CANCER MOONSHOT

Report of the Cancer Moonshot Task Force

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THE WHITE HOUSE
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Executive Summary

In his 2016 State of the Union Address, President Obama called on Vice President Biden to lead a new, national "Cancer Moonshot" to dramatically accelerate efforts to prevent, diagnose, and treat cancer—to achieve a decade's worth of progress in 5 years. By leveraging decades of scientific understanding from the study and care of cancer, creating and aggregating immensely powerful datasets, and developing unprecedented science and technological capabilities, we as a Nation are positioned to end cancer as we know it.

In pursuit of this mission, President Obama established the Cancer Moonshot Task Force charged with leveraging federal investments, targeted incentives, private sector efforts, patient engagement initiatives, and more, to support cancer research and enable progress in prevention, diagnosis, and treatment. Never before have so many government agencies come together—committing their leadership and uniting their focus—to tackle the challenges along the spectrum of cancer research and care to improve outcomes for patients.

Private sector collaborations and other efforts spurred by the Vice President's leadership, in addition to his vision for igniting new innovation within the biomedical research enterprise, are outlined in an accompanying executive report. A Blue Ribbon Panel was also formed, which recommended areas of scientific opportunity to complement the Task Force's activities. These collective efforts are not intended to replace existing cancer programs, initiatives, and policies already underway, but rather are focused on areas in which a coordinated effort can dramatically accelerate the pace of progress in the fight against cancer.

This report presents the Task Force's Implementation Plans for accelerating progress, including actions launched under the Cancer Moonshot this year, as well as longer-term plans for continuing momentum into the future. In brief, the organizing framework and recommendations are as follows:

Strategic Goal 1 – Catalyze New Scientific Breakthroughs

We are witnessing widespread and unprecedented optimism that we are on the verge of pivotal advances in oncology research. Under Strategic Goal 1**,** the Task Force is advancing the pace of scientific discovery by:

- Fostering interdisciplinary approaches for elucidating the biological mechanisms underlying cancer onset and treatment;
- Aligning research and care as a seamless and iterative process; and
- Maximizing the collection and research use of longitudinal data and biospecimens.

Strategic Goal 2 – Unleash the Power of Data

Today researchers are working with an unprecedented amount of data, in part due to the explosion of genomic information, increasing use of electronic health records, and large datasets of clinical, environmental, and public health information. Under Strategic Goal 2, the Task Force is maximizing access to and usability of these data to enhance, improve, and inform the journey of every cancer patient by:

- Enabling a seamless data environment for clinical and research data through shared policies and technologies;
- Unlocking scientific advances through open publication and storage platforms and next-generation computer architectures; and
- Developing a scientific workforce capable of using the open and connected data environment.

Strategic Goal 3 – Accelerate Bringing New Therapies to Patients

The process by which lifesaving products are moved into clinics is poised for transformation, especially given the access to new and innovative strategies for moving an idea from "bench to bedside." Under Strategic Goal 3, the Task Force is accelerating this transformation by:

- Finding efficiencies in the regulatory review and licensing processes;
- Enhancing data sharing across sectors and incentivizing pre-competitive collaborations; and
- Strengthening the oncology clinical research enterprise.

Strategic Goal 4 – Strengthen Prevention and Diagnosis

As we gain an increasing understanding of the causes of cancer, the public can gain cumulative benefits from the broader arsenal of tools for combatting this devastating disease. Under Strategic Goal 4, the Task Force is strengthening the Nation's efforts around cancer prevention and diagnosis by:

- Advancing health programs, policies, and outreach to help Americans reduce their cancer risk;
- Strengthening our understanding of environmental determinants of cancer; and
- Enhancing the cancer screening continuum.

Strategic Goal 5 – Improve Patient Access and Care

The Affordable Care Act has provided a unique opportunity for opening the door to health coverage to ensure that patients have access to resources and support throughout their cancer journey. Under Strategic Goal 5, the Task Force is building on this foundation and identifying areas with the greatest potential for meaningful impacts for patients by:

- Improving efficiencies of existing programs and expanding current efforts to increase access to health care;
- Translating knowledge into workable policies to improve cancer prevention, detection, and quality of care; and
- Finding new ways of ensuring each and every patient receives quality care during treatment and survivorship.

With these goals in mind, the Task Force launched a series of activities in 2016 and developed plans to serve as a "blueprint" for future Administrations (summarized in the table below). Ultimately, through the creation of new paradigms for generating, sharing, and integrating research and clinical data to enhance patient care, the Cancer Moonshot can accelerate the delivery of effective cancer prevention strategies, diagnostics, and treatments to patients in communities around the world.

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The Opportunity: Ending Cancer as We Know It

"For the loved ones we've all lost, for the family we can still save, let's make America the country that cures cancer once and for all." - President Barack Obama

Recognizing this unique moment in the fight against cancer, in his 2016 State of the Union Address, President Obama called on Vice President Biden to lead a new, national "Cancer Moonshot" to dramatically accelerate efforts to prevent, diagnose, and treat cancer—to achieve a decade's worth of progress in 5 years. The progress we have made in understanding cancer in all its forms over the last several decades and the declining death rate from cancer since the early 1990s[1] have shown that a future may be possible wherein:

- all segments of society have access to prevention strategies, diagnostics, and treatments that save lives;
- there are cures for some forms of cancer and others have been turned into chronic conditions that do not diminish the quality or length of life;
- cancer researchers and doctors are collaboratively engaged in a system that accelerates knowledge and breakthroughs; and
- patients and health care professionals are partners, and patients can easily access and control their health information to use as they wish, including to further biomedical research.

While bold, the goal of the Cancer Moonshot is within our grasp. Today, society has the benefit of decades of scientific understanding and vast amounts of rich data just waiting to be transformed into solutions. We now know that cancer is hundreds of diseases, largely of our genome, and we have developed new and innovative ways of capitalizing on this knowledge. We know that our behavior and environment contribute to our likelihood of getting cancer, and we are modifying our behaviors and exposures to avoid known risks. We know that prevention and early diagnosis are key to fighting cancer, and we can build these efforts into clinical care.

Added to these advances, today, are immense science and technological capabilities that have positioned us to make a quantum leap in the fight against cancer. For instance, dramatic advances in immunotherapy—engineering our immune system to selectively target cancer cells—has shown remarkable success in treating a host of cancers.[2] Over just the last two decades, the cost of whole genome sequencing has fallen from in the range of millions of dollars per genome to below $1,000.[3] The increased connectedness of people through smartphones, mobile technologies, electronic health records (EHRs), and the internet allows us to reach people across communities and enables the sharing of essential information key to improving outcomes for patients with cancer. Our ability to store, mine, and analyze the vast array of data from so many sources grows every day,[4] and the rise of data science,

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[1] National Cancer Institute. The Annual Report to the Nation on the Status of Cancer, 1975-2012.

[2] Couzin-FJ. Cancer Immunotherapy. *Science* 20 Dec 2013, 342(6165): 1432-1433. DOI: 10.1126/science.342.6165.1432.

[3] National Human Genome Research Institute. The Cost of Sequencing a Human Genome.

[4] Ernest Moniz, U.S. Secretary of Energy. Supercomputers Join the Fight Against Cancer. June 15, 2016.

machine learning, and artificial intelligence are rapidly becoming ubiquitous in consumer products.[5] And these are just the technologies of *today*.

Perhaps most importantly, the Cancer Moonshot reflects a shared national commitment to harness the vast intellectual creativity and innovation of the American people to work together to take on the scourge of cancer. The promise of translating research gains into improved treatment options, such as the emergence of precision medicine, coupled with the signing of the Affordable Care Act to expand insurance coverage, the encouraged use of EHRs for patient care, and transitioning to new models of coverage and payment that promote better care at lower cost have provided an important foundation. The Cancer Moonshot aims to realize this promise by leveraging public and private efforts focused on building a system in which patients, researchers, and clinicians can seamlessly share information on treatments and outcomes to accelerate research, guide treatment decisions, and improve cancer outcomes for people across the Nation, and ultimately the world.

The time is now. Together, we can end cancer as we know it.

[5] Jason Furman, Chairman Council of Economic Advisors. Is This Time Different? The Opportunities and Challenges of Artificial Intelligence. July 7, 2016.

The Launch: Establishment of a Cancer Moonshot Task Force

President Obama established a first-of-its-kind Cancer Moonshot Task Force (the "Task Force") uniting 20 federal departments, agencies, and White House Offices under Vice President Biden's leadership in the fight against cancer. The Task Force was charged with leveraging federal investments, targeted incentives, private sector efforts, patient engagement initiatives, and more, to support cancer research and enable progress in prevention, screening, and treatment. These collective efforts are not intended to replace existing cancer programs, initiatives, and policies already underway, but instead are focused on areas in which a coordinated effort can dramatically accelerate the pace of progress in the fight against cancer.

Concurrent with the launch of the Task Force, President Obama proposed an additional $1 billion investment by the Federal Government to jumpstart the initiative:

- $195 million targeted for cancer activities aligned with the priorities of the Cancer Moonshot at the National Cancer Institute (NCI) in Fiscal Year 2016.
- $755 million in proposed funds for new cancer-related research activities at both the National Institutes of Health (NIH) and the Food and Drug Administration (FDA) in Fiscal Year 2017 (budget request).
- Increased investments by the Department of Defense (DoD) and the Department of Veterans Affairs (VA)—the Nation's largest public health care providers—by supporting Centers of Excellence focused on specific cancers and by conducting large long-term studies in the military and Veteran populations to define cancer risk factors and improve treatment.

