

SPRING 2023

CANCER POLICY ROUNDTABLE



NATIONAL COALITION
FOR CANCER SURVIVORSHIP

EXECUTIVE SUMMARY

National Coalition for Cancer Survivorship
8455 Colesville Rd, Suite 930
Silver Spring, MD 20910
www.canceradvocacy.org

Spring 2023

CANCER POLICY ROUNDTABLE SPRING 2023

Since 1986, NCCS has been a trusted source in the cancer community and a leading voice in the field of cancer survivorship. For more than 20 years, NCCS has hosted twice yearly Cancer Policy Roundtable (CPR) meetings, convening diverse stakeholders to discuss pressing cancer policy issues.

NCCS convened another successful Cancer Policy Roundtable on Tuesday, April 4, 2023, with esteemed speakers from the Food and Drug Administration (FDA), Centers for Medicare and Medicaid Services (CMS), and National Cancer Institute (NCI), as well as clinicians, patient advocates, and policy experts. Topics included patient navigation, the implementation of the Inflation Reduction Act (IRA) prescription drug provisions, and the accelerated approval pathway for cancer drugs.



OPENING KEYNOTE

Otis Brawley, MD

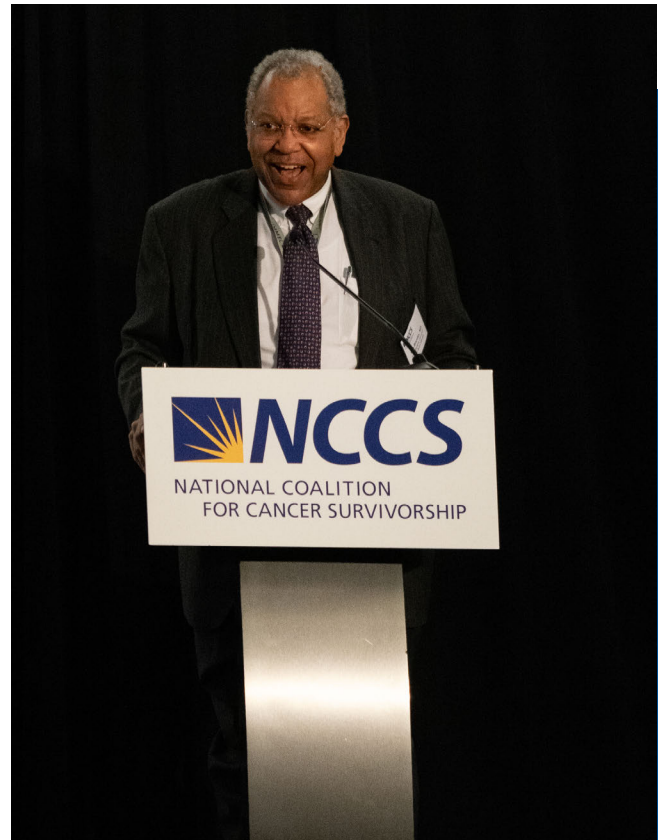
Bloomberg Distinguished Professor,
Johns Hopkins University
NCCS Board Member

For the opening keynote, Dr. Otis Brawley, Bloomberg Distinguished Professor of Oncology and Epidemiology at Johns Hopkins University and NCCS board member, delivered a presentation on the future of quality cancer control, including how we can provide high-quality care to populations that often do not receive it. He called attention to overspending and inefficiencies in the American health care system and cited estimates showing that 40% of care provided in the United States is considered unnecessary or wasteful

Part of the problem, Dr. Brawley argued, is that we often fail to follow the science and instead gravitate toward using new and expensive interventions rather than simple, inexpensive, and effective ones. He says, "Science evolves over time. As knowledge grows, the appropriate intervention may change. The practice of medicine must evolve with the science, and we need to be aware of the truths and evolve with it."

Dr. Brawley asserted that some individuals over consume resources which can be harmful to them, while others under consume resources, resulting in disparities. He says that providing access to health care can reduce health disparities. Citing Medicaid expansion as part of the Affordable Care Act as an example, Dr. Brawley explains that Medicaid expansion states experienced a reduction in disparities by race and socioeconomic status. However, disparities by state have increased due to the failure of 10 states to expand Medicaid. Now, he says, "you're better off being a black woman in Massachusetts than a white woman in Mississippi."

In closing, he calls on all survivors to understand the science and be actively involved in every facet of health care.



Cancer Care Navigation: How Can Navigation Services Improve Access to Quality Cancer Care and What is the Optimal Design of Navigation Services?

