

The Business of Stem Cells: Re-Examining Federal, State and Private Funding and Regulatory Initiatives

Wednesday, March 9, 2005, 9:00 a.m.–3:00 p.m.
Wohlstetter Conference Center, Twelfth Floor, AEI
1150 Seventeenth Street, N.W., Washington, D.C. 20036

How will the United States proceed to unlock the therapeutic promise of stem cell research, commercialize its use, and establish a flexible regulatory and ethical framework?

As scientists around the world race to explore the potential of stem cells, the regulatory and research funding picture has become increasingly complex. Acting to balance ethical concerns with research needs, President Bush in August 2001 authorized limited federally-supported funding of research of human embryonic stem cell research, which had been blocked since 1995, though restricting that support to the approximately two dozen existing stem cell lines that had been already created from embryos donated after in vitro fertilization. He also continued to authorize limited support for adult stem and cord blood stem cells. The current budget for human embryonic stem cell research is less than \$30 million a year. No federal funds may be used to investigate other lines or to create new ones.

The scientific viability and ethics of various kinds of stem cell research has been endlessly debated in recent years. This conference is not designed to revisit this important issue, but to discuss the various issues that have arisen in the United States and elsewhere in response to the 2001 federal policy edict and the slew of recent state initiatives that are encouraging private investments and public/private partnerships.

The general belief, as expressed by critics, is that federal stem cell policy has put a damper on public and private research, as companies have been unwilling to commit substantial venture capital in an uncertain political climate. It's been noted that a few countries, notably Singapore, China, the United Kingdom, Israel, and Australia, are setting up well-funded research facilities and have begun luring bio-researchers, many from the United States, to grow these new ventures. They are also attracting interest from venture capital firms.

Even in this uncertain climate, during the last three years, stem cell institutes that combine private financing with some state funding have been established at a number of institutions, including Stanford, Harvard, Cornell, Johns Hopkins, and Wisconsin. A number of states are also spearheading initiatives. The most recent dramatic development occurred last November when California voters overwhelmingly approved Proposition 71, a controversial \$3 billion bond measure that amends the state constitution to require the state to spend an average of \$925 million per year over a ten-year period on both infrastructure and research initiatives. This unprecedented amendment immediately cast California as a kind of mini-National Institutes of Health, as the state seeks to become both a research center and a dispenser of grants and seed funds. Some observers have raised concerns the Proposition 71 may open a regulatory free-for-all.

Hoping to become international stem cell research centers, Wisconsin, New Jersey, Maryland, and Massachusetts also have announced unique private/public research models in hopes of becoming leading centers in what most people anticipate will be a scientifically fruitful and financially lucrative field of research.

8:45 a.m. Registration

9:00 Introduction: JON ENTINE, AEI and Miami University (Ohio)

9:10 "Human Embryonic Stem Cells: Current Challenge and Future Promise"

Speaker: Dr. JAMES BATTEY, Director NIDCD, NIH Task Force on Stem Cell Research

Human embryonic stem cells represent one of the most promising platforms for entering the era of regenerative medicine. Dr. Battey will discuss the current challenge and future promise of this important, and controversial, area of research, with an eye towards what the National Institutes of Health can do to advance the research agenda.

9:45 **Panel I: State Models/Initiatives for Stem Cell Research**

Panelists: DAVID GOLLAHER, California Health Care Institute

When Californians approved a \$3 billion bond to fund stem cell research, they embarked on a bold civic experiment, unprecedented in the annals of science. Its sheer magnitude makes Proposition 71 the greatest application of direct democracy to science policy in history. And for both science and politics, the implications are far-reaching and profound. Dr. Gollaher will discuss the implementation of Prop. 71 in California and the road ahead.

JOHN GEARHART, Institute for Cell Engineering, Johns Hopkins School of Medicine

CARL E. GULBRANDSEN, Wisconsin Alumni Research Foundation (WARF)

Mr. Gulbrandsen will briefly describe the WiCell Research Institute, the institute founded by WARF to conduct research on human embryonic stem cells (HES cells), distribute the cells to researchers worldwide, and train researchers in the culture and maintenance and licensing of HES cells. Mr. Gulbrandsen will also address the HES cell research program at UW-Madison, the recent initiative by the Governor of Wisconsin, and the opportunity and challenge presented by the California initiative.

