built on the foundation of a federal contribution to understanding fundamental science. So it is really through federal involvement and biomedical research that has made the United States the envy of biomedical research in the world and has made us the uncontested leader in medical innovation and that is, I think, one of the major issues at stake.

So what is at stake for us as a people – for, frankly, patients with these problems? It is that there will certainly be a delay in the realization of any therapies. There will be stem cell-based therapies that will change the face of medicine. I don't know whether they will be embryonic stem cells. I don't know whether or not there will be even any cell base therapy. There may be simply drugs that are modifying the stem cells that we know we have in our body now. But it will be something that will have a great impact on the way we approach patients with chronic disease.

Where there is such an enormous demand, where there are so many unmet needs in patients with such common diseases that no doubt there will be a supply of such approaches and whether that supply comes from support by the federal government and is broadly available to us all or comes through perhaps the limited efforts in an state and their particular way in which they will decide how to distribute it, whether it will come from a place like China or Singapore or Israel or Sweden where they are making major national investments, we know that we will be paying a premium. We'll be paying a premium both in terms of the cost and the time, and we'll be paying the premium that industries that could have been spooned and located here will be elsewhere.

Now, that is the lost opportunity in really it's most narrow terms, but I think the greatest issue is that of our young people quite honestly. I think that we view ourselves

as a nation of innovation, a place where the thought economy will continue to grow and maintain our economic preeminence. But as you think about the idea of a field that is regarded as something that has the chance to really fundamentally change medicine, that has the opportunity to possibly alter the way we take care of people in the future, and young people have shown a tremendous affinity for this. Certainly, we have more undergraduates from Harvard in scientific laboratories dealing with stem cell research than we have ever seen in scientific enterprise before. And the notion that we need to invigorate the scientific enterprise in this country is one that I think has broad implications. This is one place where we can do it. Stem cells really can drive that in a very substantial way.

So we are losing that opportunity – that opportunity to really grow the scientific and technical underpinnings – the farm system for the future leaders of American science and technology. That, I think, is something we can't measure, but that we stand at great peril to lose.

So is it feasible to do this research with just the funding that is now available through states or through individuals and private enterprise? The answer is certainly yes. The question is, at what cost and is this optimal? And the answer there is, absolutely this is not optimal.

Certainly, as I believe in the great Taoist philosopher Mick Jagger, it ain't what you want, it's what you need, but I would say do we have a need to pursue with great vigor and on a national level an area that has an opportunity to change the outcome for so many who suffer with such debilitating disease? Do we have a need for being able to maintain the greatest scientific enterprise in the world? Do we have a need to try to approach a type of intervention that has the potential as the perhaps one area of medical technology that could really change the calculus of cost for medical care? That is, if we have something that can reverse the root cause of many diseases, we might actually change the ever expanding healthcare dollar and possibly see some of that money no longer needed for healthcare, but possibly other areas of our society. But I think those needs are extraordinarily compelling and not just a scientist and a physician, but as a parent and taxpayer I would say that we need to proceed with great haste.

Thank you.

(Applause.)

DR. MORENO: Thank you, Dave. We'll have a little opportunity now for interaction among our panelists. I wanted to point out to you that the Center has released a report today called "Too Much to Ask" that addresses this question of how much can we really expect the states to do. Alix Rogers and Sam Berger have just done fantastic work. Alix has convinced me that although we were supposed to live in an information society, it took her weeks to figure out how much the states are really spending on these things and nobody else so far as I know has bothered to ask that critical question.

The result of asking that question is not nearly as much as we might think and clearly although we are very grateful to the states for what they're doing, in a long term this has to be a federal effort not only because of the sheer dollars involved, but also because of the redundancy that was described and the other inefficiencies and the extent to which younger people are discouraged from moving into this area and I wondered if anyone else wants to talk more about this.

I was struck when I was in Beijing last week that a couple of dozen young scientists I was talking to as well as the senior investigators – Peking University might even be harder to get into than Harvard. Only the top ten to 15 students from each province in China are admitted to PKU as they call it and they are moving ahead very vigorously and it's very clear that there is tremendous excitement there about the possibilities here. So it's not so much a brain drain for us as a brain constraint, and we're going to experience this deficit not next year or two years or three years, but five years, ten years, 15 years when these people are getting into the peak of their scientific productivity.

So any other comments or questions from members of the panel before we open it up to the audience?

