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## News & Views

# Cancer policy in the Obama administration

*Samuel Loewenberg*

In his first address to a joint session of Congress, President Barack Obama said he would devote resources to find “a cure for cancer in our time.” While that may be political rhetoric, it signals a commitment, and specifically a dollar commitment, to research funding that had been missing in the Bush administration, where research budgets languished. Obama has promised to double research funding for cancer during his term. In his first budget, he proposed increasing cancer research funding to \$6 billion, which is about a 15 percent increase over existing levels. It is unclear what will happen by the time Congress gets through with it, but it is a promising sign.

The change in cancer policy is at the heart of a broader transformation that the new American president will try to enact in the tangled and inefficient U.S. health care system. In his push for reforms, Obama frequently tells how his mother and grandmother both died of cancer, and notes how as his mother was dying from ovarian cancer, she remained worried through her last days that her insurance would not cover her medical bills.

Passing health care reform will remain a massive political hurdle, but Obama has already made significant changes in cancer policy. The new economic stimulus bill included about \$10 billion for the National Institutes of Health, with \$1.26 billion of that money going for cancer research over the next two years. He had a key ally in Senator Arlen Specter of Pennsylvania, who recently switched from the Republican to the Democratic Party.

Officials from the NIH’s National Cancer Institute said that they would use the new infusion of funds to focus on prevention, early diagnosis, and new forms of treatments that will be more personalized and produce fewer side effects.

“Economic stimulus funds give us the chance to be visionary,” said NCI director John E. Niederhuber in a recent speech to the American Association for Cancer Research. Supporting the next generation of cancer scientists will be among the agency’s highest priorities, he said. A new NCI program will fund physician scientists and Ph.D.s who are starting out careers in translational cancer research. The “start-up pack-

ages” for the young researchers will also help them establish laboratories.

Researchers applauded the new funding but worried that two years is a relatively short time, long enough to start projects but not to finish them, in most cases. The University of Chicago’s Dr. Richard Schilsky, who serves as president of the American Society of Clinical Oncology, welcomed the infusion of funds but said that what was important was that sustained funding be kept up, and not be limited to just a one time infusion. “One of the things that the cancer community is concerned about is that this is followed by a multi-year sustained period of funding for the NCI,” said Schilsky, who chairs the university’s Cancer and Leukemia Group.



Traditionally research is expected to show some progress after five years, said Beverly S. Mitchell, M.D., the George E. Becker Professor of Medicine at Stanford University and the director of the university's Cancer Center. "It's been a big boost. But it is very directed. It has to be spent in two years. What we're looking for is something that can provide a more solid foundation," she said.



Much of the change in cancer policy under the Obama administration will be undoing the work of his predecessor. Under the Bush Administration, critics say the agency lost not only funding but focus. The National Cancer Institute was created in 1937 by Franklin D. Roosevelt. In 1971 President Richard Nixon launched his "war on cancer", and funding for cancer research steadily increased since then, even doubling during the late 1990s, but languished under the Bush administration. Since 2004 it remain flat, which adjusted for inflation means a decline of about 16.5 percent.

"The low funding had a huge negative impact on people who are doing cancer research," said Dr. Mitchell. It had made it hard "to do what you set out to do," she said. The NCI received \$4.8 billion in fiscal year 2008. Although rates of cancer deaths have fallen over the last three decades, it remains a leading cause of death among Americans, second only to heart disease, with 560,000 people succumbing a year.

In addition to the stimulus money, the Obama administration has also put forward a plan to coordinate cancer research, which is currently divided among four different agencies: the National Cancer Institute, which funds a broad range of research; the Centers for Disease Control and Prevention, which does epidemiological studies; the Centers for Medicare & Medicaid Services, which supports treatment of

cancer patients; and the Food and Drug Administration, which approves and regulates new drugs. A substantial amount of money for cancer research also goes through the Department of Defense; it is not clear if that will be consolidated as well.

