PROJECT INNOVATION
Cancer Cures Are Born of Medical Innovation

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Experts at Cancer Innovation Forum Call for Policies in 2017 That Support Patient-Centered Cancer Care

Washington, DC [December, 2016] – As the nation prepares for a new President and Congress in 2017, a coalition of cancer stakeholders meeting in Washington advocated for a policy environment that supports increased access to high quality, personalized care for the more than 1.6 million people diagnosed with cancer each year.

The meeting, convened by the Cancer Innovation Coalition (CIC), used as a starting point recent policy developments that have significant potential to shape cancer care for the foreseeable future. As positive steps, advocates encouraged widespread adoption of the Center for Medicare & Medicaid Innovation's (CMMI) new Oncology Care Model as a roadmap to provide higher quality, more highly coordinated oncology care and called on clinicians to take advantage of a new tool called COST (Comprehensive Score for financial Toxicity) to assess a patient's risk for financial distress before undergoing cancer treatment.

Conversely, advocates raised concerns about efforts to develop "value-based price benchmarks" for recently approved innovative cancer therapies without patient involvement and the possible passage of federal legislation that could weaken safety standards for regenerative medicines, including cell and gene therapies.

"This is a time of both great excitement and significant concern for the cancer community. Consequently, advocates must speak with one voice to champion policies that support precision medicine and customized cancer treatment based on the best evidence and the individual needs of each patient," said Lisa Hughes, Director of Strategic Partnerships and Projects at the National Patient Advocate Foundation (NPAF), which manages the CIC. "Our goal is to create a policy environment that ensures safe and efficacious treatments reach the market as soon as possible and patients receive the most effective care personalized to match the unique aspects of their disease."

CMMI's Oncology Care Model Sets the Stage for Moving to Patient-Centered Cancer Care
Looking to the future, advocates see opportunity in CMMI's Oncology Care Model (OCM) to deliver better care for cancer patients while also lowering costs. Launched on July 1, 2016 and running through June 30, 2021, the new payment and health delivery model incentivizes physician practices to provide higher quality care to Medicare beneficiaries undergoing chemotherapy treatment through enhanced services, such as patient navigation, access to clinical trials, and improved pain management. Currently, more than 3,200 oncologists in 31 states have entered into contracts with 17 health insurance companies to coordinate care for 155,000 Medicare beneficiaries.

Under OCM, oncologists receive regular fee-for-service payments under Medicare and are eligible for a $160 per-beneficiary, per- month reimbursement (PBPM) for care management and performance-based payments for services that lead to better outcomes, smarter spending and improvements in the patient experience. Besides the two-part payment system, the program encourages commercial payers to participate in OCM and design their own payment incentives.

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Leah Ralph, Director of Health Policy at the Association of Community Cancer Centers (ACCC), which represents more than 23,000 cancer care professionals working in 2,500 hospitals and physician practices., led a discussion about opportunity and challenges in how OCM impacts physician practices to achieve their cancer care goals. A key factor is OCM's payment structure, which rewards oncologists for delivering person-centered care based on specific "proactive transformation" requirements, such as treating patients with therapies consistent with nationally recognized clinical guidelines and providing 24/7 access to a clinician when needed.

Nic Buescher, Executive Director for Cancer Services at Lancaster General Health, a health system in Lancaster, PA, discussed how the Oncology Care Model is redefining the way cancer care is delivered in the U.S., and how through OCM, government, providers and commercial health plans have the opportunity to find solutions that support better quality cancer care and lower costs.

Opportunity to Screen for Financial Toxicity

Another positive development, according to advocates attending the policy forum, is a new screening tool that determines patients at high risk of financial toxicity – defined as the financial stresses patients face from income loss and the out-of-pocket costs for their treatment. Developed by a research team at the University of Chicago and called COST (Comprehensive Score for financial Toxicity), the tool is a questionnaire containing 11 brief statements about financial concerns that identify the factors associated with financial toxicity, such as household income, psychological distress, and the number of hospital admissions.