President Obama's Memorandum also directed the Task Force to consult with external experts, including the presidentially appointed National Cancer Advisory Board (NCAB). To ensure that the mission of the Cancer Moonshot was grounded in the best science, the NCAB formed a Blue Ribbon Panel. Recommendations made by the Blue Ribbon Panel detailing the scientific areas that will benefit from additional funding, support, and coordination were accepted by the NCAB and are described in an accompanying report. The scientific goals outlined in that report are highly synergistic with the areas described throughout this report and are intended to complement the Task Force's plans.

The Task Force also identified ways in which the Cancer Moonshot could build on the critical accomplishments of this Administration in improving our understanding of cancer and access to cancer care. The President's aggressive push to increase biomedical research funding generally, and the launch of programs like the Brain Research through Advancing Innovative Neurotechnologies (BRAIN) Initiative and the Precision Medicine Initiative (PMI) more specifically, has injected new money and enthusiasm into efforts in genomics, proteomics, technology development, data science, and immunotherapy. Critically, the landmark Affordable Care Act has provided coverage for the uninsured, eliminated discrimination based on pre-existing conditions such as cancer, begun to close the gaps in coverage for seniors needing cancer drugs, and improved access to one of the most effective tools we have against cancer—prevention screenings—without cost sharing.

However, the Cancer Moonshot is a call to action, and its mission cannot be achieved by the Federal Government working alone or in isolation. Thus, in its deliberations, the Task Force sought new ways of

mobilizing partnerships with the private sector and created new opportunities for collaboration. Additional private sector collaborations and efforts spurred by the Vice President's leadership, in addition to his vision for igniting new innovation within the biomedical research enterprise, are outlined in an accompanying executive report. In sum, the Cancer Moonshot reflects the widespread commitment of the Federal Government, the private sector, scientific researchers, nonprofit organizations, advocates, patients, families, and more working together to catalyze innovation, accelerate progress, and continuously disseminate and act on new knowledge to improve the lives of those facing cancer.

Charting the Course: Organizational Framework

The mission of the Cancer Moonshot—to make a decade's worth of progress in preventing, diagnosing, and treating cancer in just 5 years—requires renewed efforts across the spectrum of cancer research and care. Thus, the Cancer Moonshot Task Force prioritized early in its discussions the need to have an organizational framework for addressing and uniting these efforts, centered on improving outcomes for patients. In doing so, five strategic goals emerged, which are discussed in further detail in Section IV of this report. Each goal is not only critical to the overall mission, but also is intended to build on and augment the success of the other goals. It is the coordinated effort across these areas that will ultimately improve the lives of cancer patients and their families.

Cancer Moonshot Strategic Goals

- Catalyze New Scientific Breakthroughs
- Unleash the Power of Data
- Accelerate Bringing New Therapies to Patients
- Strengthen Prevention and Diagnosis
- Improve Patient Access and Care

Task Force members agreed that this unique opportunity to usher in a new era of cancer prevention, diagnostics, and therapies can only be achieved if the entire cancer ecosystem works together in new and innovative ways. Efforts pursued under the Cancer Moonshot must complement and build on activities currently underway, but cannot be "business as usual." The Task Force agreed that to be a "moonshot" any new pursuit must serve a bold purpose and embody a set of core principles that will ensure each effort undertaken has the maximum impact for the community and the individual patient. The following principles are embedded within each strategic goal and throughout the Task Force's actions and recommendations:

- Drive innovation in the current cancer ecosystem by pursuing audacious, creative, and disruptive approaches;
- Collaborate across disciplines, sectors, and borders to leverage talent and expertise; and
- Share information rapidly to drive advances and crowdsource solutions.

Under the framework established above, the Task Force immediately began working within and across federal departments and agencies to launch a series of focused actions and collaborations to harness resources, programs, personnel, and technology in support of achieving the Cancer Moonshot mission. It established an interagency working group comprising senior leadership across the Federal Government that met bi-weekly to share ideas, discuss challenges, identify new collaborations, and propose new catalytic efforts. Ultimately, the effort engaged staff at multiple levels across the entire Federal Government, demonstrating the deep commitment at all levels to achieve the vision for the Cancer Moonshot as set forth by President Obama and Vice President Biden. Accomplishments spurred by these conversations are described in detail in the next section of this report, along with implementation plans for future activities that can continue to further the Cancer Moonshot's mission.

Liftoff: Cancer Moonshot Implementation Plan

Many of the Cancer Moonshot activities proposed by the Task Force have already taken shape in 2016. Some were launched at the Cancer Moonshot Summit in June 2016 (see Igniting a National Conversation), while others were launched throughout the year. These efforts are described in further detail in the following sections.

Igniting a National Conversation: Cancer Moonshot Summit
The Cancer Moonshot Summit was convened on June 29, 2016, at Howard University in Washington, D.C. At the event, the Vice President spoke to individuals and organizations representing the entire cancer community and beyond who came together to identify ways to double the rate of progress toward ending cancer as we know it. More than 35 initiatives were announced, reflecting commitments from federal agencies and private sector organizations—industry, nonprofits, foundations, health care systems, and academic institutions—each taking on a piece of the blueprint for the overall Cancer Moonshot mission. In addition, the event inspired more than 300 local summits across all 50 states, Puerto Rico, Guam, and Washington, D.C., engaging more than 7,000 individuals to discuss how they #CanServe by commitment to the goals of the Cancer Moonshot and contributing what they are able.

Plans for continuing momentum under the Cancer Moonshot are provided below as a "blueprint" for future Administrations. These proposals are not intended to be a budget document, as all activities are subject to budgetary constraints and other approvals, including the weighing of priorities and available resources by the Administration in formulating its annual Budget and by Congress in legislating appropriations. However, they are intended to make clear the opportunities on the horizon and the importance of the President's $1 billion proposal to invest in the Cancer Moonshot.

Strategic Goal 1 – Catalyze New Scientific Breakthroughs

We are witnessing widespread and unprecedented optimism that we are on the verge of pivotal advances in oncology research. This view is based on progress in many areas, including immune-based and targeted therapies, genomics and precision medicine, advanced imaging technologies and other technological innovations, new cell-based and animal preclinical cancer models, greater understanding of the causes and molecular pathogenesis of cancer, and more. As we gain an increasing understanding of basic biology, it becomes readily apparent that greater collaboration across scientific disciplines can propel a more in-depth knowledge of what is possible. Whether it be through understanding the physical properties catalyzing cell movements or the use of nanotechnology to deliver the next critical treatment option, science will be key in driving new options for improving the lives of patients.

Research related to cancer is supported by numerous federal agencies represented on the Cancer Moonshot Task Force and the current understanding of cancer is a direct result of years of public and private investment in basic, translational, and clinical science. But more can be done to catalyze new scientific breakthroughs. Under the Cancer Moonshot, the Federal Government is prioritizing interdisciplinary approaches to elucidate the biological mechanisms underlying cancer onset and

treatment, aligning research and care as a seamless and iterative process, pursuing multidisciplinary initiatives, and maximizing the collection and research use of longitudinal data and biospecimens. Much of this aligns with the Blue Ribbon Panel's 10 recommended areas of scientific opportunity for NCI investment as part of the Cancer Moonshot (see Blue Ribbon Panel below).

Blue Ribbon Panel Recommendations
Network for direct patient engagement. Engage patients to contribute their comprehensive tumor profile data to expand knowledge about what therapies work, in whom, and in which types of cancer.
Cancer immunotherapy translational science network. Establish a cancer immunotherapy clinical trials network devoted exclusively to discovering and evaluating immunotherapy approaches.
Therapeutic target identification to overcome drug resistance. Identify therapeutic targets to overcome drug resistance through studies that determine the mechanisms that lead cancer cells to become resistant to previously effective treatments.
Creation of a data ecosystem for sharing and analysis. Create a national ecosystem for sharing and analyzing cancer data so that researchers, clinicians, and patients will be able to contribute data, which will facilitate efficient data analysis.
Fusion oncoproteins in pediatric cancer. Improve our understanding of fusion oncoproteins in pediatric cancer and use new preclinical models to develop inhibitors that target them.
Symptom management research. Accelerate the development of guidelines for routine monitoring and management of patient-reported symptoms to minimize debilitating side effects of cancer and its treatment.
Implementation of evidence-based approaches to prevention. Reduce cancer risk and cancer health disparities through approaches in development, testing, and broad adoption of proven prevention strategies.
Retrospective analysis of biospecimens from patients treated with standard of care. Predict response to standard treatments through retrospective analysis of patient specimens.
Creation of human tumor atlas. Create dynamic 3-D maps of human tumor evolution to document the genetic lesions and cellular interactions of each tumor as it evolves from a precancerous lesion to advanced cancer.
Technology development. Develop new enabling cancer technologies to characterize tumors and test therapies.