One of the most important moves that Obama has made so far is to lift the Bush administration ban's 2001 on human embryonic stem cell research. The ban stemmed from pressure by anti-abortion groups, which oppose the use of embryos in research, even though current law authorizes research only on frozen embryos that would otherwise be disposed of. Conservatives reacted strongly to the lifting of the ban, although there was little they could do about it. Said House Republican leader John Boehner: "The question is whether taxpayer dollars should be used to subsidize the destruction of precious human life. Millions of Americans strongly oppose that, and rightfully so."

The Bush ban created an unwieldy bureaucracy to enforce the prohibition on any human embryonic stem cell lines that were developed after August 9, 2001. Researchers who wanted to experiment on new cell lines needed to secure separate funding for new equipment and labs, which could not be the same as the ones receiving federal money. Researchers also said it limited their ability to work collaboratively.

Researchers complained that the 21 stem cell lines that were allowed under the Bush ban lacked genetic diversity and had abnormalities that affected research into Parkinson's, Alzheimer's, diabetes and other diseases. The lifting of the ban is expected to produce funding for hundreds of new stem cell lines.

"Being able to openly ask about stem cell biology and differentiation is going to greatly enhance our ability to understand both the origins of cancer and its response to treatment," said Dr. Mitchell.

On the other hand, some believe that limitations produce innovation. On the upside some say that the Bush ban on new stem cells forced scientists to work with mature stem cells in an attempt to reprogram them, which produced unexpectedly productive results.

Another consequence of the stagnation in recent years is that the U.S. may have lost its standing as the leader in cutting edge scientific research. During the fallow period, the NCI was forced to reduce grants by between 17 to 21 percent. "We have all worried that the pace of cancer research is becoming imperiled and that biomedical research will no longer attract the best and the brightest," said Dr. Niederhuber. "As a result, I regularly hear from investigators who have had to decrease the scope of their studies or who have had to let go a lab technician or were unable to add or replace a post-doctoral student."

The funding draught caused many in the cancer research community to become discouraged, according to leading investigators. "This was bad for scientific advances and was very problematic with respect to the development of promising young scientists who were discouraged by the lack of opportunities they perceived," said Dr. Louis M. Weiner, the director of the Lombardi Comprehensive Cancer Center at Georgetown University. He noted that in recent years only about 10 percent of applications were approved, as compared with about twice that during the 1990s.



Dr. Weiner said that he watched as cancer researchers became so frustrated by the lack of funding that, for the first time he'd ever seen, many went overseas to pursue their work in locales with better funding, like Europe, China, Japan, Singapore. "That's the kind of brain drain we can't afford."

Another major change in cancer policy in this new era could come from a law introduced this spring from the bipartisan senatorial team of Massachusetts Democrat Ted Kennedy and Texas Republican Kay Bailey Hutchison. The legislation would increase funding for the NCI; add incentives for private investment in research; and encourage collaboration between government and the private sector. It would also try to increase participation in clinical trials, invest in programs to promote healthy behavior such as smoking cessation and nutrition, provide better follow-up treatment for cancer survivors, and make it easier for people to get screening for early detection and access to care, particularly for underserved populations.

Senator Kennedy, a longtime champion of health care in the Senate, is facing brain cancer himself. In a joint article with Senator Hutchison, they noted that since the "war on cancer" began in 1971, the mortality rate for the disease has decreased only 6 percent. Particularly important for the cancer research community is their plan to establish a network of biorepositories for tissue collection and storage that will enable investigators to easily share information and samples. "Integrated research will help accelerate the progress of life-saving research," said the senators.

In keeping with the theme of cross-pollination, the NCI is currently working on creating a national network of "patient characterization centers." These facilities will bring together "genomics and genetics, proteins and proteomics, all in the interest of matching a genetically characterized patient and his or her characterized tumor to appropriate and optimal therapeutic solutions," said Niederhuber.

NCI has already started a new program in pediatric cancer genomics. Called TARGET, for Therapeutically Applicable Research to Generate Effective Treatments, it will apply

"next-generation sequencing" to more than 100 tumor specimens from childhood cancer.

