PROJECT INNOVATION
Cancer Cures Are Born of Medical Innovation

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Cancer Leaders Call for Congress to Act Quickly in 2015 to Reinvigorate Cancer Innovation in the U.S.

Caution That Reduced Investment in Cancer Innovation Is Harming Patients

Washington, DC [October 30, 2014] – Even before the next Congress is formally elected, a national group of healthcare stakeholders called the Cancer Innovation Coalition (CIC) took the unusual step of going to Capitol Hill to call for early legislative and regulatory action in 2015 that will reinvigorate cancer innovation in the U.S.

The reason, according to a panel of leading cancer researchers, clinical specialists, and patient advocates, is that important gains in cancer may have reached a plateau in this country at a time when cancerous tumors are evolving and becoming resistant to existing treatments and the number of new cancer cases diagnosed yearly in the U.S. are projected to increase 45 percent by 2030 – to 2.3 million Americans. Speaking today at a Washington policy briefing hosted by the CIC, the experts further warned that because the effectiveness of cancer treatments depends primarily on preventing resistance, new studies are needed now to show whether alternative approaches to treatment can improve outcomes. The policy briefing was convened as part of Project Innovation, a new movement spearheaded by the Cancer Innovation Coalition to elevate cancer innovation as a national priority.

"The need to accelerate cancer innovation has never been greater," said Nancy Davenport-Ennis, founder of the National Patient Advocate Foundation (NPAF), which is spearheading the CIC and Project Innovation. "Just as this nation took the lead in finding the cure for polio and turning HIV into a chronic disease, we need policy solutions that will restore the U.S. as a leader in delivering new cancer breakthroughs so many more Americans with cancer will live longer, better lives."

Declining U.S. Investment in Cancer Research Leads to Fewer American Cancer Patients Taking Part in Cancer Clinical Trials

When it comes to charting the future course of cancer innovation, the experts taking part in the policy briefing called for a reprioritization of funding from the federal government, as well as the private sector, so the U.S. – which used to be the great engine of medical innovation – can regain its competitive edge in cancer research and clinical trials.

Painting a disturbing picture of the outsourcing of cancer research and clinical trials to China and the Far East, John Harrington, a cancer survivor and retired Chief Commercial Officer for Sanofi Global Oncology, said the immediate problem is not a lack of resources, but what he called the nation's "collective complacency" regarding the continued position of the U.S. as a world leader in oncology care. While the U.S. has adopted a "Just Good Enough" attitude to biomedical discovery, other regions of the world are forging ahead of the U.S. in investing in research and drug discovery. As a consequence, 70 percent of clinical trials are now conducted outside the U.S.

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"As a nation we are seeing a lifesaving, health status improving system threatened and fundamentally changed," Mr. Harrington said. "We would not look for an automobile that had the technology of the 1960's when we shop today for a new car. We would not look at the operating system of the first computer as the comparator when selecting a new computer. There is no country or industry that can compete for the future without investing in innovation."

In terms of the immediate impact of outsourcing research to other countries, the nearly 20 percent drop in government-funded basic research since 2010 is having a chilling effect on the number of cancer patients who can participate in clinical trials. Due to significant budget cuts, the National Cancer Institute's (NCI) Clinical Trials Cooperative Group Program will only be able to enroll about 12,000 adult patients in clinical trials over the coming year – a 50 percent drop from the historical yearly average of 25,000 cancer patients enrolled in NCI-sponsored clinical trials.

Compounding the situation, reductions in federal funding for cancer research are accelerating an already serious shortage of the research workforce at a time when the nation's cadre of highly skilled scientists is aging. According to Mr. Harrington, who spent three years overseeing global commercial development of Sanofi Oncology's cancer compounds, the budget cuts are far more damaging than the policymakers recognize. Researchers at cancer centers are curtailing projects and laying off staff and many younger investigators are giving up their careers.