Year 1 Accomplishments and Plans

During the first year of the Cancer Moonshot, the Task Force established the foundation for new and more efficient scientific collaborations across federal departments and agencies, leveraging the expertise and reach of each toward a common goal. Efforts launched by the Task Force in Year 1 of the Cancer Moonshot include:

- ***Expediting Researchers' Access to Cancer Compounds for Research – NCI's Drug Formulary***

  Leveraging lessons learned through the NCI-MATCH (Molecular Analysis for Therapy Choice) clinical trial in which agents developed by different companies are tested alone or in combination under a single study, NCI is forging a public-private partnership with 20 to 30 pharmaceutical and biotechnology companies to expedite cancer researchers' access to investigational agents and approved drugs. Researchers will be able to obtain compounds through one pre-approved "formulary" list and test them for new purposes or in new combinations, thereby alleviating the need to negotiate with each company independently for individual research projects, which can take as long as 18 months. Ultimately this approach will expedite the start of clinical trials and will bring new options to cancer patients faster. The first agents are expected to be available to the research community by the end of the year.

- ***Strategic Computing Partnership Between the Department of Energy (DOE) and NCI to Accelerate Precision Oncology***

  In partnership with NCI, DOE launched three new pilot projects bringing together nearly 100 cancer researchers, care providers, computer scientists, and engineers to apply the Nation's most advanced supercomputing capabilities to analyze data from preclinical models in cancer, molecular interaction data for RAS genes, and cancer surveillance data. Four DOE National Laboratories will conduct the work—Argonne, Los Alamos, Lawrence Livermore, and Oak Ridge—in conjunction with the NCI Frederick National Laboratory for Cancer Research. By joining these forces under a coordinated effort, these projects will refine our understanding of the mechanisms leading to cancer development and thereby accelerate the development of promising therapies that are more effective and less toxic.

- ***DoD Launching Groundbreaking Longitudinal Study to Revolutionize Precision Oncology***

  DoD is establishing a groundbreaking new longitudinal study to transform our understanding of the biological underpinnings of cancer. Using the vast amount of data housed within DoD's cancer registry and serum repository, researchers will work to identify new linkages between pre-diagnostic biological markers and various types of cancer. Approximately 1,000 new cases of cancer occur annually in active duty personnel, and there are approximately 250,000 samples from the last 25 years available to undergo protein signature analysis for pre-incident cancer markers. DoD and the Environmental Protection Agency (EPA) will also work in partnership to link results with the "Environmental Quality Index" to further evaluate the environmental factors contributing to this disease.

- ***Preclinical Research Partnership to Evaluate the Potential of Particle Beam Radiotherapy***

  The National Aeronautics and Space Administration (NASA) and NCI are establishing a new collaboration to study the biological effects of particle beam radiotherapy, a novel technology that may deliver a more targeted dose of radiation to tumor cells. Currently, NCI supports several efforts in this area, including comparing the efficacy of carbon ion therapy for the treatment of pancreatic cancer, and NASA is studying the biological effects of a wide range of heavy ions to develop countermeasures for protecting astronauts from the space radiation environment. Under this new partnership, agencies will share data and biospecimens to assess the biological effects of particle beam radiotherapy and evaluate its potential value as a new approach to fighting cancer.

Plans for Year 2 and Beyond

To accomplish the priorities under this Strategic Goal, in addition to the 2016 initiatives described above, several plans for the long term are proposed.

1. ***Strengthen interactions among agencies and engage additional partners in support of multidisciplinary basic cancer research.***

   The complexities of cancer require a multidisciplinary and integrated approach to research. Efforts will be made to inform approaches to molecular modeling by facilitating more formal and robust interactions among mathematicians, modelers, synthetic biologists, and more traditional cancer researchers. These efforts could expand to include DOE, FDA, and NASA. Building on existing agreements, the principal agencies will support a series of workshops to bring multiple disciplines together around key aspects of basic cancer research. An initial workshop was held in October 2016 involving cancer researchers and systems and synthetic biologists to discuss how to engineer the immune system. An IDEAS Lab on topics identified in this first workshop, modeled after the IDEAS Lab on physical and computational approaches to clinical cancer research—jointly funded by a public private partnership involving the National Science Foundation (NSF), NCI, Stand Up to Cancer, and the V Foundation—will be used to catalyze research investments in areas identified in this first workshop. Additional workshops, followed by funding opportunities such as IDEAS Labs, are intended to be developed each year, depending on the availability of funds. The first projects are proposed to be funded in Fiscal Year 2018.

2. ***Expand the implementation of mobile devices and wearable technologies for cancer diagnosis and treatment.***

   Several DoD efforts focused on developing new technologies will be leveraged to fight the war on cancer. First, two projects will center on developing new nanotechnology to increase our ability to visualize and treat cancers at their earliest signs of development. This includes developing imaging systems for real-time analysis to detect microscopic cellular changes, and new laser devices to precisely target surgical interventions in a safer and less invasive manner. Additional projects will develop new technologies and platforms for tracking cellular changes over time, to alert patients and physicians of the earliest stages of cancer onset. These include automated and sensitive systems for tracking changes in moles that indicate future melanomas, and mapping tissue oxygenation to detect and optimize the treatment of cancer throughout the course of therapy. An additional project will develop a "cellular highlighter" to help researchers track the molecular, genomic, and proteomic signatures of cells that appear resistant to cancer treatments. By isolating and analyzing these cells, we can begin to understand the mechanisms underlying treatment-resistant cancers and develop more targeted therapies for affected patients.

3. ***Create a high-quality performance status tracking system for cancer patients during therapy and long-term follow-up.***

   A joint effort between NCI and DoD is aimed at improving the lives of cancer patients undergoing treatment, as well as members of the military attempting to complete a mission. Both cancer patients and military personnel suffer similarly from physical, physiological, and environmental stressors that affect their ability to perform as they each face potentially life-threatening challenges. An accurate, quantitative assessment could prevent doctors from

sending patients for treatment they are not healthy enough to endure—and could help commanding officers avoid sending military personnel on missions they are not healthy enough to complete. The Analytical Tools to Objectively Measure Human Performance (ATOM-HP) project will create a high-quality performance status tracking system for cancer patients during therapy and long-term follow up. The goal is to be able to assess, in real time, a cancer patient's experiences with physical, psychological, and environmental factors, among others. This is expected to advance the ways by which doctors can monitor core dynamics in cancer patients on a regular basis.

Strategic Goal 2 – Unleash the Power of Data

Data come in all sizes, shapes, and forms, and making sense of this information is essential for developing any new and effective approach to combatting cancer. Today researchers are working with an unprecedented amount of data, in part due to the explosion of genomic information, increasing use of EHRs, and large datasets of clinical, environmental, and public health information. This new era provides a tremendous opportunity for cancer research and care, but also raises significant challenges. Privacy and security issues must be at the forefront of discussions and policy decisions. Making sense of large volumes of data with varying complexity—often referred to as "Big Data"—requires advanced computational capabilities. It is also imperative that data and the insights its analyses generate are rapidly shared as appropriate with researchers, physicians, caregivers, and patients to guide new discoveries and treatment decisions.

Under the Cancer Moonshot, the Task Force is unleashing the power of data to enhance, improve, and inform the journey of every cancer patient from the point of diagnosis through survivorship. To realize this ambitious goal, three priority areas are being tackled: (1) enabling a seamless data environment through shared policies and technologies, (2) unlocking scientific advances through open computational and storage platforms and next generation computer architectures, and (3) developing a workforce capable of using the open and connected data environment. Ultimately, smart collection and use of data can enable the creation of a "learning health care system for cancer," where as a Nation we learn from the contributed knowledge and experience of every cancer patient.

Year 1 Accomplishments and Plans

The Task Force launched several foundational initiatives in the first year of the Cancer Moonshot to further the vision of establishing a national learning health care system for cancer. Efforts in Year 1 include:

- ***Creation of an Open Access Resource for Sharing Cancer Data via the Genomic Data Commons***

  As part of the Cancer Moonshot and the President's Precision Medicine Initiative (see box), Foundation Medicine is more than doubling the total number of patients represented within the NCI's Genomic Data Commons (GDC), bringing its total to over 32,000 patients accumulated in just over a month. At its launch in early June, the GDC already shared more than five petabytes of raw unprocessed genomic data from large research projects on nearly 30 tumor types from more than 14,000 patients, along with associated clinical data (e.g., clinical diagnosis, treatment history, survival data), creating a foundational system for broad sharing and analysis of cancer genomic data, which is critical for advancing the field of precision medicine and improving the care of cancer patients.

The GDC is complemented by the NCI Genomics Cloud Pilots, which were recently funded for an additional year with the goal of co-locating the computational tools developed by the three Cloud Pilots with the GDC to create a cohesive model for large-scale genomic data management and analysis. The pilots also aim to expand the GDC to other data types, such as proteomics or imaging data. The Cloud Pilots are an important part of exploring new mechanisms for data access, computation, and analysis for cancer data. The Pilots are a partnership of The Broad Institute, The Institute for Systems Biology, and Seven Bridges Genomics. They went public in Spring 2016 and are under active evaluation through September 2017. Most recently, as part of the Cancer Moonshot, NCI jointly announced a new public-private partnership designed to build a sustainable model for maintaining cancer genomic data in the cloud for use by cancer researchers through the GDC and the Genomics Cloud Pilots.

President's Precision Medicine Initiative

Precision medicine is an emerging approach for disease prevention and treatment that takes into account individual variability in genes, environment, and lifestyle. While we have seen important successes in precision medicine, notably in cancer, the practice is not currently in use for most diseases.

