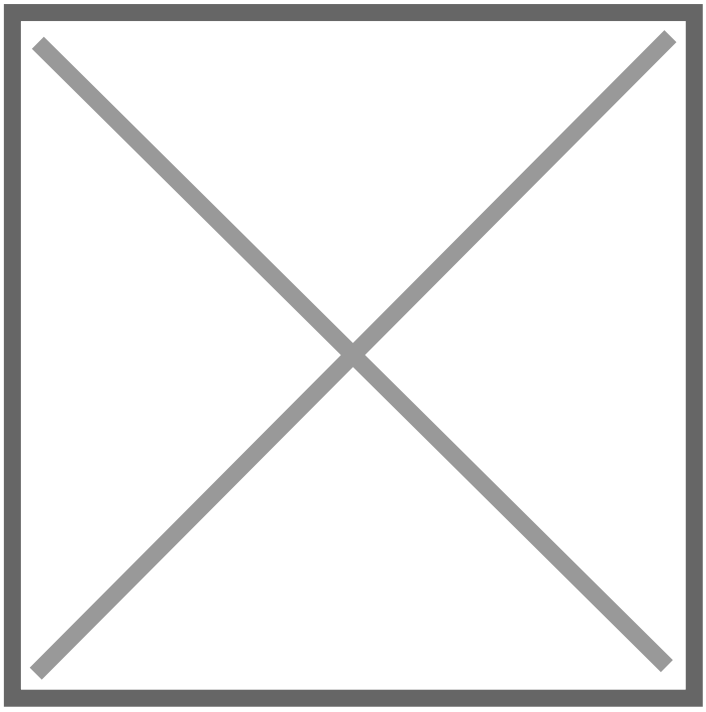
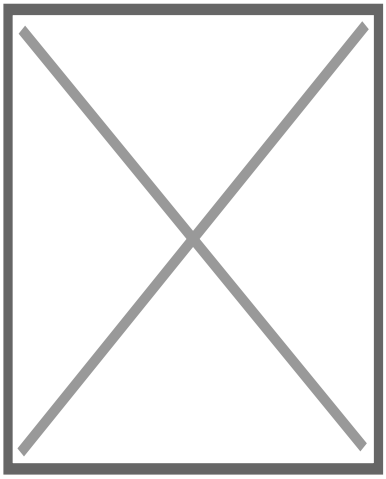
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The Obama effect on stem cell research

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The Obama effect on stem cell research



After a thumping victory over Senator McCain, President-elect Barack Obama has fuelled hopes and expectations in the life sciences industry by promising to give the green signal for embryonic stem cell research. Could he be the much-awaited messiah the stem cell community has been waiting for?

The US presidential elections 2008, will be historic for myriad reasons-election of America's first Afro-American President, for having witnessed the first Republican women nominee, Ms Sarah Palin for the post of vice president, for having two sitting senators fighting against each other (since President JF Kennedy was elected back in 1960s) and for ushering a new era of Internet or social networking campaign. Barack Obama's election can also perhaps be a turning point in the history of stem cell research in particular and the life sciences industry as a whole. The President-elect's statements during his campaigns offering support to embryonic stem cell research has given a flicker of hope to researchers. The Bush-administration had banned the use of federal government funds for embryonic stem cell research. The US federal government is a major player in the research agenda due to the enormous funds at its disposal.

With healthcare being the top most priority in his agenda list, Obama's election to the post could also spell good news for pharmaceutical and biotechnology companies, reeling under increasing cost pressures and drying R&D pipelines, with his affirmative statement for the creation of a regulatory pathway for biosimilars in the US.

The Messiah

Every winter leads to spring. The same can be said about the embryonic stem cell research community, who can now heave a sigh of relief with Obama giving the thumbs up to them. Embryonic stem cells, he declares, holds a lot of promise as cure for chronic diseases such as cancer, blood disorders, Parkinson's and Alzheimer's, which affect over 40 million of the American populace. Research on embryonic stem cells had earlier been stifled for seven years by the previous Bush regime on ethical and moral grounds. Limited federal funding of $90 million was allotted until 2005 when Bush took an extremist stance on the subject by freezing all federal funds for any further research. When the Stem Cell Research Enhancement Bill was put forward in 2006, the US academic institutions took up ambitious research projects. At the University of Illinois, it was discovered that stem cells had the potential to treat blood disorders, lung diseases, and heart damage. At Johns Hopkins, researchers were able to use mouse embryonic stem cells to repair damaged nerves and restore mobility in paralyzed rats.

In a debate session recently between Obama and Senator McCain, Obama openly criticized the Bush administration for handcuffing scientific progress in the country and slackening the wheels of progress of the US vis-a-vis other nations.

Throughout his tenure as a senator, Obama always believed in the promise of stem cells to treat and cure the millions of Americans who are suffering from catastrophic, debilitating and life-threatening diseases and health conditions.

Obama was also seen to be a co-sponsor of the Stem Cell Research Enhancement Act 2007, which was however vetoed by Bush on moral and ethical grounds. Being a propagator of the Bill himself, Obama on behalf of the Democrats emphasized that by expanding scientific access to embryonic stem cells which would be otherwise discarded, this bill will help scientists and researchers develop treatments and cures to help people who suffer from illnesses and injuries for which there are currently no cures.

While being a member of the Senate, he was also the chief co-sponsor of the Ronald Reagan Biomedical Research Act, which would specifically permit embryonic stem cell research in Illinois, and establish review of the research by the Illinois Department of Public Health.