In an attempt to broaden the perspectives it is applying to research, since last year the agency has coordinated a series of meetings that bring together traditional cancer investigators with theoretical physicists and mathematicians. The NCI is going to open up a network of physical science-oncology centers, which will study the physical forces – like heat, stress, and cellular evolution – which may play a role in cancer.

One of the fundamental changes that could occur in the revamping of cancer policy is whether to shift the focus of research from treatment to prevention. "I do not think that the NCI has devoted sufficient resources to cancer prevention in recent years," said Dr. Schilsky.

"Over the long haul, prevention is going to be the most important," said Dr. Schilsky, acknowledging that the timeframe for such a shift to come to fruition will be decades. He says that there are many things that could be implemented right now that are known to cut cancer risk which are not receiving enough attention. Among those: increasing campaigns against smoking, which remains the leading known cause of cancer; campaigns for sun block to prevent melanomas; providing vaccines for infections known to lead to cancer, like the human papilloma virus and hepatitis. "We need to employ more effectively what we know works," said Dr. Schilsky. "The problem is that the prevention goal is on the distant horizon and the need for treatment is here today."

Many advocacy groups are now mounting their own campaigns for a realignment of priorities. The Cancer Prevention Coalition, a group comprised of public health and cancer researchers, recently issued a statement calling on the NCI to devote resources to keeping people from contracting cancer in the first place by publishing a list of "avoidable" carcinogens. "Disturbingly, the NCI has still failed to develop, let alone publicize, any listing or registry of avoidable exposures to a wide range of carcinogens." The carcinogens that the group wanted addressed include pharmaceuticals, diagnostic radiation, environmental toxins, and ingredients in consumer products.

One of the coalition's members, Nicholas A. Ashford, the Policy Director of the Technology and Law Program at the Massachusetts Institute of Technology, believes that there is too much "focus on the mechanism of cancer rather than the causative agents." Prof. Ashford, who has both a doctorate in chemistry and is a lawyer, said that he believes investigators should be looking to chemicals in the environment and in consumer products as a cause of cancer.

The group argues that the current emphasis on treatment and new drugs is misguided. They cited their own findings that the U.S. spends five times more than Britain on chemotherapy per patient, and yet the survival rates of the two countries are similar.

The group also disputes the NCI's claim that new cancers have fallen in recent years, citing the agency's own statistics that show increases in cancers of the thyroid, kidneys and testes, as well as all melanomas and childhood cancers.

Another issue will be how much insurance reform impacts America's roughly 46 million uninsured. The process of reforming the health care system will directly impact the

way that cancer treatment occurs. "Many of the treatments that are now routinely employed to treat people with advanced cancer are extremely expensive and may only have a marginal benefit," said Dr. Weiner. "Where do we draw that cost-benefit line"?

That will be even truer with the new age of personalized cancer treatment. While it will be more precise and offer up innovative solutions based on an individual's genetic profile, it will also, in many cases, be more expensive.

New developments in personalized patient care present opportunities but also funding challenges. Some have predicted that a complete cancer genome analysis could become standard practice in laboratory research in five years and in patient care in ten years. NCI efforts will be directed towards the "design and construct a personalized cancer care drug development platform," said Niederhuber. He envisions being able "to match pharmacogenomically characterized patients and molecularly profiled tumor types to highly specific molecularly targeted therapies."

While new funding means new debates about spending priorities and the focus of research, the fundamentals of the cancer research establishment appear to be solid. While many government agencies fell into disrepair under the Bush administration and faced accusations of political interference that resulted in poor performance and low employee morale, the NCI seems to have fared better, according to leading cancer specialists that the *Journal of Molecular Oncology* spoke to.

While earlier Bush administration appointees faced criticism from many in the cancer field, the current crop at NCI are generally "dedicated public servants who have been forced to operate under very challenging circumstances," said Dr. Weiner. Faced being forced to operate with limited budgets and complying with political decisions, like stem cell research, "they did the best they could under those circumstances," and "they behaved in a non-partisan way, to the best of their abilities."

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