To expedite progress on this front, on January 30, 2015, President Obama launched the Precision Medicine Initiative as a bold new effort focused on catalyzing advances in personalized care. As part of this effort, NIH is supporting a precision oncology component, which focuses on using tumor samples and clinical information from patients to study the development and spread of cancer, elucidating the cellular and molecular changes that give rise to cancer, understanding treatment responses and therapeutic resistance, developing the national information technology infrastructure for future clinical trials, and testing targeted cancer therapies in partnership with patients nationwide through the NCI-MATCH (Molecular Analysis for Therapy CHoice) Trial. Taken together, this national effort mobilizes researchers, providers, and patients to work together in partnership to develop individualized care.

- ***Harnessing Big Data to Transform Veteran Health through Precision Medicine***

  VA and DOE formed a new collaboration to apply the most powerful computational assets at DOE's National Labs to more than half a million Veterans' records from one of the world's largest research cohorts—the Million Veteran Program, a cornerstone of the President's Precision Medicine Initiative. This is a 5-year, renewable commitment with $3.5 million allocated in Fiscal Year 2016. The first phase of this partnership will focus on cancer, cardiovascular disease, and mental health issues, and the resulting platform will accelerate our understanding of disease detection, progression, prevention, and treatment by combining the rich clinical, environmental, and genomic data—all while enabling top researchers in the world to perform the most cutting-edge science.

- ***Tri-Agency Coalition to Enhance Cancer Care – Applied Proteogenomics OrganizationaL Learning and Outcomes (APOLLO) Consortium***

  DoD, VA, and NCI formed a new collaboration using state-of-the-art research methods in proteogenomics to more rapidly identify unique targets and pathways of cancer for detection and intervention—a critical big data challenge. These methods will look at a patient's genes that may lead to cancer and the expression of these genes in the form of proteins, with potential impact on disease formation and treatment for cancer patients. Initial collaborative efforts will focus on a cohort of 8,000 lung cancer patients within the Nation's two largest health care systems and will make data broadly available to the research community. Ultimately, the effort will be expanded to additional cancer types to reach more cancer patients within VA and DoD, providing knowledge scalable for physicians across the country treating the more than 1.6 million new patients diagnosed with cancer each year.

Plans for Year 2 and Beyond

The Task Force anticipates that the activities described above will continue to grow and expand in scope into Year 2 and beyond, as discussed below. To build on and sustain this momentum, efforts and resources will be needed for developing:

- Best practices for appropriately and respectfully obtaining consent from patients to use their data, and mechanisms for patients to access their health records and contribute them to research such as Sync for Science and Blue Button;
- Effective strategies for generating data standards, especially in cases where there are no existing organizational frameworks;
- Additional mechanisms for making data shareable, especially across multiple repositories and registries, that include approaches to protect data privacy and security;
- New computational and organizational capabilities for obtaining scientific understanding from complex datasets;
- Enhanced strategies for accelerating the translation of basic scientific findings to improved patient outcomes;
- Platforms and collaborations that bring together private-sector data scientists and cancer researchers, such as through data challenges; and
- Incentives for embedding data science training within the research career path and supporting the next generation of data scientists.

Much of the groundwork for these efforts was laid in 2016, with opportunities for sustaining and augmenting them described below.

1. ***Rapidly analyze the molecular profile of thousands of tumors.***

   Advances in molecular profiling of patients are difficult to test and rapidly deploy in the current translational pipeline. The APOLLO network (see above) will strengthen and develop research cooperation in using state-of-the-art methods in proteogenomics to characterize and compare tumors, develop a deeper understanding of cancer biology, and identify potential targets and pathways of cancer prevention, detection, and intervention. Developing these methods will lead to better diagnostic tools and effective treatments once disease pathways are discovered.

Collaborations between the APOLLO consortium and the new DoD and VA Infrastructure for Clinical Intelligence (DAVINCI) project will synergize the data-sharing infrastructure. Protocols for data sharing will be reviewed by appropriate Institutional Review Boards and pilot projects will validate the feasibility of sharing existing samples. Ongoing prospective tissue collection will occur into the next 3 years as will mergers with APOLLO genomic and proteomic workflows.

2. ***Create a shared resource of linked clinical datasets.***

   Linked clinical datasets, with appropriate and required privacy and security measures, would facilitate better care and potentially and sharing of data for research. Such a resource should link a wide range of datasets, for example, vaccine registries, HIV registries, or administrative data, as well as include a mechanism to identify cancer patient cohorts. Initially, DOD and VA will share data from their respective enterprise data warehouses (medical management and registry capabilities), an effort that has been pioneered in the DAVINCI project. Sharing computable data derived from the two departments' respective EHRs in a mutually understood data model is one early capability of this effort.

   Existing policy and agreements between the departments enable the secure sharing of protected data from the millions of patients who have received care in both systems, which includes nearly all Veterans. Expanding this system will enable a Veteran's health record to be augmented with his or her active duty health record. In the future, the architecture may be expanded to include additional datasets such as radiologic images, and, with appropriate access management and subject consent, data collected in joint research projects. DAVINCI sustainment will be addressed through ongoing modernization and rationalization of the DoD health information technology (IT) portfolio. Resources will be needed to accommodate new use cases as well as currently recognized registry support.

3. ***Improve the clinical data available for research by creating a tool that converts narrative into standardized data.***

   Despite the development and implementation of data standards over the last decade, some health data stored in medical records, laboratory reports, and other clinical reports are only available in free-form text narratives (e.g., clinical notes). Over the next 2 years, the Centers for Disease Control and Prevention (CDC) and FDA will collaborate to create a Natural Language Processing (NLP) Web Service that accepts different types of unstructured health data and returns standardized data for easier integration into databases. When clinical information is incomplete and not available to researchers because it is in narrative rather than data form, research is stymied. This initiative intends to build a resource that can help to solve that problem by converting text into data, which would then be available for quantitative analysis. The NLP Web Service would complement current standardization work. An extensive review of published and existing NLP activities needs to be conducted for possible inclusion on the NLP Web Service, which will be built on a shared platform. Once developed, FDA and CDC intend to pilot test it using cancer data from CDC and surveillance data for blood products and vaccines from FDA. FDA and CDC anticipate that the findings from the pilot project will be used to develop guidance for other federal agencies, public health agencies, academic centers, and commercial vendors as they transition the NLP Web Service into practice. Of note, the NIH-supported Bioportal Annotator API and the NIH Big Data to Knowledge (BD2K) activities include a number of relevant capabilities.

4. ***Advance secure and scalable platforms for data and metadata management for sharing and analysis.***

   Extracting meaningful molecular data from patients with cancer poses significant challenges: data are of different types, they are often stored in disparate repositories, and they contain private information that must be protected. Surmounting these challenges will require collaborative and cooperative efforts to advance secure and scalable platforms for data and metadata management, sharing capabilities for distributed teams of scientists (or virtual organizations), and customized analysis pipelines for high-performance and cloud computing.

   The NSF-funded CyVerse project has developed and deployed a cyberinfrastructure platform that currently incorporates state-of-the-art features that could be adapted to meet many of these challenges. CyVerse leadership will host a summit in Winter 2017 to bring together leaders of federal cancer-related projects to discuss common needs and challenges and to explore how capabilities such as those incorporated in the CyVerse platform could meet the challenges. A foreseeable outcome of the summit would be development of ideas for a pilot project to facilitate scalable analysis while preserving privacy of cancer-related datasets used for genotype-to-phenotype analysis via high performance computing workflows. Development of the pilot and submission of a proposal to test it could be completed 60 to 90 days after the workshop. One follow-on activity could carry out the pilot to test enhanced abilities to store, share, and analyze data in a secure environment and to appropriately deliver results to investigators or clinicians while preserving privacy of the underlying data. Next steps could include issuing new solicitations for proposals at the interface of the biological and computational sciences that would leverage and expand capabilities for large-scale analysis of cancer data, with the aim of enabling discovery of the basic underpinnings of cancer development and progression. The results of this research would complement and enhance the predictive capabilities of efforts supported by partner agencies.

5. ***Develop predictive computer algorithms to rapidly develop, test, and validate predictive preclinical models.***

   Combined efforts across NCI and DOE will provide a practical, scalable approach to preclinical screening aimed at opening up new therapeutic options for cancer patients. These models will seek to support the treatment choices of physicians and patients with the goal of achieving the best possible clinical outcome. To lay the groundwork for this effort, a Memorandum of Understanding between DOE and NCI was established in July 2016. It outlines the agencies' intentions to collaborate in developing a shared technology ecosystem and targeted applications to bring advanced computing capabilities to biological research, thereby transforming drug and treatment development and improving patient care and outcomes. NCI and DOE will begin by: (1) identifying key data gaps, (2) developing initial frameworks and reference implementations, (3) establishing standards of use for data to support model development, and (4) extending involvement to other agencies, academia, and industry. The partnership then aims to develop a set of models that can predict drug responses across a range of cell lines and intends to develop an approach for integrating mechanistic models and mechanism-based constraints into the machine learning framework.