Having now become the President-elect, and all set to become the country's 44th President on January 20, 2009, Obama is well aware of the limitations of the adult stem cells and with all determination will not leave any stone unturned in ushering in the new age of science, streamlining federal funding to embryonic stem cell research which can even go up to billions with all the requisite legislative supervision and oversight.

Obama Vs Bush

Back in 2001, President George Bush was a promise to the scientific community. He adopted a balanced stand between scientific progress and ethical interests. At that time, 60 genetically diverse stem cell lines already existed and received private funding. They were created from embryos that had already been destroyed, had the ability to regenerate them indefinitely, creating ongoing opportunities for research. Given the situation. Bush vouched for adult stem cells, which he believed had the potential to cure chronic diseases. He in a way overlooked the fact that adult cells can be harvested and cultured but in limited amounts. This perhaps could be the reason for him backtracking completely, axing embryonic stem cell research in 2005. The ethicist took the better of him.

Obama strongly believes that there is nothing that can match embryonic stem cell therapy. The promise this therapy holds overshadows the potential benefits of adult stem cells. The Bush government may have spent close to $90 million on embryonic stem cell research. On the other hand, at least $250 million had been spent on umbilical cord placenta, adult and animal stem cells, which do not involve the same moral dilemma. Obama on the other hand has fuelled hope and intends to channelize billions of dollars of federal funding for embryonic research.

While other nations have made progress with success stories like the recent organ transplant of a windpipe using stem cell lines of a Spanish patient, US in a way lags far behind.

Obama perhaps, has foreseen this and intends to put his nation on the brass tracks if not at par with Europe at least towards that direction. While Bush's regime was marked by a failure to induce any sort of regulation and legislative action into the matter, Obama, many analysts believe, is hell-bent on going forward by looking into the matter with rigorous oversight.

A PWC Report on Obama's Policy Impact for Pharma and Biotech

What They're Facing	Positive Implications	Negative Implications
Big pharma continues to restructure, coping with challenging research and development (R&D) pipelines, slower sales growth, increasing generic substitution, and raising research costs.	More insured means more demand for drugs and less need for free drug programs.	Direct negotiation of drugs for Medicar to erode profits.
An estimated $60 billion in sales of brand-name drugs in the United States will be lost because of expired patents over the next four years.	Obama said he supports continuing the R&D tax credit.	Comparative effectiveness may cut int branded drugs, especially for high-cos Similarly, pressure could rise to adopt drugs.
Research firm Sanford C Bernstein estimates that generic erosion will knock between 2 percent and 40 percent off the revenues of the top 10 companies by 2015.	Obama sponsored personalized medicine legislation and could provide more incentives and funding for research.	Pressure to reduce premium growth m insurers to move some drug costs now medical benefit to the drug benefit, wh sharing tends to be higher.

The ethical stand point

However, this certainly does not indicate that the President-elect is averse to the Christian values of creation and human life. It is a tricky situation and he has very well kept in mind the ethical aspect of the dilemma, what with the Vatican out rightly opposing his stand on the subject requesting him to rethink again. While embryonic stem cell research has been given the gold start over adult stem cell research, Obama has maintained that he will see to it that there is a balance between science and ethical and moral duties.

In a debate again, Senator Obama had explained that hundreds of thousands of embryos stored in the US in in-vitro fertilization clinics will not be used for reproductive purposes, and will eventually be destroyed. I believe that it is ethical to use these extra embryos for research that could save lives when they are freely donated for that express purpose.

Biosimilars

Biosimilars could also get a new lease of life with Obama taking the mantle this January. Says an expert from PWC (PriceWaterhoueCoopers), UK, "Obama has made three statements that should support biosimilars-allowing re-importation of safe drugs from other countries; increased use of generics in Medicare/ Medicaid; prohibit large drug companies from keeping generic competition out- and all of these are positive for the biosimilars pathway." Apart from being pro-generics to lower healthcare costs, Obama has also pledged to push the bill to create a pathway for the biosimilars in the US. The bill for biosimilars was earlier passed in the Congress but reached a dead-end as no compromise could be reached between the generics and biopharma companies. The President-elect also intends to reduce the exclusivity of branded biologic products from 14 years.

The logistics

It will be a Herculean challenge once the President shifts to the White House. Obama is taking up the mantle of Presidentship at a time when the global economy is going through a critical financial crunch along with prolonged recession. So despite declaring elaborate promises to the healthcare and research sector, there could be delays in execution. According to a PWC report, the new President will face tight budgetary constraints related to the national deficit, national spending priorities, and slow economic growth.

In September, the Congressional Budget Office projected that the national deficit could reach $407 billion in 2008, $535 billion in 2009, and $518 billion in 2010.

Till date, new research in the United States has been funded primarily by states, including California and New Jersey, and by private capital. The USD 3 billion California fund is the largest source of funding for stem cell research in the world. That could mean no new funding for healthcare initiatives unless the initiatives themselves save money.

Will Obama fulfill all that he has promised in his election campaign or will he go the Bush way? A wait and watch situation indeed.

For the moment, he is following a slow and steady mantra as was mentioned in his speech, post-victory "The road ahead will be long. Our climb will be steep. We may not get there in one year or even one term, but America-I have never been more hopeful than I am tonight that we will get there. I promise you-we as a people will get there."

Nayantara Som