

Cures Acceleration Network Act

A Bridge Across the Valley of Death: The Cures Acceleration Network Act

(04/25/09 Senator Arlen Specter)

<http://specterforthecure.com/theInitiative.html>

Every day 1500 of us die from cancer. 1 in 150 of our children has autism. Nearly every family is touched by a parent or grandparent facing Alzheimer's. And the list goes on and on.

From my first days in the Senate, I've fought for more money for medical research. The NIH is the crown jewel of the federal government. Nothing is more important than curing the diseases that damage our spirits, hurt our families and take our lives.

My own hard won victory over cancer has only given me more passion for this cause. I get it.

On my watch on the Appropriations Committee, funding for the National Institutes of Health has gone from \$12 billion in 1996 to \$30 billion and I recently helped persuade Congress and President Obama to include another \$10 billion in the Economic Stimulus bill.

But I have not simply acted. I have listened and learned. As my friend Michael J. Fox and others counsel me, more money alone won't get us faster cures.

As Newsweek magazine (*same article we will post*) reported last year, the "barriers to 'translational' research... have become so daunting that scientists have a phrase for the chasm between a basic scientific discovery and a new treatment. It's called the valley of death... The valley of death is why many promising discoveries - genes linked to cancer and Parkinson's disease: biochemical pathways that ravage neurons in Lou Gehrig's disease - never move forward."

It has been a decade since Hans Keirstead demonstrated some biomedical wonder - injecting stem cells into paralyzed rats, thereby making them walk almost normally. But only a few weeks ago did clinical trials designed to test the technique in humans get approved. (*good perspective statement*)

Just in the last couple of weeks, a new paper was published about the discovery of a gene in a subset of young women which makes them four times more likely to develop melanoma. Who will standardize, commercialize, and develop protocols for the appropriate clinical use of a test for this gene? Clearly, if we could identify these women at grave risk of a deadly disease, we could save untold suffering and an enormous financial burden. How many needless cancers will occur before just this one of so many similar discoveries has a practical effect on our healthcare system? (*good position*)

So it is my intention to build a bridge across the valley of death. There have been, in fits and starts, efforts at the NIH and elsewhere – particularly many private disease research foundations – to address this problem, but nothing like what truly needs to be done. *(SKC will also do this, specifically for pediatric cancer and improve upon previous efforts)*

As Keith Yamamoto, Chairman of the Board on Life Sciences, has written, “results from basic research in the life sciences, even those with the potential for development, typically are not advanced beyond publication in a scientific journal, suggesting that there is a growing mass of untapped scientific knowledge with great potential for humanitarian and economic benefit”. *(outstanding quote which succinctly/eloquently states this part of the problem well. Consider sourcing this exact quote)*

We must do this on the scale and with the focus of the way we sent astronauts to the moon. *(we have used this exact analogy many times)* And we need to start now. Americans battling cancer, autism, Alzheimer’s, Parkinson’s, diabetes and so many other dreaded diseases have not a minute to waste.

Our government knows how to do this – the Defense Department has, for decades, converted research discoveries, like radar and lasers, into practical tools for the battlefield. But in the even more important world of saving lives, the passage across the valley of death remains unpaved. *(good perspective)*

The remainder of the article isn’t so relevant. From reading this article, I put together a draft statement about SKC that could be used as a basic identity statement or headline. The website uses “A Giant Leap In Turning Research into Cures”. Since SKC wants to clearly state that we aren’t about research but rather therapeutic development for pediatric cancer that translates into improved survivorship for kids now and making survivorship possible by 2015, I would like to say something like “Turning research into survivorship” though that may not be so easily understood. We have to educate people that SKC’s model is that research in itself is not the answer, more money is not the answer. That leveraging the treasure trove of valuable research is part of the answer.

So, when I return to Washington next week, I will introduce a bill aimed at unstrangling medical innovation – the Cures Acceleration Network (or “CAN”) Act. This plan will be an urgent focus of my campaign for re-election and of my next term in the Senate. We CAN make this bill the law of the land and through it we can redouble our efforts to cure diseases.

The CAN Act has two principal components.

First, we reauthorize the National Institutes of Health at a new baseline funding level of \$40 billion per year – incorporating the stimulus funds into the permanent budget of the NIH. We must do this in order to avoid creating a cliff off of which promising research, funded by the stimulus, would otherwise fall, if no additional funds were provided. We

must also do this because for the last seven years the cost of living adjustments required for NIH work to keep pace with inflation have not been met, leading to a net actual decline of more than \$5billion per year in funding and associated across the board cuts in research.