DR. GEARHART: Is this on? The issue of the young – of the trainees, whether they are graduate students, post-docs, or fellows is a very serious one. I just wanted to support what David said.

We, too, have experienced the greatest influx of students in the lab wanting to work on stem cells – some aspect of it – from all areas of science and medicine. We graduated this year I think five students or so from our program. If it hadn't been for the state of California, I don't know where they would have gone. I mean, that's true. I say that and that's like another country, too, but the issue is that was an option. Before that, my students went to Europe, and so that's one aspect.

The second is the culture that has sprung up around this. I think we're almost in a defensive posture where many students are coming in wanting to learn also how to get involved in the public policy side – that we should be out there discussing our work, talking to policymakers, et cetera, and they are asking, well, where are the kinds of courses and training that we can get to do this? Well, I mean, as someone who was behind a bench for many, many years and then all of a sudden a light came on, fortunately there are these programs and companies that give you these quick courses in how not to look stupid basically in trying to interface and talk to individuals about what you're doing. And I think universities have to begin to think about this, particularly in the sciences, so we've seen those two things happening.

DR. MORENO: Thank you. So let's open it up now for a discussion from the floor. First, if there are any journalists, we'd like to give you the first shot, as is our wont here in Washington I'm told. And so if you could just raise your hand, Mike Nguyen will

find you with the microphone. Anybody else then? Anyone else? Yes. Please identify yourself and your organization.

Q: I'm Susan O'Brien. I'm with Maryland Families for Stem Cell Research. John Gearhart is our hero. Sorry. I'm actually a media person. I wanted to know – this has been astounding, and I'm sorry Harkin and Governor Doyle left and I'm sorry that John Podesta left because he's a great political mind, but maybe there's someone still left here who can answer this question because I hate to ask this question of Bernard and John and Dave. Obviously, the only way this is going to happen is that if we changed the dynamics of the U.S. Congress.

You guys can do all the most amazing work in the whole world, but if we can't tell the average Joe back in Baltimore that electing Michael Steele is never going to make this happen, we need to – I need to know, because nonprofits can do this because of the IRS laws, what we can do to have a forum like this to raise the money in these PACs, which there's one that I know of, StemPAC. It sent out an e-mail yesterday. They've raised \$10,000 to help five or six targeted candidates to take out the guys that voted against stem cell bill – \$10,000 – \$10,000. I mean, raised \$10,000 sneezing at Hopkins the other day, so my point is why can't we –

DR. MORENO: Could you sneeze around here, please? (Laughter.)

Q: John was standing there with me. But my point is you guys can do all these wonderful stuff, you can make these amazing NAS guidelines, you can do all this wonderful stuff. If we don't get these bozos out of Congress, then nothing is going to change. So where is the momentum, where is the fire, where is the money to get these candidates that want to take these guys out the support they need and the messaging and the air time that they need to get these messages across with the back-up of you guys, because that's the back-up right there.

DR. MORENO: I'll take it as a rhetorical question. (Laughter.)

We are having all the time with respect to the party, but only with respect to people who are interested in advancing ethics and science simultaneously. So we are ready at American Progress to help as much as we can and we've been actually doing that for the last year and we'll continue. Sir? Partial answers are good.

Q: My name is Michael Goodman. I am the president and executive director of a 527 called Don't Deny Hope, Inc. If anyone would like to go to our website, [www.dontdenyhope.org](http://www.dontdenyhope.org), you will see that we have targeted over 40 congressmen or congressional candidates that hold an anti-stem cell view with the targeted candidate who is running against him who is pro-stem cell. We are a 527, which means that we can put massive resources into any district or state that we decide to go into. Example – John Kyl, Arizona, an anti-stem cell proponent. He's in trouble. There's a pro-stem cell candidate running against him. We can do something there. We are not limited to

\$5,000 as StemPAC is. We're a 527, something like [www.moveon.org](http://www.moveon.org), where we can take resources and move into a state. Thank you.

DR. MORENO: Thank you. Anyone else? Yes.

Q: My name's Dr. Deborah Schumann. I have been working with the Maryland Citizens Health Initiative to try to get healthcare insurance for our Marylanders, so I'm not really that much up on stem cells, but I have learned a lot today and thank you very much.

Actually, my question is kind of the flipside of her question and my question is, where is all the information getting to the public that is opposed to stem cell research? Like what organizations are fanning the flames of that? I mean, the president is obviously – that's his agenda. Who else and where is – who's giving money to that?

