PROJECT INNOVATION
Cancer Cures Are Born of Medical Innovation

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Experts at Cancer Innovation Forum Call for Improving Cancer Research Ecosystem

Cite Barriers to Genetic Testing, Access to New Therapies as Thwarting Progress

Washington, DC [October 22, 2014] – At a time when cancer drug development is at a critical juncture, accelerating the delivery of promising new treatments will depend on one critical requirement: ensuring that patients, individually and collectively, are actively involved in the cancer research and drug development process from beginning to end.

This was the consensus of leading scientists, advocates and government officials meeting in Washington at the first national policy forum convened by the Cancer Innovation Coalition (CIC), a collaboration of cancer stakeholder organizations and 21st century thinkers working through a national campaign called Project Innovation to elevate cancer innovation as a national priority. To move cancer discovery forward, experts also called for greater use of innovative clinical trial designs, creating clinical trials networks, more data sharing, and streamlining the institutional and regulatory obstacles that add years to scientific discovery and drug development.

"Innovation is the key to progress, but it is not happening fast enough, which is why we need new solutions to close the gap between the advances this country has made in science and technology and the regulatory and funding obstacles that are driving up the costs and delaying the development of new cancer therapies," said Nancy Davenport-Ennis, founder of the National Patient Advocate Foundation (NPAF), which is managing Project Innovation. "Through Project Innovation, stakeholders and policymakers can chart a new roadmap to bring promising new treatments to patients."

Based on the insights from this meeting and other roundtables being held across the country, the Cancer Innovation Coalition is developing specific recommendations for federal legislation and regulatory policies that will speed the pace of biomedical discovery in cancer. Plans call for announcing this cancer innovation policy agenda in early 2015.

Creative Clinical Trial Designs Are an "Elegant Solution"

Because cancer care is rapidly moving from a one-size-fits-all treatment approach to personalized medicine, meeting participants addressed the immediate need to improve the "ecosystem" of cancer research through greater use of innovative clinical trial designs and master protocols, which create a single clinical trials infrastructure for testing many drugs at the same time.

Noting that only one in ten drug candidates that show promise in early studies succeeds all the way to approval from the Food and Drug Administration (FDA), Dr. Janet Woodcock, Director of FDA's Center for Drug Evaluation and Research (CDER), acknowledged that cancer discovery has become increasingly inefficient and expensive in the U.S. Currently, it takes nine or more years from discovery to approval for a new cancer therapy compared to an average time of two years for HIV drugs.

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Further, because drug development is an uncertain process, a 2010 Tufts University study puts the cost of developing one innovative cancer drug at upwards of $1 billion. Accordingly, a priority for the CIC is to understand the major drivers behind high drug development costs, especially the added time to enroll patients in cancer clinical trials, where it is estimated that almost half of the $1 billion spent on cancer drug discovery (48 percent) can be lowered by such efforts as improving patient recruitment, expanding the pool of eligible candidates and decreasing the time to trial completion.

To improve this situation, Dr. Woodcock said the agency now accepts trial designs that use a single pivotal clinical trial, and in many cases, trials involving relatively small groups of patients for shorter durations. FDA also supports adaptive trial designs where biomarkers—which can include specific cells, genes, enzymes, hormones and other measurable substances—are able to predict which patients will respond best to a new drug and employ master protocols that use a common biomarker to test multiple drugs concurrently. These targeted approaches are considered the keys to lowering drug development costs and expediting approval, at least for patients in whom the drug can be quickly and effectively be demonstrated as an effective therapy.

Echoing Dr. Woodcock's assessment, Dr. Meg Mooney, Chief of the National Cancer Institute's (NCI) Clinical Investigations Branch, said NCI is currently implementing a national strategy for precision medicine to sponsor a series of large-scale trials based on the molecular characteristics of specific cancers. Among the precision medicine trials now underway are ALCHEMIST (the Adjuvant Lung Cancer Enrichment Marker Identification and Sequencing Trials), which identifies early-stage lung cancer patients with specific alterations in two genes, and the Exceptional Responders Initiative, which will study the molecular reasons why a small number of patients respond well to an investigational cancer agent when most do not. NCI is also a lead partner in 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. Other Lung-MAP co-sponsors are Friends of Cancer Research, Foundation Medicine, the Foundation for the National Institutes of Health (FNIH), SWOG (formerly the Southwest Oncology Group), and five pharmaceutical companies (Amgen, Genentech, Pfizer, AstraZeneca, and AstraZeneca's global biologics R&D arm, MedImmune).

In addition to federal government initiatives, the policy forum addressed new ways that drug sponsors are moving through clinical testing much faster by employing a model called the "bring the protocol to patients," or P2P clinical trials concept. One such effort is Novartis' Simplified Institutional Review Board Process, called "SIGNATURE," where cancer patients are tested for genetic abnormalities in their tumor and then treated with an investigational therapy based on the tumor's molecular blueprint.

