PROJECT INNOVATION
Cancer Cures Are Born of Medical Innovation

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Cancer Innovation Forum Addresses Opportunities for Patients Through Proposed Congressional Legislation and the President's Precision Medicine Initiative

Washington, DC [March 23, 2015] – Now that Congress and the Obama Administration have set their sights on accelerating the pace of cures in the U.S., a coalition of cancer stakeholders meeting in Washington called on government leaders to put patients first when introducing new legislation and implementing the President's Precision Medicine Initiative.

The meeting, convened by the Cancer Innovation Coalition (CIC), allowed the cancer community to hear directly from lead House and Senate Committee staffers and specialists with the White House Office of Science and Technology Policy (OSTP) on federal priorities to transform cancer research and drug discovery in the U.S. Through this discussion, cancer advocates underscored the need for policies that better match patients to lifesaving clinical trials, increase data sharing, expand coverage of genetic tests, and incorporate patient experience data into the framework used by the Food and Drug Administration to assess the benefits and risks of new cancer medicines.

"Patients are the most important participants in the medical innovation process, which is why they must be the central focus of legislative and regulatory efforts designed to deliver more innovative therapies quickly and save lives," said Alan Balch, PhD, chief executive officer of the National Patient Advocate Foundation (NPAF), which manages the CIC. "Our goal is to give cancer patients a greater voice in shaping policies to accelerate the discovery, development, and delivery of promising new treatments and to expand access to these new therapies."

Based on insights from this meeting, the CIC will submit specific recommendations for empowering cancer patients to participate in clinical trials and for a regulatory structure that ensures patients, individually and collectively, are involved in the cancer research and drug development process from beginning to end.

Cancer Is Near-Term Focus of the President's Precision Medicine Initiative

One of the immediate opportunities to integrate the patient's voice is new federal policies in the Precision Medicine Initiative, which has as its near-term focus pursuing a more individualized, molecular approach to cancer care. Announced January 30 with an initial investment of $215 million dollars in the President's 2016 federal budget, the program earmarks $70 million in new funds to the National Cancer Institute to scale up efforts to identify genomic drivers in cancer and apply that knowledge in the development of more effective treatment approaches.

According to Claudia Williams, Senior Advisor for Health Technology and Innovation at the White House, cancer leads the emerging field of precision medicine, laying the groundwork for new ways to detect and treat diseases. Accordingly, NCI will use the new funds through the Precision Medicine Initiative in three areas: 1) to expand genetically based clinical cancer trials; 2) to identify approaches to overcome drug resistance in cancer treatment; and 3) to establish a national "cancer knowledge network" that will generate and share new approaches to cancer care that will improve patient outcomes.

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Building on the NCI initiative, the longer-term priority is for the National Institutes of Health to develop a national network of at least one million Americans who volunteer to participate in research. As such, this "cohort" of American patients will help plan the network and be asked to give consent for extensive genetic testing as well as behavioral and lifestyle information, all linked to their electronic health records. With appropriate protection of patients' privacy rights, data from the network will be made available to qualified researchers, setting the stage for a new way of doing research through engaged participants and open, responsible data sharing.

Explaining this will be an "all hands on deck efforts, Ms. Williams said the national cohort represents a new model for conducting science that emphasizes engaged patients and responsible data sharing.

Proposed Legislation to Keep America at the Forefront of Medical Innovation Would Expand Patient Participation in Clinical Trials and the Drug Discovery Process

As the Precision Medicine Initiative takes shape, staffers for the House Energy and Commerce Committee and the Senate Committee on Health, Education, Labor and Pensions (HELP) outlined an ambitious process by which the committees are working to introduce companion bills intended to hasten the discovery, development, and delivery of new cures and medical treatments in the U.S. While the timing differs in the House and the Senate, the goal is to have bipartisan legislation for President Obama's signature by the end of 2015.

For the House Energy and Commerce Committee, the next step through its 21st Century Cures Initiative is to release a second "discussion draft" of legislative proposals based on extensive comments to the Committee's previous 400 plus page document issued on January 27. Calling the first discussion guide "a work in progress," staffers encouraged members of the cancer community to keep new ideas coming, especially on ways to integrate patient perspectives into the regulatory process. Plans call for issuing the second discussion guide in April and to have a 21st Century Cures bill in front of front of the House around Memorial Day.

On the Senate side, a bipartisan working group is spearheading efforts to review comments in response to the report, "Innovation for Healthier Americans," also issued in January by HELP Committee Chair Lamar Alexander (R-TN) and Senator Richard Burr (R-NC). Focusing primarily on ways to modernize the FDA and NIH, the report called for stakeholder feedback by February 23 on three central questions:

- Why does it cost so much to bring new medicines through the pipeline to patients?
- Why does the discovery and development phase take so long in the U.S.?
- What can be done to modernize the Food and Drug Administration (FDA) so the agency has the scientific knowledge and new approaches to review and approve new medical products and the clinical methods used to test them at an accelerated pace?

The HELP Committee also plans a series of Senate Hearings as members work through a bipartisan process to agree on a legislative package. According to HELP committee staffers, the legislation will include legislative and regulatory changes to expand and improve early-stage research, decrease the failure rate of early-stage clinical trials, significantly increase patient enrollment in clinical trials, and reduce the barriers to efficient and streamlined clinical trials.

Although the legislative process is well underway, the committee staffers emphasized it is not too late for cancer stakeholder organizations to offer their ideas. They also stressed that innovation and patients go hand in hand, which is why a necessary component of the companion bills is to create a regulatory structure that ensures patients are involved in improving clinical trials and the drug development process.

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About the Cancer Innovation Policy Meeting and Cancer Innovation Coalition
Taking place in Washington on March 4, the meeting with lead House and Senate Committees and the White House Office of Science and Technology Policy was part of a series of forums the Cancer Innovation Coalition is holding around the country as part of Project Innovation, a national initiative highlighting the need to stabilize and accelerate innovation in cancer care.

Experts briefing the CIC members were Melissa Pfaff, MPH, health policy advisor to the Senate HELP Committee and Chairman Senator Lamar Alexander; Andi LipsteinFristedt, senior health policy advisor to the Senate HELP Committee and Ranking Member Patty Murray (D-WA); Katie Novaria, staff member with the Health Subcommittee of the House Energy and Commerce Committee; Tania Simoncelli, Assistant Director for Forensic Science and Biomedical Innovation at the White House Office of Science and Technology Policy; and Claudia Williams, Senior Advisor for Health Technology and Innovation at the White House Office of Science and Technology Policy.

Members of the Cancer Innovation Coalition include: the American Cancer Society Cancer Action Network, Inc.; American Association for Cancer Research; Association of Community Cancer Centers; Bladder Cancer Advocacy Network; Cancer Support Community; Council for Affordable Health Coverage; Colon Cancer Alliance; Community Oncology Alliance; CureSearch; Cutaneous Lymphoma Foundation; Fight Colorectal Cancer; FORCE: Facing Our Risk of Cancer Empowered; Friends of Cancer Research; National Patient Advocate Foundation; Oncology Nursing Society; Personalized Medicine Coalition; 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.

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 chair emerita.

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