DR. MORENO: Actually, there is a women's bioethics organization based in Seattle that has a very interesting analysis of how funding has been going with respect to these issues in the last few years, so I'd refer you to the women's bioethics initiatives – their website and their report. The reality is that some organizations who have been involved in other issues that many of us wouldn't regard as informed by science have tried to exploit this issue, so we don't have a lot of organizations on the other side who are as well organized and have as grassroots an effort historically. That's one of the things we're trying to do here. I'll let the others answer this as well.

DR. GEARHART : I think clearly one of the major organizations has been the National Council of Catholic Bishops – absolutely – and were always paired with some member or some spokesperson from there or Dr. David Prentice and some ersatz scientist of some kind who was just debunked recently – you probably saw this, where he has for years been testifying there were over 60 diseases that are treated by adult stem cell therapies, nothing from embryonic. We knew that this data at least individually was not accurate and sure enough there was a paper published in *Science* a few weeks ago that went through this complete list and I think it came out to nine – nine could be verified of that. But anyway, they are a major player. You may have seen recently, too, that one of the senior cardinals of the Vatican came out with a statement that any Roman Catholic that's working on embryonic stem cells should be excommunicated.

And finally, the European Union, which has been dealing very carefully with a program for funding stem cell research in the EU, this past week came up with what they thought was a compromise to be able to fund investigators in a number of countries and as soon as this was published, the Vatican immediately claimed that anybody working in this area were murderers. So I think this one of, obviously, the major voices against this work.

DR. MORENO: One of the problems we have also is that the theological voices that are organized have tended to be against this area and fortunately in the last year or two, partly through the efforts of Melody Barnes, who's here, the Center for American

Progress has been working with other organizations with theologians who have a different view of these matters, and so one of the problems we have again is to help these folks get through to the grassroots and note that there are different views on these questions. Even, I dare say, among the denominations that might be perceived to be unified and uniform, there is in fact disagreement.

Other comments, questions? Sir? The mike – we need the microphone. Oh, sorry. Sean, we'll give you the first shot and then we'll come over here.

Q: Sean Tipton with the Coalition for the Advancement of Medical Research. I want to take advantage of actually having scientists here and ask a sort of scientific questions. I would like to hear more about what it's like day to day for scientists and investigators as they have to deal with the implications of the policy. I seems like you all have alluded to some of it, but I would like hear sort of on a very practical level what the policy shortcomings mean for you and your colleagues in the laboratory.

DR. GEARHART: I don't know where to begin, Sean, to tell you the truth. Clearly, in the laboratory it's the research that drives – I mean, this is what the entity is. It's an exciting place to be. I would offer people to come and witness this to – as far as a research endeavor is concerned. But what plays into this very keenly, and I will be frank with you, is funding. There is nothing that saps the morale, I think, of any investigator – I mean, worrying about funding. I mean, whether it's NIH grants or anything else, we're always on that edge. We are risk-takers. We have to be. But it's funding issues, number one.

Number two, and Dave alluded to this. I think so did Bernie – this issue today of being extra cautious in the laboratory and if you're working on a registered line, a federal approved line or we actually do most of our work on the Harvard lines and you have to be extremely careful on the logistics of this and the bookkeeping. That is just incredible. Whether you had solutions or pipette tips or portions of people's salary – where does your salary come from? We have this complicated structure of overhead, as you know, coming into these laboratories and it's just one of these things where anxieties are extremely high about crossing up on something and doing something that is out of bounds.

Now, the ramifications of this is dire. I mean, we have been told that if you don't do this and something good – the whole institution could lose its federal funding. I mean, that – all of a sudden for what you have done could put you in peril like this. We're not quite clear yet what the ramifications are for a single individual who does it. I mean, this is another issue and that's, I think, an institutional based thing. So that is always there.

We also every morning have a meeting as to what has developed lately in the news. I mean, like, the morning to go over research papers that have been published or claims that have been made because we know we were going to get questioned about this in some aspect either through the institution, through the media and we have to be prepared.

So these are just some of our examples of what it's like on a day-to-day kind of thing. Maybe Dave has a comment.

DR. SCADDEN: I'd just amplify this notion of the concerns about funding are enormous. The amount of time that we spend trying to seek out funds to be able to supply the additional reagents, the additional people, the additional equipment and the additional space for the embryonic stem cell research using the non-sanctioned lines really is a tremendous encumbrance. So for the people day to day in the trenches, it means that they are doing work with a limited number of tools usually. They have to spend a great deal of time being attentive to the issues of where things are derived from and the different ordering that's required, et cetera.