Underscoring the importance of screening patients early, Jeremy O'Connor, MD, at the Yale School of Medicine and one of the developers of COST, said financial toxicity is directly associated with early mortality and is a growing problem among cancer patients. According to a study Dr. O'Connor and his colleagues recently published in the journal *Cancer*, between 30% and 40% of patients undergoing chemotherapy for stage IV cancers experience moderate to high levels of financial toxicity and can face poorer outcomes as a result.

Advocates Highlight Impediments to Patient-Centered Care

In terms of problems on the horizon, the policy forum examined the possibility that policies to assign a "value" to recently approved drugs for serious and often life-threatening diseases will erect barriers to quality cancer care. Of immediate concern are the efforts of the Boston-based Institute for Clinical and Economic Review (ICER), which recently issued "value-based price benchmarks" for newly approved multiple myeloma (a rare blood cancer) and non-small cell lung cancer therapies and is moving rapidly to complete assessments of novel treatments for 15 to 20 serious diseases and rare disorders by the end of 2017.

Unlike physician-guided tools, called "value frameworks," that allow oncologists to assess the cost-effectiveness of new diagnostics and therapies based on specific criteria, ICER's "value-based price benchmarks" apply a cost-effectiveness threshold when assessing the "value" of novel treatments and assign a cap on the price of each drug. Accordingly, advocates worry that ICER's findings will be used by commercial health plans to determine which new therapies are available to patients. ICER has also come under criticism from cancer organizations for applying a "one-size-fits-all" approach to assigning an economic value to different therapies, which does not reflect the reality that most cancers are not homogeneous diseases but rather a collection of many subsets of disease.

According to Andrea Stern Ferris, President and Chairman of the Board of LUNGevity, ICER's just completed evaluation of seven new therapies for non-small cell lung cancer (NSCLC) highlights the problems with ICER's review process. After publishing its draft evidence report for public comment, ICER did not involve physician specialists in NSCLC as evaluators or take into account information on the many subtypes of NSCLC and how providers sequence and combine different therapies based on the individual patient. The process, she said, is "concerning to all of us" in the cancer community because ICER's population-wide assumptions devalues the lives of patients with serious diseases, who are more expensive to treat.

Another policy concern discussed is possible Congressional action on the "Reliable and Effective Growth for Regenerative Health Options that Improve Wellness Act" or "REGROW" (S. 2689/HR 4762), a bill intended to speed access to regenerative medicine treatments, such as cell and gene therapies, by weakening regulatory requirements that ensure these treatments are safe and effective. Specifically, the bill would compel the Food and Drug Administration (FDA) to allow cell and tissue-based treatments on the market under a "conditionally approved" status without first providing rigorous evidence of safety and efficacy to the FDA.

While supporting development of more cell therapies to treat injury, burns, stroke, and many diseases, the advocates agreed the ramifications of passing the REGROW Act would be far-reaching and urged Congress not to move forward. Specific concerns include leaving patients vulnerable to unproven medicines and creating disincentives for the hundreds of American companies now following FDA's safety standards when developing new regenerative medicines.

About the Cancer Innovation Policy Meeting and Cancer Innovation Coalition
Taking place in Washington on October 26, the meeting is part of a series of forums the Cancer Innovation Coalition (CIC) hosts as part of Project Innovation, a national initiative highlighting the need to accelerate innovation in cancer care. Spearheaded by the National Patient Advocate Foundation, the CIC is comprised of: the American Brain Tumor Association; American Cancer Society Cancer Action Network; American Association for Cancer Research; Association of Community Cancer Centers; Bladder Cancer Advocacy Network; CancerCare; Cancer Support Community; Colon Cancer Alliance; Community Oncology Alliance; Council for Affordable Health Care; CureSearch for Children's Cancer; FORCE: Facing Our Risk of Cancer Empowered; Friends of Cancer Research; Lung Cancer Alliance; Men's Health Network; Oncology Nursing Society; Personalized Medicine Coalition; Prevent Cancer Foundation; Sarcoma Foundation of America and US Oncology Network.

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