6. ***Build collaborative relationships with the private sector and academia.***

   Academic partners not only bring scientific and medical expertise, but they also can provide a richness of data tied to their patient care needs. The technology sector can help co-develop next

generation instruments and technologies at many scales that can be driven by the priority questions being tackled. Drawn together, these can be important resources for unleashing the power of data in cancer treatment. Currently, the University of California, Intel, IBM, and General Electric have engaged DOE and NCI to build on their existing resources, technologies, tools, data, collaborations, and governance expertise to focus on the intersection of technology, cancer, and data. With this collective potential to collect, aggregate, integrate, share and analyze vast and diverse datasets, these partnerships could enable discoveries to transform cancer prevention, detection and diagnosis, accelerate therapeutic development, and advance a patient-centered learning health care system. The overarching vision includes a virtual data ecosystem (drawing from the UCHealth Data Warehouse, which brings together ~15 million patient records), The Parker Institute for Cancer Immunotherapy, Athena Breast Health Network, and the University of California's five NCI-designated comprehensive cancer centers, and potentially a physical co-location at the University of California, San Francisco, that unites researchers, physicians, engineers and computer scientists from academia, national laboratories, health centers and the private sector. This collaborative, synergistic framework will be a key driver for achieving precision medicine—with cancer at the leading edge. Such a regional center will serve as a powerful model, and hub, for national-scale activity.

7. ***Create a knowledgeable, sustainable, and agile biomedical data science workforce.***

A multi-pronged approach is needed to address the skills and workforce gaps in biomedical data science, from early education exposure to data science of those being trained in the biomedical sciences, to educating established biomedical and clinical investigators about applying computation to biomedical research questions. It is important to note that successful efforts across the Federal Government to achieve these goals are underway and will continue to be a priority. However, to truly support biomedical data science, the Federal Government needs to send a strong signal to the academic community that the development of the tools and algorithms for data analysis is a valued and "legitimate" scientific discipline. This signal should come in the form of dedicated set-aside funding for biomedical data science undergraduate and graduate education by departments and agencies such as DOE, NIH, NSF, and NCI. Support should be included for:

- Undergraduate and graduate education programs
- Cancer data science curriculum development grants (including medical schools)
- Early career grants
- Grants to support integrated teams of biomedical/clinical experts and computational experts, building on efforts such as the NIH/NSF Innovation Lab and the NCI Applied Mathematics in Germinating Oncology Solutions (AMIGOS)
- Interagency fellowship programs to place data science fellows throughout the research and care continuum, building on efforts like VA's Big Data-Scientist Training Enhancement Program (BD-STEP) to expand to other agencies such as NSF, FDA, or CDC. This should include dedicated resources for VA to manage BD-STEP and build data science curricula and community
- Continuing education workshops in data science for biomedical scientists and physicians

Federal departments and agencies involved in the Cancer Moonshot must also have the capability to recruit top talent and provide training for existing staff for developing, deploying, and disseminating

novel technologies and best practices for big data analytics. This can be achieved by leveraging and scaling FDA's Information Exchange and Data Transformation (INFORMED) initiative.

Strategic Goal 3– Accelerate Bringing New Therapies to Patients

The development of lifesaving products for patients depends on the success of moving an idea from "bench to bedside." The long arc of the commercialization lifecycle—for any product or breakthrough treatment—includes time, capital investments, intellectual property protections, licensing agreements, meaningful clinical trials, robust data analyses, and appropriate regulatory mechanisms that balance patients' needs with product effectiveness and safety. This process can be arduous for a researcher and frustrating for a patient, often costing too much money and taking too much time.

Under the Cancer Moonshot, a number of federal agencies have convened to find efficiencies in this process, whether it be through enhancing data sharing across sectors, incentivizing pre-competitive collaborations, strengthening the clinical research enterprise, or innovating patent review. For instance, the Task Force prioritized efforts to enhance participation in clinical research while keeping patient safety at the forefront. Through new efficiencies at the U.S. Patent and Trademark Office (USPTO) and new initiatives at FDA, the federal agencies are taking steps to ensure that all efforts are being made to accelerate the delivery of new safe and effective products to patients. DOE and NCI are leveraging high-performance computing applications to gain new insights into patient outcomes. And by releasing such data via third-party application programming interfaces (APIs), academics, application (app) developers, and others can further analyze the efficacy of treatments and develop additional tools for the public, while NIH and others bring new partnerships online to stimulate even more research.

Year 1 Accomplishments and Plans

In Year 1 of the Cancer Moonshot, the Task Force focused on accelerating the pace at which ideas get protected, manufactured, tested, and ushered to clinical treatment centers. Several of these efforts described below will require additional effort spanning the next few years, but the Task Force agreed that their initiation was critical in Year 1 to ensure the swift movement of discoveries to clinical care.

- ***Creation of a New Program to Accelerate Cancer Product Regulatory Review***

  FDA hired an Acting Director of its new Oncology Center of Excellence (OCE). The OCE will unite cancer product regulatory review to enhance coordination and leverage the combined skills and clinical expertise across FDA centers. Under the Cancer Moonshot, the Acting Director is charged with accelerating the establishment of a program that brings together oncologists across the FDA in an effort to expedite the development of novel cancer-related drugs, biologics, and devices and support an integrated approach to tackling this devastating disease.

- ***NIH Public-Private Partnership for Accelerating Cancer Therapies***

  NIH is collaborating with 12 biopharmaceutical companies, multiple research foundations, philanthropies, and the Foundation for the NIH to develop a new program under the Cancer Moonshot, the Partnership for Accelerating Cancer Therapies (PACT). PACT will fund pre-competitive cancer research and share broadly all data generated for further research, ultimately bringing more new therapies to patients in less time. Potential initial focus areas include understanding responses to cancer therapies, clinical trial platforms for combination therapies, predictive modeling approaches, and therapies for rare cancers.

Companies involved in the design of PACT include GlaxoSmithKline, Bristol-Myers Squibb, Boehringer Ingelheim, Eli Lilly, EMD Serono, Amgen, Takeda, Genentech, Novartis, Bayer, Merck, Pfizer, AbbVie, and AstraZeneca. Through consultation with PACT partners, NIH identified two focus areas ideally suited to such a multi-sector and coordinated effort: (1) identification and validation of biomarkers for response and resistance to cancer therapies, with a special emphasis on immunotherapies; and (2) establishment of a platform for selecting and testing combination therapies. The first focus area will address fundamental gaps in our understanding of how cancer therapies, especially immunotherapies, work in patients, and enable precision monitoring of a patient's progress during treatment. The second effort will take a collaborative approach to identify and test new combinations of the collective toolkit of the pharmaceutical industry. For both efforts, NIH will serve as a hub of coordinated efforts and information sharing across public and private sectors. A draft plan for specific potential projects, milestones, and timelines for completion will be finalized and shared with potential PACT partners by early December 2016.

- ***Forging New Partnerships to Catalyze New Drug Discovery and Development***

  DOE, NCI, and GlaxoSmithKline are engaged in a new public-private partnership designed to harness high-performance computing and diverse biological data to accelerate the drug discovery process and bring new cancer therapies from target to first-in-human trials in under 1 year. This partnership will bring together scientists from multiple disciplines to advance our understanding of cancer by finding patterns in vast and complex datasets to accelerate the development of new cancer therapies.

- ***Patents 4 Patients: Establishment of Fast-Track Review for Cancer Treatment-Related Patents***

  In June the USPTO launched a free and accelerated pilot program that aims to cut in half the time it takes to review patent applications in select fields of cancer therapy (in less than 12 months). This "fast track" is open to any applicant, including early-stage biotechnology companies, universities, and large pharmaceutical firms alike, and entities who have products already in FDA-approved clinical trials will be able to opt into the acceleration program. With approximately 900 applications received annually from around the world in the cancer immunotherapy space alone, this pilot program aims to catalyze innovative new treatments from conception through regulatory approval in order to reach the patient's bedside faster.

- ***Crowdsourcing Intellectual Property Data to Guide Cancer Investments***

  In September, USPTO launched the "USPTO Cancer Moonshot Challenge" to use intellectual property datasets to map and identify trending cancer technologies, enabling more precise funding and policy decisions regarding promising new treatments. With data and a new Cancer Treatment/Therapy API released through the USPTO Developer Hub, the challenge empowered app developers, academics, and coders to build rich visualizations of patent data—often an early indicator of meaningful R&D—and combine them with other economic and funding datasets. In September, USPTO and the Office of Science and Technology Policy announced three winners of the prize challenge who presented data-driven findings focused on how genetics and epidemiology of cancer relate to rates of patenting of diagnostics, and how federal funding of cancer research is amplified by dissemination of discoveries through patenting.

- ***Making Clinical Research Trials More Accessible to Cancer Patients***

  NCI, in partnership with the White House Presidential Innovation Fellows, is re-designing how patients and oncologists learn about and find information about cancer clinical trials. The goal is to ensure that patients and their care teams have access to the information they need at the right time, as well as strengthen participation in cancer research studies to help accelerate medical discoveries and treatments for cancer. The first phase will make cancer clinical data hosted on cancer.gov available through an API for advocacy groups, academia, and others in the cancer ecosystem to access directly. The API will enable third-party innovators, including Smart Patients, Syapse, Cure Forward, and Trial Reach, to use the new cancer clinical trial API to build applications, integrations, search tools, and digital platforms tailored to individual communities that bring clinical trial information to more providers, patients, and their family members.

- ***Strengthening and Clarifying the Requirements for Public Availability of Clinical Trial Information***

  In September, the Department of Health and Human Services (HHS) issued a final rule for clinical trial registration and results information submission to ClinicalTrials.gov, a database of publicly and privately supported clinical studies of human participants conducted around the world, to increase the availability of information about ongoing clinical trials and summary results. NIH and FDA also announced a series of efforts and policies accompanying the rule to improve the quality and efficiency of clinical research, including activities focused on helping people find trials, enhancing clinical trial design, and increasing the efficiency of the drug and device development process. Ultimately these efforts will help prevent the unnecessary duplication of unsuccessful or unsafe trials, increase the efficiency of drug and device development processes, improve clinical research practice, and build public trust in clinical research.