For those of us who are more in the office than at the bench, it means many more meetings associated with making sure that everything is carefully done, many more meetings trying to raise money, and frankly just a whole lot less time doing research.

DR. MORENO: Up front here I think and then – I think we have time for one more question, so –

Q: I am Philip Cato from the Episcopal Diocese of Washington. This past year – my bishop, John Chane, is out of town and asked me to come today. This past year at my suggestion we ran a conference for all the clergy of the Diocese of Washington to educate them about human embryonic stem cell research. We had Jim Battey there and Phyllis and some other people from NIH and I have myself gone and testified before the appropriate committee in the state of Maryland of this issue.

Clergy can be strong allies in getting the word out about the science as well as the morality of these issues. I have been urging some of my friends over at NIH, where I sit on several committees, to do more public education. Otherwise, you leave it to the ideologues and I think that's not a good thing. And they seemed to have captured the press to a considerable degree, so I would urge education programs among clergy because I think it's a good place to begin. Thank you.

DR. MORENO: Over here on the left, Michael, and we'll go just as long as we can, but I think we only have a couple of minutes left.

Q: Dana Weckesser of Pan American Health and Education Foundation. I attended today because we have a bioethics award that supports young scholars in Latin America and the Caribbean. However, my comment has nothing to do with our foundation.

I live in Baltimore, Maryland, and recently my family went to a neighborhood eatery in Baltimore. We were waited on by a young 23-year-old lady. Somehow we got into a conversation and I asked her what she does other than – because she said she goes to Hopkins and she – as a stem cell researcher at Hopkins and I asked her a question and I

didn't understand her answer because I'm not molecular biologist, but she got so excited and passionate and so eager to talk. I mean, I couldn't get her to be quiet. We were hungry, but it was great and I needed to share with everybody here, because I'm hearing so much kind of negativity. I think we all need a little something that's upbeat, so I wanted to share that with everyone. And thank you, Dr. Gearhart. I'm assuming you're one of her mentors. Thank you.

DR. GEARHART: Well, you can see how we have to support this. I mean, this is part of the issue here. (Laughter.) It used to be actors who were waiting tables; now it's stem cell biologists.

DR. SCADDEN: I'd like to sort of amplify a theme that we've talked about, that's sort of the training of the next generation of stem cell scientists. And to pick up on Sean, what's it really like for a young person thinking about a career in stem cell science?

We've heard from our bench researchers there's a lot of interest in undergraduate medical students, but they have to be realistic and we'd be remiss as mentors if we didn't say to them don't just be passionate about the science, but you've got to be practical about how are you going to pay the bills. The reason NIH funding is so important is that is what attracts the brightest people into academic research careers. And why is that? Because the NIH has a graduated series of grant programs that take you from the time you are just beginning a research career with career development words that give you three to five years of time to build your own research program to really set your own path. And then there are competitive awards that if you're successful – and they are all peer reviewed, so it's not a lifetime annuity, but it's an opportunity to keep your ideas fresh and if you're successful you can have a career being supported with federal funds.

And many of our eminent scientists have sort of built their careers with the knowledge that if they're good and if they stay good, they have a prospect of long term success. In California, the first set of grants we funded with privately funded money to the California Institute of Regenerative Medicine were fellowship programs for people just beginning their research careers. So it's how do we give them the skills, put them in contact with the leading scientists of the day?

That's just the first step. If we train them and there's not a job for them to take up, if there's not grant funding to set their research labs up, they are going to drop out and that money will not bear fruit. The NIH is how traditionally we have supported long-term careers in innovative science and I think that's where we need to turn.

DR. MORENO: Thank you. As a professor, it's painful for me to ignore raised hands, but there are some people over here who will remove my stem cells forcibly if I don't call this to a close (laughter), so I want to thank again our panel – our wonderful panel. They'll be around for a few minutes I gather to answer questions. Thanks so much to the many people at the American Progress who make these events look easy, though they're not: Anna Soellner, Michael Nguyen, Alix Rogers, and Sam Berger as my

coauthors on our report, Nick Rathod, Tyler Hall, Alex Pryor and our amazing communications team.

Here at CAP, we support progressive policies, not parties, not candidates, and if you want to talk to us more about how we can help you do that on this issue, we'd be most delighted to communicate with you.

So thanks again for being with us. We look forward to see you again at another event soon. And thanks again to our panel.

(Applause.)

(END)