Bonny Morris, PhD, MSPH, RN

American Cancer Society

Kashyap Patel, MD

Carolina Blood and Cancer Care

Robert Winn, MD

VCU Massey Cancer Center

Sharon Rivera Sanchez

Trials of Color, Saving Pennies 4 a Cure

Shelley Fuld Nasso

National Coalition for Cancer Survivorship



In our first panel, a group of experts discussed how patient navigation services can improve access to quality cancer care and explored the challenges associated with delivering these services.

Sharon Rivera Sanchez, a cancer survivor and member of NCCS's Cancer Policy and Advocacy Team, leveraged her position as the founder of Saving Pennies 4 a Cure and Trials of Color to survey cancer survivors in her network about their personal experiences with patient navigation. During her treatment, Ms. Rivera Sanchez received limited assistance from a patient navigator who helped her schedule a few appointments. Of the cancer survivors she surveyed, many had never heard of patient navigators or had been referred to navigation services but had never been contacted. Others had to seek out navigators whose services were fortunately covered by their insurance. However, they all thought patient navigation services were or would have been helpful during their treatment.

The panelists discussed significant needs cancer patients have, including understanding treatment options and the different specialists involved, accessing support for psychosocial and financial needs, and finding resources to help with food insecurity, transportation, and housing. Dr. Kashyap Patel, CEO of Carolina Blood and Cancer Care and immediate past President of the Community Oncology Alliance, raised concerns about the fragmentation of the health system and the isolation patients experience when they are lost in the system. He adopted Mahatma Gandhi's principle to become the "voice for the voiceless," which he tries to do through navigation. He described No One Left Alone, the nonprofit organization he founded to help provide his patients with housing, employment, and health insurance assistance. Because of our fragmented system, he says providers often do not know about the

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availability of community resources for patients. He said helping patients access these resources "is not rocket science. The countries that have invested heavily in the social safety network – which is almost like the navigation system – they have about five to seven years more life expectancy compared to the US...social determinants of health actually dictate outcome." Members of the panel stressed the need for a multi-level, or team, approach to address barriers to care at multiple levels. Dr. Bonny Morris, Senior Director of Patient Navigation at the American Cancer Society and a former oncology nurse navigator, reflected on her own challenges caring for her father who was diagnosed with metastatic cancer while living in a rural community. She said,

despite her knowledge, connections, and resources, she needed support from a team of navigators, including a rural and financial navigator, to effectively address her father's needs.

Additionally, the panelists collectively stressed the importance of building trust in communities. Ms. Rivera Sanchez called for providers to partner with survivors to help bridge the gap between health systems and communities. She said survivors are in a better position to reach and build trust with the community while also bringing hope to other cancer patients. Dr. Robert Winn, the Director and Lipman Chair in Oncology at VCU Massey Cancer Center, suggested establishing stronger connections and increasing community involvement by developing activation programs within communities. Health systems can provide jobs to trusted members in the community who others could call to "activate" the patient navigation process. He said, "the investment of building trustworthiness is going to take big, bold actions and will at the end of the day save us more than it will cost... even if you have the miracle drug, they may not take it from you because they don't trust you, but they may take it from someone else."

Finally, members of the panel discussed various models of navigation to address these needs, as well as how to pay for navigation and make it sustainable. Reimbursement, they said, will be a key issue. Dr. Patel, whose community practice does not receive federal funding, discussed his use of the Chronic Care Management code, a reimbursable code that helps his practice address his patients' health-related social needs through local community resources.

AFTERNOON KEYNOTE

Ellen Lukens Deputy Director, Center for Medicare & Medicaid Innovation

Ellen Lukens, Deputy Director of the Center for Medicare and Medicaid Innovation (CMMI), delivered the afternoon keynote during which she shared the vision and future of CMMI, including next steps with the upcoming Enhancing Oncology Model, future payment models, engagement with stakeholders, and proposals in response to President Biden's Executive Order on Lowering Prescription Drug Costs for Americans.



After engaging with stakeholders, including beneficiaries, providers, health plans, and states, CMMI adopted a “refreshed” strategic vision: A health system that achieves equitable outcomes through high-quality, affordable, person-centered care. Ms. Lukens highlighted the drivers of their work that will help CMMI achieve their vision, which included driving accountable care, advancing health equity by ensuring a broad range of providers participate in CMMI’s model tests, supporting innovation among participating providers, addressing affordability for beneficiaries, and partnering with stakeholders to achieve system transformation.