Having seen to it, through this provision, that basic research is fully protected and funded adequately to move into future years prepared to take advantage of the enormous scientific opportunities our golden age presents, the other key component of my CAN Act specifically addresses the “valley of death”.

The bill will create a new, independent, federal agency – The Cures Acceleration Network – authorized to spend \$2billion in its first year and designed to do what the name says.

CAN will, for the first time, create an official of the government of the United States, reporting to the President of the United States, whose job it will be to turn discoveries in biomedical research into better health for the American people.

The need for the CAN is clear: capital raised by America's biotechnology companies fell 55 percent in 2008 compared to 2007. Also relative to 2007, 90 percent of small public biotechnology companies are now operating with less than 6 months of cash on hand. In the last five months alone, at least 24 U.S. public biotech companies have either placed drug development programs on hold or cut programs altogether. These companies have postponed clinical trials to treat melanoma, cervical cancer, lupus, chemotherapy side effects for breast cancer patients, multiple sclerosis, diabetes and atherosclerosis, drug trials to treat non-Hodgkin's lymphoma, testing of pandemic flu vaccine, trials to treat plaque psoriasis and heart disease, and a treatment for mesothelioma.

In short, without adequate funding - these companies will be unable to take these products to the development stage, the basic research done by the NIH will be lost, and many patients will die waiting for drugs and devices to give them a better quality of life.

Creating CAN is an essential step to convert what we actually currently have in this country – a “sickness care” industry, into a genuine “health care” community.

Key features of the CAN include –

CAN will be a \$2billion independent agency, providing funds to translate research discoveries from the bench to the bedside.

CAN will make awards outside of traditional funding streams, to accelerate the development of cures and treatments including, but not limited, to drugs, devices, and behavioral therapies.

CAN will have a flexible and expedited review process to get monies into the hands of the grantees as quickly as possible. These funds will complement the NIH, not compete or take funds from the NIH.

CAN will fund two types of grant awards, each authorized at \$1billion in the first fiscal year.

The Cures Acceleration Grant Awards will provide funds to applicants who do not have access to private matching funds and the Cures Acceleration Partnership Awards, requiring a match of three federal dollars to one grantee dollar.

Eligible grantees would include biotech companies, Universities, patient advocacy organizations, pharmaceutical companies and research institutions.

To provide for expedited FDA approval, the grantees will establish protocols to meet regulatory requirements at all stages of medical product development, review and approval.

CAN grant proposals will be evaluated by a distinguished twenty-four member board, representing a broad range of disciplines, including – venture capitalists and businessmen with experience in technology companies; scientists with expertise in basic science, clinical medicine, drug discovery and delivery, gene therapy and medical instrumentation and representatives of patient advocacy organizations.

The Chairman and Vice Chairman on the CAN shall be appointed by the president with the advice and consent of the Senate and include ex-officio members representing the NIH, the FDA, the Department of Defense, the Department of Veterans Affairs and the National Science Foundation.

The moral imperative to make the CAN Act law is obvious. So is the fiscal imperative.

President Obama has spoken frequently about the unfunded costs of America's healthcare system, going out the next several decades, being an unsustainable tsunami which could actually make our current financial crisis look small. About this he is absolutely correct.

Here is just one startling fact. If healthcare costs grow at the same rate in the next four decades as they have in the last four (and with our aging population, there is every reason to believe this will be the case) the cost of Medicare and Medicaid will grown from 5% of our economy to more than 20% consuming essential the entire federal budget as it stands today. What will we do? At the moment there are only two bad options – raise taxes on the younger workers of the future to the point where our standard of living dramatically declines or ration healthcare.

None of wants to live in that sort of country, but the numbers are stubborn facts.

I believe America CAN reshuffle this deck. I believe we can have a better alternative. I believe that we can live not only longer lives, but healthier lives, by harnessing and applying the genius of our biomedical research community and getting about the task of accelerating cures. If we can reduce the number of people who come to face the diseases which today require intensive, invasive and expensive care, we not only save the quality of their particular lives, we save the future of the American economy.

So the stakes on this initiative could not be higher. And I am asking you and, through the media and the internet I will be asking all Americans, to join me in this cause. We must insist that the President and the Congress incorporate the Cures Acceleration Network Act into any comprehensive health reform proposal which comes to the Senate floor for a vote.

Please visit the website I have created to be the national gathering place for discussion of and action on the CAN proposal - SpecterForTheCure.com.

I hope to have your help. You'll always have mine.
Thank you.

Turning research into survivorship