Despite Beneficial Changes to Trial Designs, Enrollment Rates Remain Poor

Despite positive developments in designing cancer clinical trials, scientists and patient advocates at the policy forum painted a disturbing picture of overly restrictive eligibility criteria, patients not knowing about the availability of trials, complex consent forms, burdensome procedures at institutions, and a negative clinic environment – all of which keep eligible patients from enrolling in cancer trials. Due to these problems and the added time and costs involved in enrolling patients, 70 percent of all clinical trials now take place outside the U.S. Even academic sponsors are also looking to conduct trials internationally.

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"Clinical trials should be 'standard of care' for cancer patients," said Dr. Joan Schiller, a cancer researcher at the University of Texas Southwestern Medical Center. "We need to address these issues in a scientific, quantitative fashion to determine what works and what doesn't work—just like we address all clinical issues."

One possible solution are programs promoting shared decision-making between patients and physicians, such as Open to Options™, a free national program of the Cancer Support Community (CSC) where patients are trained to ask questions of their physicians and communicate their goals for treatment effectively. According to Vicki Kennedy, CSC's Vice President of Program Development & Delivery, a three-year pilot program showed 49 percent of patients trained through Open to Options™ discussed participating in a clinical trial with their doctor and 8 percent enrolled in a clinical trial—far above the national average of 2–5 percent today.

Barriers to Genetic Testing Thwarts Progress
While regulators and scientists advocate for greater use of biomarker-driven clinical trials, experts attending the policy forum raised flags about barriers to genomic testing due to major differences in the way these tests are regulated and the fact that the promise of using biomarkers in cancer trials has gotten ahead of laboratories being able to prove "clinical validity" to Medicare and commercial payers. To address these problems, several experts called for greater access to clinical records in real time and a coordinated effort to collect clinical outcomes data about genomic testing through registries of all types.

Once Approved, Many Patients Still Don't Have Access to State-of-the-Art Cancer Therapies
At the same time, experts called for immediate action to address the inequities that are limiting patient access to innovative cancer treatments, especially the practice by Medicare and commercial health insurers to 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.

Calling this practice a "travesty," Ted Okon, CEO of the Community Oncology Alliance (COA), said that compared to lower co-pays for physician services and hospitalizations, which are covered as a medical benefit, insurers cover cancer medicines taken at home as a pharmacy benefit and are able to require much higher co-pays, even though cancer drugs have been shown to help reduce overall cancer treatment costs. Compounding the problem, cancer patients, including those covered under the new state insurance exchanges, often don't know if their medications are on a payer's formulary list when they sign up for coverage, leaving patients in the dark until it is too late to consider another insurance plan.

Cancer specialists also raised alarm bells that the increasing trend of hospitals and health systems buying out physician-owned community cancer clinics is shifting cancer care to hospital outpatient departments, restricting access to patients living in rural areas and adding higher costs for patients, Medicare, private payers and taxpayers. In fact, data from the American Society for Clinical Oncology (ASCO) finds that since 2008, more than 1,200 community cancer care centers have closed, consolidated, or reported financial problems. Also of concern, experts cite the expansion of cancer care in 340B hospitals through the acquisition of community cancer practices that treat underserved populations as leading to higher costs for the Medicare program.

Lauren Barnes, a Senior Vice President at Avalere, said, "The current system is broken and involves network problems, difficulties getting access to specialists, and shifting costs of cancer medicines to patients through formulary policies. We need to discuss the total patient burden if we are going to improve access and transparency for patients."

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About the Cancer Innovation Policy Forum
Taking place in Washington on September 30, the national policy forum was the first in a series of regional forums, town halls and workshops the Cancer Innovation Coalition will host around the country as part of Project Innovation to identify the obstacles impeding cancer innovation and drug discovery. From these sessions, the CIC will develop a national cancer innovation policy agenda with specific recommendations for Congress and the federal and state governments to accelerate the delivery of promising new treatments to patients. Primary funding for this initiative comes from NPAF, with additional support through research grants from Celgene Corporation, Eli Lilly, Novartis and Pfizer.

More information about Project Innovation is available at www.projectinnovation.org, @projectinno on Twitter, https://facebook.com/ProjectInno on Facebook, and 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 Project Innovation
Managed by the National Patient Advocate Foundation (NPAF), Project Innovation is a new initiative to highlight the need to stabilize and accelerate innovation in cancer care. Specific remedies will be driven by a national group of stakeholders called the Cancer Innovation Coalition.

The impetus for Project Innovation was the release in June 2014 of a new 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.

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