In response to President Biden's Executive Order on Lowering Prescription Drug Costs for Americans, Ms. Lukens shared that CMMI proposed three prescription drug models, which supplement the work of the Inflation Reduction Act in addressing drug affordability and access. The models would cap the cost of certain generic drugs used to treat chronic conditions, provide state Medicaid programs access to costly but innovative cell and gene therapies at a lower cost, and allow for payment adjustments to accelerated approval drugs if confirmatory clinical trials that verify effectiveness and benefit have not been completed.

In closing, Ms. Lukens emphasized CMMI’s commitment to incorporating the patient voice and placing patients at the center of their work.

Implementation of Prescription Drug Provisions of the Inflation Reduction Act

Lori Reilly, JD

PhRMA

Brian Connell

The Leukemia & Lymphoma Society

Lara Strawbridge, MPH

Centers for Medicare & Medicaid Services

Tricia Neuman, ScD

Kaiser Family Foundation

Shelley Fuld Nasso

National Coalition for Cancer Survivorship



In our next panel, our panelists highlighted the challenges and opportunities of implementing the provisions of the Inflation Reduction Act (IRA). Dr. Tricia Neuman, Senior Vice President and Executive Director for Program on Medicare Policy at KFF, provided an overview of the IRA's prescription drug provisions and polling results demonstrating the public's support for reducing drug costs. She said that cost is often a barrier for patients to fill prescriptions, stating, "Doctors don't like to have conversations about costs with patients...sometimes they might prescribe a drug and not even know that their patient isn't coming in and getting that drug because they can't afford it." She also shared that most people are unaware of the beneficial provisions in the IRA. For instance, less than 30% know there is a cap on out-of-pocket spending, while two-thirds of people do not

know about the provision allowing the federal government to negotiate drug prices. Dr. Neuman said that the people who will benefit most from the provisions are people who take very expensive drugs, like cancer patients.

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Lara Strawbridge, Deputy Director for Policy within the Medicare Drug Rebate and Negotiations Group at the Centers for Medicare and Medicaid Services (CMS), focuses specifically on implementation of the inflation rebate program and drug price negotiation program. She shared CMS's plan for drug price negotiation and multiple opportunities for stakeholders to provide input into the process. To address concerns about the proposed drug price negotiation process, specifically, she referred to CMS's initial guidance that was recently open for comment. CMS will consider a number of factors before making an initial offer for a drug chosen for negotiation. They will then receive a counteroffer and schedule a series of meetings with the manufacturer to discuss the clinical benefit of the drug. CMS will also consider input from stakeholders on the clinical benefit. Ms. Strawbridge also emphasized the need to strike a balance between improving access and affordability for patients and preserving innovation. Paraphrasing Meena Seshamani, Director of the Center for Medicare, she said, "What is innovation if no patient can afford the drug?"

Brian Connell, Executive Director of Federal Affairs at The Leukemia & Lymphoma Society, described the cap in out-of-pocket costs, a hard-fought win that will make a huge difference for patients. He also discussed the smoothing provisions, which will allow patients to spread drug costs over a year rather than paying them all at once. High drug costs at the pharmacy counter, he said, can be a major deterrent for patients. For example, four out of ten patients who face a bill that is \$2,000 or more leave that drug at the counter. Both the out-of-pocket cap and smoothing provisions will be a critical benefit for patients. However, he stressed the importance of doing the outreach and education necessary for cancer patients to understand and opt in to this benefit.

Lori Reilly, Chief Operating Officer at PhRMA, celebrated the out-of-pocket cap and smoothing provisions for patients but highlighted concerns about the unintended consequences of the IRA on research and development, including the disincentives for small molecule drugs and for development of follow-on indications, which are particularly important in cancer. She emphasized the need to address other parts of the supply chain that contribute to drug unaffordability and pass along more savings and rebates directly to patients.

Accelerated Approval Pathway: FDA Actions Related to the Pathway & Developments Related to Payment for Accelerated Approval Drugs

Kelsey Lang

Avalere Health

Gautam Mehta, MD

US Food and Drug Administration

William Flood, MD

Optum Health Solutions

Shelley Fuld Nasso

National Coalition for Cancer Survivorship



Our final panel of the day addressed the US Food and Drug Administration's (FDA) accelerated approval pathway. Panelists discussed the challenge of balancing the need to get drugs to patients when they need them while also ensuring they offer clinical benefit.

Dr. Gautam Mehta of the FDA's Office of Oncologic Diseases described the recent guidance aimed at reducing clinical uncertainty during the time between accelerated approval and confirmation of clinical benefit. Accelerated approval, he explained, allows for marketing authorization based on an early clinical endpoint that is reasonably likely to predict clinical benefit. The early clinical endpoint must be verified by later trials that definitively show that clinical benefit. Oncology approvals make up over two-thirds of the accelerated approvals granted by FDA.

