

A NATIONAL INITIATIVE TO SUPPORT POLICIES THAT FOSTER PROGRESS AGAINST CANCER

Turning the Tide Against Cancer Principles: Advancing Patient-Centered Solutions for Sustaining Patient Access and Innovation in Cancer Care

The rising cost of cancer care represents a growing concern for patients, caregivers, researchers, health care providers, physician-scientists, and payers. Direct medical costs for cancer care were estimated to be \$125 billion in 2010 and are projected to rise more quickly than costs in other healthcare sectors. The reasons for this growth are varied, and include significant scientific advances that now are beginning to be translated into better approaches to diagnosis, treatment and management of cancer, as well as broader factors such as population growth, expansion of insurance coverage, and market consolidation of cancer practices into higher-priced hospital-based settings. The reasons for this growth are varied, and include significant scientific advances that now are beginning to be translated into better approaches to diagnosis, treatment and management of cancer, as well as broader factors such as population growth, expansion of insurance coverage, and market consolidation of cancer practices into higher-priced hospital-based settings.

However, this is also a time of tremendous progress. Scientific innovation has the potential to transform care and outcomes for many cancer patients, and initiatives such as Vice President Biden's Cancer Moonshot, President Obama's Precision Medicine Initiative, and privately funded programs, are generating excitement from patients, providers, researchers, payers, the biopharmaceutical industry, and policymakers, as well as the public at large.

It is in this environment of significant scientific opportunity and pressure for system-wide change that many stakeholders are offering proposals to address these challenges. Some of these proposals, while well-intentioned, risk chilling continued clinical progress against cancer by failing to recognize the changing state of science and patient care or by limiting patient and provider choice. As leaders in the field of cancer research and patient care consider transformative policy proposals, we urge policymakers to adopt those that embrace emerging science and support personalized approaches to oncology care, research, and delivery, rather than those grounded in single, population-level value thresholds.

This is a time of unmatched opportunity in which scientific innovation can lead the way to better prevention, diagnosis and treatment strategies. As leaders in the fight against cancer, we have been working with stakeholders to identify concrete, mutually agreed-upon, practical reforms that sustain progress against cancer, control spending, and result in better value. Vy, Vi, Vii, Vii, Viii, Viii The recommendations below are informed by our collective understanding of:

- the ongoing importance of putting the patient at the center of cancer care reforms;
- the rapid advances occurring in basic science and clinical research;
- our growing ability to tailor patient care based on underlying genetic and molecular characteristics of disease;
- the challenges in managing and utilizing both clinical trial and real world data; and
- growth in health informatics, decision-support tools, and alternative payment models (APMs).

Turning the Tide's goal is to advance solutions and enable efficient and effective cancer care, while fostering scientific and clinical research that addresses the unmet needs of cancer patients. In order to meet these goals, proposals must:

• Strengthen the Evidence Base for Better Patient Value

- Support the comparative effectiveness research of the Patient-Centered Outcomes Research Institute (PCORI) and encourage a greater focus on cancer research
- Leverage and learn from the clinical experience of all patients with cancer through a continuous learning system to accelerate drug development and potentially decrease costs
- Expand tools for continuous learning in oncology via reforms such as HIT interoperability and inclusion of genomic and related diagnostic data in registries as well as medical records







Identify public and private mechanisms for robust support of basic and translational research

• Develop and Apply New Tools for High-Value Decision-Making in Health Care

- Develop tools for patient-provider shared decision-making and patient-focused value assessment
- Implement evidence-based physician-driven cancer clinical pathways that keep pace with science
- Create incentives for shared decision-making in payment reform
- Amplify the patient voice and encourage patient engagement in development and use of new tools

• Expand Patient-Centered Value-Based Payment Models

- Align APMs with the development and utilization of personalized medicines
- o Strengthen quality and performance measures and evaluation techniques used in APMs
- o Engage patient and research communities early in design of new APMs
- o Ensure APMs improve quality and efficiency and maximize value across the spectrum of cancer care
- o Incentivize the development and use of innovative technologies that address quality of life issues and holistically treat patients, including prevention, risk assessment, and early detection of disease

Modernize Regulatory Pathways to Keep Pace with Science and Research

- Modernize and clarify regulatory requirements to keep pace with science and spur the introduction of highvalue advances in diagnosis and treatment
- Reduce regulatory uncertainty in the FDA review of novel medicines and diagnostics (including the coordinated review of combination diagnostic-therapeutic products)
- Incorporate the use of novel clinical trial designs and outcome measures (including biomarkers and patientreported outcomes) to accelerate clinical development

Adapt to Continual Scientific Advances and Modern Oncology Practices

- Ensure that payment models include mechanisms that support patient access to innovative treatments, and allow physicians to tailor care to individual patient needs
- Support the development of molecular diagnostics via coverage and payment policies that provide adequate reimbursement for novel, evidence-based molecular diagnostics

Ensure Transparency in Design of Tools and Models

- Establish regulatory and policy requirements to encourage collaboration in which all stakeholders, particularly patients, are translating scientific discoveries into patient care
- Ensure that demonstration and pilot programs launched by the Center for Medicare and Medicaid
 Innovation are transparent and meaningfully engage a range of stakeholders
- o Incentivize data sharing, including data related to precompetitive collaborations, clinical trial data, and federal and state electronic datasets (e.g., Medicare claims data)

 $^{{\}it viii}\ http://clincancerres.aacrjournals.org/content/early/2015/04/14/1078-0432.CCR-15-0827.full.pdf$







 $[^]i\,http://cancer progress report.org/2015/Documents/AACR_CPR2015.pdf$

ii http://www.asco.org/research-progress/reports-studies/cancer-care-america-2016#/message-ascos-president

iii IMS Health Institute. Developments in Cancer Treatments, Market Dynamics, Patient Access and Value: Global Oncology Trend Report 2015

iv http://turningthetideagainstcancer.org/sustaining-progress-discussion-paper.pdf

v http://turningthetideagainstcancer.org/-/docs/Turning-the-Tide-Roundtable-Proceedings_FINAL_062314.pdf

vi http://turningthetideagainstcancer.org/-/docs/a-pathway-for-change_turning-the-tide-against-cancer_issue-brief.pdf

vii http://clincancerres.aacrjournals.org/content/20/5/1081.full.pdf