Plans for Year 2 and Beyond

Efforts focused on augmenting Year 1 accomplishments include:

1. ***Modernize eligibility criteria for clinical trials.***

   In coordination with the American Society of Clinical Oncology, Friends of Cancer Research, and other stakeholders, FDA will evaluate clinical trial entrance criteria that may unnecessarily restrict clinical trial access—such as brain metastases, HIV status, organ dysfunction, and age restrictions (e.g., pediatrics)—to better assess when restrictions are warranted for specific clinical trials to protect patient safety. Safely removing certain exclusion criteria and broadening eligibility criteria would render the results of clinical trials more generalizable to the actual patients who will receive drugs in clinical practice and provide patients with access to promising new drugs. Moving forward, FDA will work with sponsors to improve the use of science-based, clinically relevant eligibility criteria to allow greater patient access to clinical trials while maintaining patient safety. This project is currently underway and should be completed over the next 1 to 2 years.

2. ***Pilot large simple trials.***

   Large simple trials have been conducted in certain therapeutic areas, such as cardiovascular diseases, frequently using overall survival as the trial's primary endpoint. These trials focus on clinically relevant, easily evaluated endpoints and minimize the data elements to be collected

throughout the clinical trial. Therapies evaluated in these trials generally have been evaluated in previous clinical trials with a prior safety profile being demonstrated. Because of this prior experience with these therapies, extensive new data collection may be unwarranted. These trials also have less restrictive entrance criteria and reflect the clinical practice situations where these therapies will actually be used. Within the next year, FDA plans to convene a meeting or workshop for industry and other stakeholders to discuss novel trial designs and aims to obtain commitments from several sponsors to pilot such designs.

3. ***Develop site/tissue agnostic trials and broaden indications.***

   Oncology has conventionally been organized with a specific disease/organ site orientation, which is reflected in the design of clinical trials (e.g., breast cancer trials, lung cancer trials, colon cancer trials). With the advent of molecular profiling of tumors, we now know that cancers from a wide variety of disease sites may share the same actionable mutation or marker. Hence, clinical trials focused on a molecular target or marker independent of the disease site—"tissue or site agnostic"—may be necessary to evaluate these targeted therapies in a wide array of conventionally defined organ site diseases. To expedite the development of novel therapies for a broader range of oncology indications, clinical trials encompassing multiple different cancers (site agnostic) with the same molecular target are being conducted in a single trial. These trials are presently exploratory trials and greater clarity is needed to develop the regulatory approach for drug approval of these site agnostic indications. The NCI MATCH trial and the Pediatric MATCH trial will contribute to our understanding of how these trials should be run and evaluated. Within the next year, FDA will convene a workshop on this topic and sustain engagement with sponsors to facilitate the development of site agnostic trials.

4. ***Increase the usage of common control and expansion cohort trials.***

   To date, the gold standard clinical trial for a commercial sponsor is to compare an individual investigational new product to a standard control arm in a randomized trial. However, clinical trials using a common control with the investigational arm comprising multiple agents of the same therapeutic class from different commercial sponsors would decrease the number of patients needed for enrollment and reduce time to completion of the trials, while providing the same statistical rigor in formulating decisions. Such expansion cohort trials already have been used in the development of PD-1 immunotherapies, and significantly reduced time and regulatory expenditures compared to the conventional Phase 1/Phase 2/Phase 3 approach. As part of the Cancer Moonshot, FDA will take the lead in encouraging sponsors to consider this type of trial design as well as discussing these designs at upcoming conferences, recognizing that clarification from FDA on the design, conduct, and regulatory submission of common control trials would foster interest from commercial sponsors and decrease cost and completion time of trials.

5. ***Achieve greater interaction with pharmaceutical sponsors on international trials.***

   Currently, pharmaceutical sponsors engage both U.S. and foreign investigators to establish clinical trial sites and generate trial accrual. Commercial sponsors frequently accrue a vast majority of patients from foreign trial sites. Not only does this lack of U.S. patients reduce the access of novel investigational agents to U.S. patients, but also data generated from these trials may not reflect the broader patient population, especially racial and ethnic subgroups that will use the drug when approved in the United States. To enhance the number of clinical trials

conducted in the United States and to expedite site selection and patient accrual, the Task Force proposes fostering clinical trial agreements for registration trials.

6. ***Create a pilot program for oncology products that utilize real-world evidence.***

   "Real world" evidence generated through electronic medical information is an untapped source of regulatory information. This evidence could provide important new safety information on approved drugs and insight into how the drug is being used in a post-approval setting, information that can complement data obtained through clinical trials. Capturing real world evidence could transform evidence generation, simplify the capture of data, and streamline clinical development, while reducing cost. Under this proposed pilot, FDA would hold a workshop on methods development in using real world evidence to generate clinical evidence for regulatory decision making. It is expected that this pilot could ultimately have implications for other therapeutic areas, including rare diseases. Under this proposed pilot, and consistent with proposed Prescription Drug User Fee Act VI (PDUFA VI) commitments, FDA would hold a workshop within 4 to 6 months examining potential uses of real world evidence in oncology following agreement with the agency.

7. ***Strengthen the quality of intellectual property rights to invest in innovation.***

   The Department of Commerce and USPTO are heavily investing in continually improving the clarity and consistency of intellectual property rights. By improving the quality and clarity of the patents issued, through efforts like the recently launched Enhanced Patent Quality Initiative, USPTO can increase the market's confidence in the certainty of those intellectual property rights. Such certainty enables greater capital investment, further spurs research and development efforts, and promotes greater cross-licensing opportunities for biotechnology companies looking to invest in new patient-centered treatments by building on prior breakthrough discoveries. Moreover, such investments bring greater accuracy to patents issued, helping to curb the rate of law suits that concentrate around those sorts of patents, which may have vague claims or scant prosecution history—freeing up financial capital to be spent on innovation rather than litigation. USPTO appointed a Deputy Commissioner for Patent Quality in 2015. Beginning in 2016 and continuing into 2017, USPTO has begun implementing a series of initiatives to minimize ambiguity as to what precisely a patent for a new medical breakthrough is claiming, and to increase transparency of who owns the patent, so as to enhance licensing opportunities among companies looking to build on each other's inventions, including therapeutic breakthroughs.

Strategic Goal 4 – Strengthen Prevention and Diagnosis

As scientists gain an increasing understanding of the causes of cancer, the public can gain cumulative benefits from the broader arsenal of tools for combatting this devastating disease. Today we know that there are effective strategies for defeating certain forms of cancer. In some cases, these strategies may require avoiding behaviors that increase our risk, while in other cases we must employ screening efforts to detect and diagnose cancer before it spreads. Cancer prevention and early detection improves life expectancy and reduces the need for costly treatments. For instance, about one-third of adults aged 50 and older—22 million people—have not been screened for colorectal cancer as recommended.

Increasing colorectal cancer screening rates to 80 percent would prevent more than 200,000 deaths in this age group by 2030.[6]

Despite the opportunities afforded by a growing knowledge base, significant barriers stand in the way of achieving the full promise of prevention. One-third of cancer deaths are still linked to smoking cigarettes. Vaccinations for human papilloma virus (HPV), a cancer-causing virus, remain low for both adolescent girls and boys. Reducing environmental exposures to known cancer-causing agents remains a challenge. The Affordable Care Act is a significant step in the right direction, including requirements for new health plans to cover recommended preventive screenings and the creation of new support for prevention interventions through the Prevention and Public Health Fund. Building on these efforts, under the Cancer Moonshot the Federal Government will continue to address barriers to cancer screening and prevention by advancing health programs and policies that reduce cancer risk. Prioritized efforts include increasing outreach and funding for effective prevention strategies, enhancing the understanding of environmental determinants of cancer, and enhancing the cancer screening continuum.

Year 1 Accomplishments and Plans

In the first year of the Cancer Moonshot, the Task Force identified and aligned several high-impact initiatives to begin to move the needle on cancer prevention. Examples of efforts launched in the first year include:

- ***Promoting HPV Vaccination as Cancer Prevention***

  Under the Cancer Moonshot, CDC is advancing its efforts to promote cancer vaccines as a safe and effective strategy for combatting various types of cancers. As part of this effort, in September CDC renewed its commitment to the National HPV Vaccination Roundtable for an additional 5 years, which will include increased state-level support for this effort. The Roundtable, managed by the American Cancer Society, is tasked with bringing together immunization and cancer prevention stakeholders to provide education, outreach, and training to the public and to health care providers. The National HPV Vaccination Roundtable will be working to increase HPV vaccination rates by decreasing missed opportunities, raising awareness about the importance of vaccinating males and females ages 11-12, and maximizing access to and opportunities for vaccination.

- ***Partnership to Avoid Carcinogenic Risks by Reducing Radon Exposure***

  Radon is the second leading cause of lung cancer and the leading environmental cause of cancer mortality in the United States. Under the Cancer Moonshot, the EPA is partnering with American Lung Association, HHS, the Department of Housing and Urban Development (HUD), and several industry and health advocacy organizations to significantly reduce radon-induced lung cancer and ensure that radon testing and mitigation, along with radon-resistant construction, are embedded within public policies and across industry practices. With the added momentum of the Cancer Moonshot, the National Radon Action Plan has a goal to reduce radon in 5 million homes and save 3,200 lives annually by 2020.[7]

[6] Meester RGS, et al. Public health impact of achieving 80% colorectal cancer screening rates in the United States by 2018. *Cancer*, 2015; 121: 2281–2285. doi:10.1002/cncr.29336

[7] Environmental Protection Agency. The National Radon Action Plan: A Strategy for Saving Lives.