While accelerated approval has been an effective program, it does have some inherent risks and uncertainties. If the confirmatory trials do not verify clinical benefit, the drug is pulled from the market. To get a better understanding of why and when this happens, the FDA's Project Confirm promotes transparency of outcomes related to oncology accelerated approvals. Thus far, 183 accelerated approvals have been granted in oncology, 90 of which have verified clinical benefit and been granted full traditional approval, while 23 have been withdrawn. To optimize the program, the FDA is trying to increase the success rate and reduce the amount of time it takes between granting accelerated approval and withdrawing potentially ineffective or harmful drugs.

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Kelsey Lang, Principal at Avalere Health, explained accelerated approval reform provisions that Congress passed last year, as well as a proposal by CMMI to test a payment model that incentivizes completion of confirmatory trials. The recent reforms give the FDA the regulatory authority they need to operate effectively and in a timely manner. The reforms required the FDA to set a timeframe for manufacturers to initiate confirmatory studies, gave the FDA new authorities to revoke approvals if confirmatory studies are not completed or new evidence comes to market suggesting approval is no longer warranted, and make failure to complete a confirmatory study a criminal offense for which manufacturers can face prosecution. Previously, withdrawing an ineffective or potentially harmful drug typically required agreement from the pharmaceutical company or participation in a lengthy formalized process to remove the drug from market.

Ms. Lang highlighted the growth in the use of the accelerated approval pathway, from 7% of approvals in 2018 to 28% in 2021, which she argues has contributed to some of the scrutiny around accelerated approval. She acknowledged that FDA and CMS both have a number of levers at their disposal to address concerns with the accelerated approval pathway but must determine the best lever to ensure the balance between getting medicines to market quickly for patients with significant unmet need and ensuring that medicines are safe and effective and work for the conditions they are intended to treat.

Dr. William Flood, Senior Medical Director for Oncology at Optum Health Solutions, discussed decision-making by clinicians and patients about drugs with accelerated approval and implications of payment models tied to approval status. He referenced the Institute of Medicine's definition of value in cancer care, which is getting the patient the right treatment at the right time at the right price. Addressing the sensitivity around introducing a new therapy, as a payer, he argues that the value equation should include the analysis about how safe and how effective it is.

In closing, Dr. Mehta emphasized that accelerated approval is a program for patients, whom they always try to keep at the center of their work at the FDA. The purpose of the program is to get safe, effective drugs in the hands of patients as early as possible.

CLOSING KEYNOTE

Emily Tonorezos, MD

Director, Office of Cancer Survivorship,
National Cancer Institute

Dr. Emily Tonorezos, the National Cancer Institute's (NCI) Director of the Office of Cancer Survivorship (OCS), delivered the closing keynote where she highlighted the important work of the OCS and the challenges of delivering quality cancer survivorship care. She emphasized the importance of improving survivorship care in the primary care setting since more than two-thirds of the 18.1 million cancer survivors in the US receive their care there. Dr. Tonorezos acknowledged that primary care providers



are willing and able to take care of cancer survivors. However, there are challenges that are specific to cancer survivors who are treated in primary care. Some of the challenges primary care physicians encounter include identifying cancer history; accessing updated diagnosis, treatment history, and recommendations; identifying which provider is responsible for different components of care; communicating regularly with oncology providers and across different health systems; treating a growing number of survivors; and being aware of symptoms that may be related to a patient's cancer diagnosis and treatment.

She also touched on issues experienced by cancer survivors living with metastatic or advanced cancer. As of 2018, more than 600,000 cancer survivors in the United States are living with advanced and metastatic cancer, but they are often excluded from survivorship programs. Just like survivors with early-stage cancer, this population still suffers side effects from treatment and needs management of their comorbidities; however, they are often told that survivorship care is not applicable to them.

Dr. Tonorezos described NCI funding opportunities to address the primary care needs of cancer survivors and the needs of people living with metastatic or advanced cancer. She also discussed their efforts to support the next generation of survivorship researchers. Finally, she shared examples of how OCS interacts with advocates, highlighting meaningful stories from cancer survivors who have engaged with their office, and opportunities for advocates to get involved. Cancer survivor stories, she said, are important, "not just to other cancer survivors, but to researchers and advocates who are looking to be inspired and informed."

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877-NCCS-YES
Info@CancerAdvocacy.org