

PREPARED STATEMENT OF DOUGLAS R. LOWY, M.D.
ACTING DIRECTOR, NATIONAL CANCER INSTITUTE

Mr. Chairman and Members of the Committee, I am pleased to present the President's Fiscal Year (FY) 2017 budget request for the National Cancer Institute (NCI) of the National Institutes of Health (NIH).

NCI BUDGET OVERVIEW

The FY 2016 budget that this subcommittee approved for NCI reflects a genuine understanding that this is a transformational moment for cancer patients and cancer research, and that the era of precision oncology is within reach. The \$70 million that you approved to fund the precision medicine for oncology initiative will foster a new era of medical practice where detailed genetic and other information about a patient's cancer is routinely used to deploy effective, patient-specific remedies to treat it. Other increases for FY 2016 will allow NCI to broadly advance and successfully integrate the many disciplines necessary to improve outcomes for patients with all types of cancer.

For FY 2017, NCI is advancing a new \$680 million initiative – known as the Cancer Moonshot Initiative – to accelerate progress across the entire field of cancer prevention, treatment, and discovery. However, in addition to the resources for the Moonshot initiative, NCI's \$5.9 billion budget supports a range of other research that is essential to achieving sustained progress in cancer. This includes:

- basic research, including genetics, cell biology, and cancer pathogenesis;
- translational and clinical sciences to prevent, screen, and diagnose cancer, and to develop and test drugs, biomarkers, imaging, diagnostics, and radiotherapies; and
- population studies, including epidemiological, environmental, and behavioral research.

Cancer Prevention: During FY 2017 and beyond, preventing cancer and screening for cancer will remain a central priority for NCI. Prevention takes many forms, such as controlling tobacco use, vaccinating against cancer-causing infectious agents such as human hepatitis B virus and human papillomaviruses, limiting exposure to sunlight, and limiting exposure to asbestos and other carcinogens. These priorities have contributed to reducing the incidence and mortality rates for many cancers. NCI continues to invest heavily in cancer screening and prevention because we know that much more progress is possible for those at risk of cancer.

In parallel with our focus on prevention, NCI also will give increased attention to cancer health disparities – the differences in cancer incidence, prevalence, treatment response, and mortality among different population groups. Reducing and eliminating cancer health disparities requires a deeper understanding of the complex interplay among a range of factors – biological, behavioral, environmental, and socioeconomic – that may contribute to the unequal burden of disease.

VICE PRESIDENT'S CANCER MOONSHOT INITIATIVE

For FY 2017, NCI will launch a bold and promising cancer research initiative designed to make broad advances across a range of exciting opportunities to prevent, diagnose, and treat cancer. The resources supporting this FY 2017 initiative will allow NCI to accelerate the pace of discovery in ways that produce tangible benefits for patients with all types of cancer, those at risk of cancer, and the growing population of cancer survivors.

The NCI budget justification identifies seven elements that form the core of the FY 2017 initiative. These seven elements also can be organized into two broad themes: research on cellular analysis and research on novel approaches to prevent, diagnose, and treat cancer. In addition, some elements of the initiative contribute to both of these themes.

Theme I – Cellular Analysis: Three elements of the FY 2017 NCI initiative support the cellular analysis theme.

A. Detecting Cancer Earlier: Even small tumors shed biomarkers into fluids of the body, such as the blood, saliva, and urine. Recent advances in genomic and proteomic technologies have greatly increased the sensitivity of methods to detect biomarkers in fluids, which raises the possibility of using such methods to screen for and identify cancers earlier. Such minimally invasive methods have recently been used for assessing whether cancer has recurred in individuals who were previously diagnosed and treated. The exciting new opportunity, for which NCI will use the resources in this FY 2017 initiative, is to now apply these methods to cancer screening. The goal is to detect at a very early stage a range of cancer types for which we do not yet have effective screening methods and to improve the detection of cancer types for which screening is already established practice.

B. Research on Mutations: The resources in the FY 2017 initiative also will allow NCI to support discoveries related to mutations and the mechanisms of cancer. Gaining a greater understanding of the mutations that occur within the cancer cell, the changes that occur within surrounding stromal tissues, and the nature of the immune system's response to cancer will serve as a springboard to advance immunotherapy and targeted drug therapy.

Such research also can identify mechanisms used by cancer cells to co-opt the vascular tissue and other parts of the micro-environment near the cancer. Moreover, this approach can identify what type of immune response is already present, but may need a boost to combat the cancer. Coupling this information with the clinical response to drug therapy and immunotherapy could greatly enhance our understanding of the therapeutically relevant interplay between the tumor and the many cell types that surround it, leading to an increased ability to improve patient responses to treatment.

C. Speeding Progress on Childhood Cancers: Cancer in children poses unique challenges. Childhood cancers generally possess many fewer mutations than adult cancers and are less likely to have activation of enzymes known as kinases, which are the most frequent targets of cancer drugs for adult tumors. Furthermore, characteristic molecular changes that drive many childhood cancers arise in transcription factors and other cellular targets that are often considered “undruggable.” However, new technologies, built upon advances in chemistry that allow the preparation of libraries of small chemical molecules with a much more complex arrangement of molecular shapes, offer the promise of identifying inhibitors for the abnormalities found in pediatric cancers. The resources in NCI’s FY 2017 initiative will support research such as this to deliver advances and treatments for pediatric cancers.

Theme II – Novel Approaches to Prevent, Diagnose, and Treat Cancer:

Two elements of the FY 2017 NCI initiative will advance the novel approaches theme.