Plans for Year 2 and Beyond

Longer-term projects for advancing efforts in improving prevention and diagnostic capabilities include: (1) increasing HPV vaccination rates by expanding efforts to support states; (2) implementing a comprehensive tobacco control framework; (3) building collaborative partnerships among federal agencies (on existing platforms and resources to investigate environmental determinants of cancer); and (4) promoting cancer screening to increase the number of Americans who are screened as recommended.

President's Cancer Panel
The President's Cancer Panel was established by the National Cancer Act in 1971 to monitor the activities of the National Cancer Program and report to the President on barriers to progress in reducing the burden of cancer. Comprising distinguished members of the scientific and public communities, the panel works to develop actionable solutions in the fight against cancer. In recent years, the Panel energized efforts in HPV prevention by recommending a multipronged strategy for accelerating vaccine uptake in the United States and globally. By supporting HPV vaccination as an urgent health priority, the U.S. National Cancer Program has an opportunity to contribute to the prevention of millions of avoidable cancers in men and women worldwide.[8]

1. ***Improve HPV vaccination rates in the United States.***

   Every year, more than 30,000 HPV-related cancers are diagnosed,[9] and only 42 percent of adolescent girls and less than 30 percent of adolescent boys have completed the recommended HPV vaccination series.[10] Since 2013, CDC has supported a multicomponent approach to increasing HPV vaccination coverage among U.S. adolescents, and the agency proposes to expand the current work to a larger scale. This strategy focuses on improving provider practices in HPV vaccination as well as increasing public awareness about the benefits of the vaccine and risks associated with HPV-related diseases. This strategy includes: (1) developing a jurisdiction-wide joint initiative with immunization and cancer stakeholders; (2) launching a comprehensive communication campaign targeted at parents; (3) implementing strategies to improve provider practices including Immunization Information System (IIS)-based reminder/recall for adolescents aged 11-18 years; (4) using assessment and feedback to evaluate and improve the performance of immunization providers in administering the HPV vaccine series consistent with current Advisory Committee on Immunization Practices recommendations; and (5) executing communications strategies targeted to immunization providers.

   CDC will work with its Immunization and Comprehensive Cancer Control program awardees and national organizations to implement this multicomponent strategy at the national, state, and provider levels. The agency will provide funding and technical assistance to awardees to implement IIS-based reminder/recall and use assessment and feedback to evaluate and improve

[8] President's Cancer Panel Annual Report 2012-2013. Accelerating HPV Vaccine Uptake: Urgency for Action to Prevent Cancer.

[9] Centers for Disease Control and Prevention. How Many Cancers Are Linked with HPV Each Year?

[10] Reagan-Steiner S, et al. National, Regional, State, and Selected Local Area Vaccination Coverage Amon Adolescents Aged 13-17 Years—United States, 2015. *MMWR Morb Mortal Wkly Rep* 2016;65:850-858. DOI: http://www.cdc.gov/mmwr/volumes/65/wr/mm6533a4.htm

the performance of immunization providers in administering the HPV vaccine series. The National Comprehensive Cancer Control Program (NCCCP) will work with the Immunization awardees and national partners to provide support for the development and implementation of jurisdiction-wide plans through its state, tribal, and territorial program awardees. CDC's health communicators and its public health partners will develop a national public campaign to promote HPV vaccination and develop targeted communications strategies to improve provider practices related to HPV vaccination. Also, of note, NCI will continue to conduct randomized control trials on two- and single-dose vaccination protocols, which will potentially affect HPV vaccination efforts internationally. In addition to ongoing technical assistance provided to states for reporting on this measure, the Centers for Medicare & Medicaid Services (CMS)—in partnership with CDC and the Health Resources and Services Administration (HRSA)—will launch an HPV Vaccination State Affinity Group to support states in the development and/or implementation of strategies to improve uptake of HPV vaccine.

2. ***Implement smoking cessation strategies across the Medicaid population.***

   By dramatically increasing the use of smoking cessation treatments among Medicaid enrollees, Massachusetts reduced smoking prevalence in this high-risk population from 38 percent to 28 percent over a 2.5-year period, with improvements in health outcomes and health care cost reductions.[11] Tobacco priorities within CDC's "6/18" initiative include increasing Medicaid enrollees' access to and use of evidence-based tobacco cessation treatments in order to reduce tobacco use in this population. CMS and CDC will further explore activities to support states in replicating the success in Massachusetts by working together to address coverage, awareness, and operational barriers to smoking cessation. Specifically, these include efforts by state Medicaid and tobacco control programs to: (1) remove barriers to accessing Medicaid cessation coverage, including copayment; (2) promote use of these services to Medicaid enrollees and health care providers; (3) support provider quality improvement programs to ensure the sustained delivery of high-quality smoking cessation services; (4) enhance quitline services to support quit attempts by providing robust counseling and initial distribution of cessation medications while reducing physician/health system burden; and (5) assess the effectiveness of these interventions.

3. ***Screen environmental chemicals through high-throughput in vitro assays.***

   The 2008-2009 Annual Report of the President's Cancer Panel concluded that the "true burden of environmentally induced cancer has been grossly underestimated." To better identify environmental chemicals that may pose human health risks, EPA, the National Institute of Environmental Health Sciences National Toxicology Program, the National Center for Advancing Translational Sciences, and FDA formed the Toxicology Testing in the 21st Century (Tox21) consortium in 2008 to use quantitative high-throughput screening methods to test thousands of chemicals across dozen of *in vitro* assays representing known toxicity pathways. A complementary effort by EPA, Toxicity ForeCaster (ToxCast), has tested fewer chemicals across a greater number of assays. A subset of the Tox21 and ToxCast high-throughput screening assays have been mapped to the 10 key characteristics of carcinogens developed by the International Agency for Research on Cancer to support chemical hazard assessment. The Tox21 consortium

[11] Massachusetts Department of Public Health, Fiscal Year 2009. Massachusetts Tobacco Cessation and Prevention Program Annual Report.

will work to develop an expanded suite of high-throughput *in vitro* assays that fill current assay gaps and more comprehensively cover the 10 key characteristics. Using robotic technology, the consortium will screen the entire Tox21 chemical library of approximately 10,000 environmental, industrial, pesticidal, and food-additive chemicals in concentration response across the expanded assay set to identify chemicals that may possess previously unknown carcinogenic characteristics or that may be acting through multiple characteristics to produce synergies in environmental carcinogenesis.

4. ***Expand colorectal cancer screening efforts in the United States***.

   CDC currently funds the NCCCP to support comprehensive cancer control across the United States. The NCCCP convenes state-level stakeholder coalitions to leverage resources to prevent and control cancer. All NCCCP programs have made access to colorectal cancer screening a priority and are supporting the National Colorectal Cancer Roundtable's (NCCRT) "80% by 2018" initiative to increase colorectal cancer screening rates of eligible adults to 80 percent by 2018. State coalitions are critical to the success of the initiative because they are uniquely positioned to convene the appropriate stakeholders (e.g., health care providers, health systems, communities, businesses, community health centers, state and local government, survivors, and others), build appropriate momentum, and generate collective support in every state and several tribes and U.S. territories.

   Earlier this year, NCCCP, in partnership with the American Cancer Society, NCCRT, NCI, HRSA, and other colorectal cancer stakeholders, coordinated an inaugural training with 11 state teams to solidify action to improve colorectal cancer screening rates. Participants developed specific state and jurisdiction plans to increase screening rates. Moving forward, CDC is planning two additional state team training forums in Fiscal Year 2017. CDC will continue to leverage partnerships to expand its reach to realize the ambitious national colorectal cancer screening goals proposed by Healthy People 2020, the National Prevention Strategy, and other initiatives, such as the National Colorectal Roundtable's "80% by 2018" Initiative.

5. ***Remove barriers that limit access to colorectal cancer screening.***

   Under the Affordable Care Act, a screening colonoscopy is required to be performed without co-payments or co-insurance for adults over 50. For Medicare beneficiaries, however, if a tissue biopsy or polypectomy is done during the procedure, then co-payments and/or coinsurance are required. The President's Fiscal Year 2017 budget proposes legislation to waive co-payments when polyps are removed during screening colonoscopy. Moving forward, CMS will provide technical assistance as needed as Congress considers legislation.

Strategic Goal 5 – Improve Patient Access and Care

For patients to be successful in the fight against cancer, they must have access to resources and support throughout their cancer journey. Cutting-edge cancer diagnostics and treatments must be disseminated rapidly and equitably, and today's technologies can help make this a reality. However, the challenges facing patients with cancer can be overwhelming and feel insurmountable, and the journey does not end despite the word "remission." Many patients have pressing health needs that they have not been able to address because, without insurance coverage, they could not afford to see a doctor or obtain necessary medications.