CHARLES JENNINGS, Harvard Stem Cell Institute

Mr. Jennings will summarize the rationale for creating Harvard Stem Cell Institute (HSCI), and the plans and aspirations for the future. HSCI is currently seeking regulatory approval to derive new embryonic stem cell lines by somatic cell nuclear transfer (sometimes known as 'therapeutic cloning'). Mr. Jennings will discuss the rationale for this line of research, and some of the obstacles to be overcome. I also talk more generally about the challenges posed by the current regulatory and political climate, and about the role of different funding sources (federal, state, philanthropic and commercial) for stem cell research in an academic setting.

WISE YOUNG, Rutgers University's Keck Center for Collaborative Neuroscience

Dr. Young will explain why Congress ought to significantly increase NIH funding for human neonatal and adult stem cell research. World supplies of even umbilical cord blood (150,000 units worldwide) or bone marrow stem cells (250,000 registered donors) are insufficient to treat millions of people, should stem cells prove to be beneficial for even one of the following conditions: diabetes, heart failure, neurodegenerative diseases, multiple sclerosis, brain or spinal cord injury. He will discuss the benefits of growing and programming large populations of stem cells to treat many conditions and people.

11:00 Break

11:15 **Discussion on State Initiatives**

12:15 p.m. Luncheon

12:45 **Luncheon Keynote: Beyond Bioethics: New Approaches to the Governance of Human Biotechnology**

Speaker: FRANCIS FUKUYAMA, Bernard L. Schwartz Professor of International Political Economy, The Paul H. Nitze School of Advanced International Studies, Johns Hopkins University

Professor Fukuyama will present the results of a study that recommends the creation of a new federal agency modeled on the Human Fertilisation and Embryology Authority in Britain or the Assisted Reproduction Agency of Canada to regulate reproductive biomedicine in the United States.

1:30 **Panel II: Private v. Public Financing of Stem Cell Research: Opportunity and Concern**

Moderator: LORI KNOWLES, University of Alberta

Nations around the globe continue to create policy that will allow stem cell science to proceed while respecting the values each society holds dear. Ms. Knowles will discuss the challenges of finding the balance between these two goals. A survey of selected regulatory responses around the world, with particular emphasis on the United Kingdom and Canada, reveals that the result of international stem cell initiatives is a regulatory patchwork that continues to evolve. While there are a number of policy alternatives for regulating human embryonic stem cell research, all require political willingness to engage in transparent and controversial political debate and a commitment of both time and money.

Panelists: DEBORA SPAR, Harvard Business School

Currently, the business of stem cells is tiny: a handful of private firms in the United States, investing only minimal sums of money. Ms. Spar will discuss the emerging stem cell sector from the lens of other breakthrough technologies, and particularly technologies that were as radical, and as controversial, at the times of their own emergence. She will look at the evolution of these industries – at the telegraph, for example, and contraception, and IVF – in order to glean valuable lessons into the probable path of stem cells, and the policies that are likely to track the industry's evolution.

KEN GIACIN, StemCyte

Mr. Giacin will discuss the business model and unique assets of Stemcyte, one of the largest umbilical cord blood stem cell banks in the world. He will also discuss its collaborations and address recent developments that may impact StemCyte's business plan, including Prop. 71 and the Stem Cell Institute of New Jersey.

ROBERT LANZA, Advanced Cell Technology and Wake Forest University School of Medicine

Mr. Lanza will address how stem cell progeny may be able to reconstitute more complex tissues and organs, including myocardial patches, kidneys, and even entire hearts, in conjunction with the generation of functional replacement cells such as cardiomyocytes, neurons, or insulin-producing cells. He will also discuss the numerous scientific challenges and many years of research standing between the promise of stem cell therapies and real treatments, paying particular attention to the new world of private/public funding opportunities and prospects brought about by the passage of Proposition 71 and other stem cell initiatives

3:00 Adjournment