Mr. Harrington said: "In my global role, I often met U.S. investigators who were working in other countries, as a high percentage of clinical trial patients are now enrolled outside the U.S. This impacts the premier research sites, fellowships and staffing. We need to know that this is coming at a cost to our own medical schools and research institutions and we could be in danger of losing a generation of cancer researchers in this country."

Providing the perspective of a cancer researcher, Edith P. Mitchell, MD, Clinical Professor of Medicine and Medical Oncology with the Kimmel Cancer Center at Thomas Jefferson University, said now is the time when strengthening the capabilities of future generations of clinicians, leaders and scientists is critical because the opportunity to develop new cancer breakthroughs has never been more promising. Besides her medical achievements, Dr. Mitchell is a retired Brigadier General, having served as the Air National Guard Assistant to the Command Surgeon for US Transportation command and headquarters Air Mobility Command (AMC) based at the Scott Air Force Base in Illinois, and was the first female physician promoted to this rank in the history of the U.S. Air Force.

"This is an extraordinary time in oncology, one in which we continuously develop new research ideas propelling new knowledge and technology to empower us to deliver the best treatments and therapeutic outcomes for our patients," Dr. Mitchell explained. "There has never been more potential opportunity and a greater need to collaborate and enhance research to achieve goal of conquering cancer."

Ensuring Cancer Patients Reap the Benefits of Molecular-Based Medicine

Experts attending the CIC policy briefing also called for implementing policies that will ensure American cancer patients reap the benefits of the nation's investment in the Human Genome Project, an international effort led by the U.S. that ran from 1988 to 2003 and resulted in the mapping of the human genome.

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Although research equates the U.S. investment in the Human Genome Project with nearly $1 trillion worth of economic growth for the country, the panel cautioned that other countries, especially China, are now spending billions on gene sequencing and other aspects of genomic research. In particular, the Chinese company BGI – founded by U.S.-trained Chinese researchers – recently acquired the world's largest capacity for human genome sequencing by purchasing a U.S. genomics company.

This development is of great concern to the cancer community, which is pressing for policies that will accelerate the move from a one-size-fits-all treatment approach to molecularly based medicine, also known as precision medicine, where the genetic and molecular profile of the patient's cancer determines the best treatment strategy. This means regulatory approaches that support the increased use of large-scale trials based on the molecular characteristics of specific cancers, including the recently initiated Lung Cancer Master Protocol (Lung-MAP), where patients with advanced squamous cell lung cancer are assigned to one of five different investigational drugs based in part on their genetic profiles.

While citing positive developments in moving towards molecularly based cancer research in the U.S., cancer leaders nonetheless cautioned that without legislative action, many Americans will not have access to genomic testing due to major differences in the way these tests are regulated and difficulties getting commercial payers to cover the costs. At the same time, experts called for immediate action to address the inequities that are limiting patient access to innovative cancer treatments, especially when Medicare and commercial health insurers move newer cancer therapies into the highest "specialty tier" and charge patients a percentage of the drug's cost, from 25 percent up to 71 percent, according to recent estimates.

Moreover, the panel of experts took aim at outdated federal policy that covers oral chemotherapy drugs differently than those administered intravenously or by injections, burdening patients with far greater co-payments for oral cancer medicines, even though these therapies have been shown to help reduce overall cancer treatment costs. To correct this situation, the cancer advocacy community helped pass oral parity laws in 33 states and the District of Columbia and advocates are now pressing for federal legislation that will require health plans to cover oral anticancer medications and injectable therapies equitably so that patients pay the same cost percentage for each type of treatment.