The Affordable Care Act has opened the door to health coverage for millions of people who may never have had insurance before or who may have been uninsured for a long time. With increased health care coverage as the foundation, the Task Force scanned the current health care landscape for short- and long-term opportunities with the greatest potential for meaningful impacts for patients. Throughout this analysis, the Task Force identified opportunities to improve efficiencies of existing programs; expand or extend current efforts through patient and clinician education, outreach, and technology; and translate knowledge into workable policies to improve cancer prevention, detection, and quality of care. Additionally, the Task Force remains committed to finding new ways of ensuring each and every patient receives quality care during treatment and survivorship.

Year 1 Accomplishments and Plans

Our most significant challenges will come from the need to work across different federal departments and agencies with distinct missions and authorities, and across levels of government (e.g., federal, state) with differing mandates and constraints. Funding and resource limitations are an ongoing challenge. Nonetheless, the vision is to improve existing programs so that they work optimally, efficiently, and with a broader perspective on their opportunities to improve health care quality and the health of people with and at risk of cancer. Efforts launched in Year 1 include:

- ***Improving Patient Access to Medications and Information***

  FDA is scaling up its efforts to provide accessible and timesaving information for physicians and patients pursuing expanded access requests for investigational drug treatments in cases of serious or life-threatening conditions. Most recently the agency published three new guidance documents, including one focused on reducing the time it takes for physicians to make expanded access requests. To further these actions, the agency is accelerating its efforts, including discussions with external parties, to serve as a connection point between patients, providers, and drug developers to facilitate expanded access requests.

- ***New Federal Incentives for Coordinated Cancer Care***

  CMS announced the enrollment of nearly 200 participating physician practices including more than 3,200 oncologists in its Oncology Care Model, a multi-payer model focused on incentivizing high-quality, high-value, patient-focused cancer care. Participants constitute a geographically, clinically, and organizationally diverse group of practices providing roughly $6 billion in care for an estimated 155,000 beneficiaries per year during the 5-year model who have committed to providing enhanced services to Medicare beneficiaries such as care coordination and navigation. These practices also agree to use national treatment guidelines for care and CMS will supply practice feedback data for continuous care improvement.

- ***Improving Cancer Survivorship through Art***

  The National Endowment for the Arts (NEA) is designing a pilot project with members of its network of State Art Agency partners to develop art programs within designated cancer centers and health facilities at the state level. Building on its successful work in using the arts to create therapeutic activities for military members, Veterans, youth, and aging populations, the NEA along with its state partners anticipate that this pilot will demonstrate the efficacy and benefits of therapeutic arts activities for cancer patients and survivors.

Plans for Year 2 and Beyond

In the first year of its efforts, the Task Force aimed to make significant progress in strengthening working relationships with relevant departments and agencies, and began the process of detailing deliverables described below. Near- and long-term priorities include:

1. ***Identify and implement culturally and linguistically appropriate cancer education and outreach efforts.***

   Work across CMS, CDC, HRSA, and state Medicaid agencies will support efforts to build relationships with underserved communities to foster productive communication with eligible groups that have not purchased health insurance. Such efforts will lay the groundwork for most effectively encouraging eligible people to enroll. Federal partners will conduct focus groups and listening sessions with under-enrolled groups to identify outreach needs in order to improve uptake of cancer prevention and screening services (including smoking cessation and HPV vaccination efforts), and clinical cancer management services. These sessions will inform the development of educational materials and messaging for public audiences that emphasize the importance of cancer screening tests, and provide information about treatment options, including the availability of clinical trials. All education and outreach initiatives should be designed and disseminated in a culturally and linguistically appropriate manner with emphasis on addressing cancer disparities in various populations. VA will develop tools for integration into the EHR to help clinicians synthesize elements of a patient's care into a survivorship care plan that can be further individualized by the clinician before being given to the patient, communicated to other clinicians participating in the patient's post-treatment care, and to serve as the backbone for task tracking to implement the plan.

2. ***Require expedited coverage decisions for patients with a cancer diagnosis in the VA system.***

   For Veterans who are new to the VA and who have a cancer diagnosis, VA will work to create more seamless processes for eligibility screening and enrollment into VA care. For both new and known VA patients with cancer, VA will aim to implement direct scheduling by the Veteran into oncology care so that any unnecessary delays associated with requiring a primary care physician to authorize the specialty referral can be eliminated.

3. ***Comprehensively identify cancer survivorship issues and develop solutions to improve health outcomes for cancer survivors.***

   The medical, psychosocial, and economic challenges facing cancer survivors are an increasingly important and complex set of issues, especially as more Americans survive cancer diagnosis and treatment. NCI estimates that there are currently 14.5 million cancer survivors in the United States. Although a body of research exists on this topic, more work remains to be done to comprehensively identify survivorship problems and solutions, and to translate those solutions into effective policies. Under the Task Force's leadership, federal agencies, including CMS, VA, DoD, CDC, and NIH, will engage in a series of efforts related to addressing survivorship challenges. Initial priorities include hosting a summit on the topic of cancer survivorship, with follow-up activities focused on developing a framework for addressing the medical, psychosocial, and economic challenges encountered by cancer survivors and integrating relevant elements of this framework into EHR standards.

4. ***Map cancer service delivery and care across the Nation.***

   Mapping the current state of cancer service delivery is foundational for developing strategies to improve the health of the U.S. population and enhance care for all those suffering from cancer. CMS and CDC in collaboration with other partners are working together to identify ways in which cancer screening and prevention services, along with care delivery, can be tracked and assessed across the Nation, and to further identify disparities across communities and regions.

   One example is the CMS Office of Minority Health Mapping Medicare Disparities tool, which can be modified to map disease prevalence nationally and regionally by race, sex, and other demographic characteristics. In addition to mapping disease prevalence and health care service delivery, it is noteworthy that quality reporting programs exist across care settings from the physician's office to post-acute to long-term care facilities. CMS will be repackaging existing quality products pertinent to cancer screening and management for ease of use for health care providers, as well as delineating quality measure gaps that can inform future quality measure development. These activities will occur on an ongoing basis over the 2017-2019 period and beyond.

5. ***Improve access to care by leveraging technology such as virtual networks.***

   Federal efforts are currently underway to capitalize on advances in virtual technology that are being developed and implemented across the Nation. These efforts include use of these solutions to facilitate entry into health care, improving continuity of care plan implementation, expanding provider training, and improving the quality of health information for decision making, to mention a few.

   The Medicare and Medicaid programs, as well as the VA, are exploring the use of technology and virtual solutions to increase access to care, particularly in rural areas. For example, Medicaid allows states the option of covering a broad range of telehealth services and most states use telehealth in their Medicaid programs. Additionally, the national expansion of such bundled payment models (and their included waivers) may be a potential solution to barriers to care in general, and may help to mitigate care fragmentation generally, enabling better care coordination across cancer and general health care for patients. CMS has begun to explore the feasibility of applying virtual technical solutions to address transportation and other issues that may affect access to high quality cancer care. Some worthy of mention include care that is guided through virtual consultation (e.g., Project ECHO, VA).

   VA has long been a leader in telemedicine, providing more than 2,140,000 telehealth episodes of care last year to more than 677,000 patients in more than 45 specialty areas. For example, VA has a centralized genetic counseling service that currently reaches 80 of the 152 VA medical centers and clinics. Veterans are engaged using the VA's telehealth system, generally with a synchronous audio-visual session. This service will continue to expand to allow genetic counseling to be provided as Veterans with germline cancer susceptibility syndromes are identified through the VA's Precision Oncology Program.

   VA is identifying and scaling best practices in virtual cancer care delivery through its "Diffusion of Excellence" initiative. Virtual Cancer Centers will enhance the cancer care experience of Veterans by providing an Oncology Patient Aligned Care Team medical home model that facilities communication and coordination of care. Services are delivered through virtual tumor boards, electronic consultations, and telemedicine directly to patients. In virtual tumor boards,

experts for each type of tumor provide guidance on clinical pathways for patient care and meet regularly for virtual discussions of individual Veterans' cases. Care plans are iteratively implemented, measured, and improved through implementation science, learning health care, and precision oncology. Patients who have been evaluated by virtual tumor boards have been able to start treatment much faster than those who have not had such an evaluation.

Moving forward, in consultation with CMS and VA, these efforts could be augmented by funding additional networks, targeting specific cancer-relevant areas, or enhancing capabilities and reach of current networks.

Reaching Target: Ending Cancer as We Know It

Taken together, these current efforts and future plans signify an initial down payment for accelerating gains in preventing, diagnosing, and treating cancer—that is, aiming to achieve 10 years of progress in half the time. Ultimately, through the creation of new paradigms for generating, sharing, and integrating research and clinical data to enhance patient care, the Cancer Moonshot can accelerate the delivery of effective cancer prevention strategies, diagnostics, and treatments to patients in communities around the world. The effort isn't about scientific research or technology development; it isn't about computational power or capability; it isn't about health care records management—these are simply the innovative strategies and tools we now have to deploy in the fight against cancer. The Cancer Moonshot is about the entire cancer ecosystem working together to use our resources and tools intelligently and aggressively to catalyze improvements in care and our understanding of cancer.

This is the "moonshot" for our time. In 1961, President Kennedy called on the Nation to "commit itself to achieving the goal, before this decade is out, of landing a man on the moon and returning him safely to the Earth." Similarly, President Obama and Vice President Biden are calling on the Nation, and the world, to unite around a common mission—to harness our vast scientific and technological capabilities to dramatically change the incidence of cancer and the experience and outcomes of cancer for patients, keeping the needs of patients at the center of it all. Together, we can end cancer as we know it.