A. Cancer Immunotherapy and Combination Therapies: For FY 2017, NCI will provide increased support to promising research that employs the cells of the immune system to attack cancer. Immunotherapy is based on the principle that a patient’s immune system, when properly primed, can often detect and destroy cancer cells.

However, the challenge of immunotherapy is two-fold: first, tumors often effectively blunt anti-tumor immune responses, and second, the immune system must be successfully primed to recognize the tumor. Despite these challenges, during the past few years there have been some remarkable successes in overcoming these problems. NCI is working to extend these early successes in cancer immunotherapy to virtually all tumor types through improved understanding of the mechanisms that enable and limit immunotherapy.

This element of the initiative will also support advanced research on combination therapies. Compared with single agent treatment, combinations of drugs that impair the growth and development of tumors along multiple molecular pathways are more likely to prevent the development of resistance and to produce long-lasting remissions. However, to benefit more patients, we urgently need to identify and understand the most effective combinations of targeted agents or targeted agents used in combination with immune-modulating molecules.

B. Vaccines to Prevent or Treat Cancer: Vaccines against cancer-causing infections can prevent certain cancers. The NCI research that led to pediatric vaccines to prevent infection with human papillomavirus (HPV) – and thereby prevent cervical and some other mucosal cancers – represents an important milestone in cancer prevention. The most advanced HPV vaccine prevents the infections that account for about 90 percent of these cancers. Cancer vaccine development will receive increased resources under NCI’s FY 2017 initiative.

Developing vaccines to treat early stage cancers and pre-malignant lesions not related to infections is another exciting opportunity that NCI will target with additional resources under the FY 2017 initiative. Such vaccines can target unique or signature genetic changes found in cancers and premalignant lesions. Candidate lesions include those found in patients with early prostate cancer, patients with premalignant lesions such as ductal carcinoma in situ (DCIS) in the breast, and patients with genetic abnormalities that place them at high risk of colorectal cancer.

III – Important Cross-Cutting Elements: Finally, two elements of the NCI FY 2017 initiative will broadly contribute to both of the themes identified above.

A. Data Sharing to Speed Discovery and Verify Treatment Response: Robust data science – managing enormous sets of molecular and clinical data – is essential in modern cancer research. “Big data” is a critical requirement for work that ranges from cancer genomics to research on cell signaling and to clinical trials, using efficient collection, storage, retrieval, analysis, and distribution of information. Without robust data science and a strong informatics infrastructure, the pace and scope of cancer research will be limited.

Establishing this advanced information technology capability will allow NCI to assemble tens of thousands of cases that have been carefully annotated with clinical and detailed molecular information. These shared bioinformatic resources will greatly increase our understanding of cancer and improve our ability to select the most appropriate treatment for patients.

B. Exceptional Opportunities – Funding Other Promising Research: The Exceptional Opportunities element of the initiative will allow NCI to capitalize on exciting scientific opportunities by awarding research funding – prioritized through a competitive process – to pursue innovative new ideas that target intractable problems in cancer science. NCI will examine novel opportunities in any area of oncology research ripe for expansion, from basic science, through translational approaches, to clinical trials. NCI will support Exceptional Opportunities research at academic sites and through public-private partnerships as a means of generating breakthrough results in cancer science and treatment.

THE ROLE OF NCAB

The National Cancer Advisory Board (NACB) will provide advice and recommendations to NCI on the Moonshot initiative. In addition, on April 4, 2016, NCI announced the membership of a Blue Ribbon Panel of scientific experts, cancer leaders, and patient advocates as a working group of NCAB. The panel will share their insights on the scientific direction and goals for all elements of the initiative and offer recommendations on other compelling research opportunities. This will allow NCI to receive broad scientific counsel about the design and implementation of the initiative and its research and resource priorities, including the Exceptional Opportunities Fund.

We are eager to receive recommendations from NCAB and the Blue Ribbon Panel about the direction and emphasis for proposed research under the FY 2017 initiative.

CONCLUSION

The NCI budget supports core, ongoing biomedical research that will advance scientific discovery and continue to reduce the burden of cancer in America. Our budget will also fund a compelling new initiative that offers the potential to accelerate the rate at which we translate discoveries into cancer clinical practice and deliver benefits to patients.

Despite meaningful progress in recent years, too many Americans face a cancer diagnosis, and far too many die from the disease. There will be more than 1.6 million new cases of cancer in the United States during 2016, and more than 600,000 will die from cancer. As these statistics demonstrate, much work remains to meet the needs of those suffering from cancer, those at risk of cancer, and the growing population of cancer survivors. The FY 2017 budget will allow NCI to advance our cancer research mission and deliver important results for the patients we serve.

Douglas R. Lowy, M.D.
Acting Director, National Cancer Institute

Dr. Lowy is the Acting Director of the National Cancer Institute (NCI), National Institutes of Health (NIH), and Chief of the Laboratory of Cellular Oncology. He was Deputy Director of NCI from 2010 to 2015. Dr. Lowy received his medical degree from New York University School of Medicine, and trained in internal medicine at Stanford University and dermatology at Yale. He has directed a research laboratory at NCI since 1975, after receiving training as a Research Associate in the National Institute of Allergy and Infectious Diseases. Dr. Lowy is a member of the National Academy of Sciences (NAS) and of the National Academy of Medicine (formerly the Institute of Medicine) of the NAS. For his joint research with John Schiller on technology that enabled the preventive HPV vaccines, he and Dr. Schiller have jointly received numerous honors, including the 2007 Federal Employee of the Year Service to America Medal from the Partnership for Public Service, the 2011 Albert B. Sabin Gold Medal Award, and the 2012 National Medal of Technology & Innovation (awarded in 2014). Dr. Lowy has also received the National Medal of Honor for Basic Research.