Echoing the need for these actions, cancer survivor Heather Follweiler of Windsor Mill, MD, relayed her story of having a metastatic tumor removed from the right side of her brain and then being told she had another "unknown primary" cancer thought to be "consistent with lung tissue. After trying and failing several forms of chemotherapy and having more surgery, Ms. Follweiler received a genomic test that identified her cancer as "MET amplification," or multiple mutations of a gene called ALK (anaplastic lymphoma kinase), the cause of a rare form of non-small cell lung cancer (NSCLC). With this information, her oncologist prescribed ceritinib, a new targeted oral therapy for patients who are ALK-positive, which shrank her tumor by 60 percent within the first three months. Subsequent PET scans now show the tumor is completely gone.

"I share my story because I am a successful benefactor of cancer care innovation," Ms. Follweiler said. "Admittedly, I am one of the lucky ones. Not only was genomic testing offered to me as an option, it provided a cure. Millions of other American patients, with devastating cancers similar to mine, have no idea that these types of tests and resulting therapies even exist. An abundance of hurdles – whether they are knowledge based or because of regulatory, legislative or insurance obstacles – shouldn't jeopardize access for cancer patients in need of care when positive outcomes such as mine can be occur."

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Cancer Innovation Policy Agenda Planned for Early 2015
Based on the issues raised at this policy forum and other meetings being held across the country, the Cancer Innovation Coalition will develop a national policy agenda with specific recommendations for Congress and federal and state governments to accelerate the delivery of promising new treatments and to patients. Plans call for announcing this cancer innovation policy agenda in early 2015.

"Our goal is simple and straightforward," said Nancy Davenport-Ennis. "We plan to submit a cancer innovation blueprint to Congress and the Administration that advances specific policy solutions that will move cancer discovery forward in the U.S."

For more background on the information contained in this release, please visit www.projectinnovation.org and view videos from leading oncology researchers and clinicians.

About the Cancer Innovation Coalition and Project Innovation
Managed by the National Patient Advocate Foundation (NPAF), the Cancer Innovation Coalition is a national group of healthcare stakeholders working through a new initiative called Project Innovation to seek remedies that will stabilize and accelerate innovation in cancer care. The impetus for Project Innovation was the release in June 2014 of a new NPAF white paper, *Securing the Future of Innovation in Cancer Treatment*, which identified institutional, regulatory and funding hurdles that are driving up the costs and delaying the development of new cancer therapies – factors that ultimately limit patient access to much needed treatment. Primary funding for this initiative comes from NPAF with additional support through educational grants from Celgene Corporation, Eli Lilly, Novartis and Pfizer.

Members of the Cancer Innovation Coalition are: Amgen, American Association for Cancer Research, American Cancer Society Cancer Action Network, Association of Community Cancer Centers, Bladder Cancer Advocacy Network, Bristol-Myers Squibb, Cancer Support Community, Celgene Corporation, Colon Cancer Alliance, Community Oncology Alliance, Council for Affordable Health Care, CureSearch, Cutaneous Lymphoma Foundation, Fight Colorectal Cancer, Friends of Cancer Research, Eli Lilly & Company, Genentech, GlaxoSmithKline, National Patient Advocate Foundation, Novartis, Oncology Nursing Society, Personalized Medicine Coalition, Pfizer, Prevent Cancer Foundation, and US Oncology Network.

More information about Project Innovation is available at www.projectinnovation.org, @projectinno on Twitter and https://facebook.com/ProjectInno on Facebook or by contacting the National Patient Advocate Foundation at www.npaf.org or (202) 347-8009. Project Chair: Nancy Davenport-Ennis, NPAF's Founder and Chairman of the Board of Directors.

About the National Patient Advocate Foundation
Based in Washington, DC, the National Patient Advocate Foundation (NPAF) is a national non-profit organization providing the patient voice in improving access to, and reimbursement for, high-quality healthcare through regulatory and legislative reform at the state and federal levels. The advocacy activities of NPAF are informed and influenced by the experience of patients who receive direct, sustained case management services from NPAF's companion organization, Patient Advocate Foundation (PAF). NPAF/PAF were established in April 1996 by Nancy Davenport-Ennis, founder and chairman of the board.

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