The National Cancer Policy Summit: Opportunities and Challenges in Cancer Research and Care: Workshop Summary

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The National Cancer Policy Summit

OPPORTUNITIES AND CHALLENGES IN CANCER RESEARCH AND CARE

Meeting Summary by
Margie Patlak, Sharyl J. Nass, and Erin Balogh

National Cancer Policy Forum

Board on Health Care Services

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The serpent has been a symbol of long life, healing, and knowledge among almost all cultures and religions since the beginning of recorded history. The serpent adopted as a logotype by the Institute of Medicine is a relief carving from ancient Greece, now held by the Staatliche Museen in Berlin.

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Willing is not enough; we must do."
—Goethe

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This report has been reviewed in draft form by individuals chosen for their diverse perspectives and technical expertise, in accordance with procedures approved by the National Research Council's Report Review Committee. The purpose of this independent review is to provide candid and critical comments that will assist the institution in making its published report as sound as possible and to ensure that the report meets institutional standards for objectivity, evidence, and responsiveness to the study charge. The review comments and draft manuscript remain confidential to protect the integrity of the process. We wish to thank the following individuals for their review of this report:

Nancy Davenport-Ennis, Founder, Patient Advocacy Foundation, Hampton, VA

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Barbara K. Rimer, Dean, Alumni Distinguished Professor**,** University of North Carolina Gillings School of Global Public Health, Chapel Hill, NC

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Although the reviewers listed above have provided many constructive comments and suggestions, they did not see the final draft of the report before its release. The review of this report was overseen by **Enriqueta C. Bond,** President Emeritus, Burroughs Wellcome Fund. Appointed by the Institute of Medicine, she was responsible for making certain that an independent examination of this report was carried out in accordance with institutional procedures and that all review comments were carefully considered. Responsibility for the final content of this report rests entirely with the authors.

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INTRODUCTION

Many ongoing changes are likely to have an impact on cancer research and care. For example, technological advances are rapidly changing the way cancer research is conducted, and the recently passed healthcare reform legislation has many implications for cancer care. There is a growing emphasis on molecularly targeted therapies, information technology (IT), and patient-centered care, and clinical cancer research has become a global endeavor. At the same time, there are concerns about shrinking research budgets and escalating costs of cancer care.

Considering such changes, the National Cancer Policy Forum (NCPF) of the Institute of Medicine held a National Cancer Policy Summit on October 25, 2010. The Summit convened key leaders in the cancer community to identify and discuss the most pressing policy issues in cancer research and cancer care. With panel presentations and discussions led by experts in topics such as healthcare policy, oncology research, public health, palliative care, and behavioral economics, the Summit explored policy issues related to cancer research, implementation of healthcare reform, delivery of cancer care, and cancer control and public health needs. These discussions among Summit participants and Forum members will guide the Forum's strategic planning and ensure that NCPF activities are responsive to priorities in the cancer community. This document is a summary of the Summit, authored by NCPF staff. The agenda is in the Appendix.

Several recurring themes surfaced during the meeting that participants identified as important policies issues in cancer. These themes included

- providing IT to support a learning healthcare system;
- determining new and financially sustainable models for cancer care;
- facilitating patient-centered cancer research and care, including research that documents patient quality of life and care that considers pain management and the support needed by caregivers;
- restructuring the research, clinical, and regulatory arenas to address current challenges;
- fostering precompetitive collaboration;
- taking a global approach to both health research and regulation;
- adopting standards of care and essential health benefits in the implementation of the Affordable Care Act (ACA);[1] and
- advancing successful cancer risk reduction and prevention efforts.

Many of the panelists also put forth suggestions for policy actions to address the needs and challenges they had identified. For example, it was pointed out that although a goal of healthcare reform legislation was to reduce healthcare disparities, some provisions are not consistent in this regard. The ACA prohibits health insurers from denying an individual access to an "approved" clinical trial (including those funded by the National Institutes of Health [NIH]) and requires coverage for routine patient care costs in those trials; but the legislative provisions pertaining to Medicaid do not include such language, so low-income patients could still be denied access to novel therapies in clinical trials. Several panelists suggested that this could easily be remedied. However, Medicaid is administered at the state level, and many of the healthcare reform provisions will be implemented at the state level, so there likely will be 50 different approaches to healthcare reform and Medicaid coverage policies.

Participants identified several major challenges again and again, and offered similar potential solutions. For example, combination therapies that target multiple key pathways in cancer cells are increasingly seen as the primary hope for new breakthroughs in cancer treatment. Yet the

[1] In this workshop summary, the Affordable Care Act refers to the final version of the healthcare reform law, including the Patient Protection and Affordable Care Act (P.L. 111-148) signed into law by President Barack Obama on March 23, 2010, and amended by the Health Care and Education Reconciliation Act of 2010 (P.L. 111-152) on March 30, 2010.

co-development of novel agents entails unique challenges that are not encountered when developing single agents. Panelists and Forum members repeatedly asserted that new incentives, such as increased market exclusivity, are needed to encourage drug developers to overcome these obstacles. Many participants also stressed that interoperable informatics systems will be critical for making advances in cancer research and care.

RAPID LEARNING HEALTHCARE SYSTEMS

Many of the comments voiced at the Summit centered around the goal of harnessing information technology to create rapid learning healthcare systems, in which data collected on patients can be used in real time to better tailor treatments and determine care that is the most effective with the fewest risks and costs. "The entire backbone of everything we do, for all stakeholders, will be in the area of information—gathering information in a quality way so health information exchange can take place in a real-time system," said Dr. William Dalton, president, chief executive officer (CEO), and director of the Moffitt Cancer Center. He suggested building this information system so it is useful to researchers, patients, clinicians, policy makers, and administrators, all of whom are aiming to create an evidence-based approach that will make health care more affordable, more accessible, and of higher quality. "To do this we have to build an information system that has the ability to extract data and follow patients throughout their lifetimes. . . . The patients themselves are the centerpiece—we always need to come back and say what is best for the patient," said Dr. Dalton. He added that "we can't assume we know what patients want." Many patients want to know what research is being done with their data and biological samples, so it will be important to create patient portals for information exchange, he said. The role of patient consent and information dissemination in research using patient databases was addressed in a recent IOM consensus report (IOM, 2009).

Citing the NCPF's report on rapid learning healthcare systems (IOM, 2010b), Dr. Dalton said that it described the direction in which cancer research and care should be heading, adding, "It's a grand idea, but it doesn't exist yet and must be built in an iterative process." He noted that the healthcare reform legislation will help foster a rapid learning healthcare system, with its support of accountable care organizations. These organizations provide a medical home for patients that consolidates healthcare providers and tracks the effectiveness of their care, making it

easier to gather patients' longitudinal data and to collect and store their biospecimens.

Analytical tools still have to be created, however, to enable investigators to conduct research on the data collected, according to Dr. Dalton. He envisions such tools as especially useful to patients and their physicians in helping them make informed decisions about the optimal care most likely to work for each individual patient. Ideally such decision assist tools would be rapidly construed from the data collected and analyzed in the system, he said. In addition, Dr. Dalton envisions being able to survey a database to find the most appropriate patients for enrollment in a clinical trial and contacting them directly about their participation. Policy makers will also find a rapid learning healthcare system useful for conducting comparative effectiveness research and cost analyses, he added.

"My plea as we move forward is that we consider gaining expertise and input on those that build these sort of information exchanges from all facets—academia, industry, and users. We, as a body of researchers, policy makers, and advocates, can influence how the healthcare reform is implemented and deployed, but we must be active and have a major priority be the architecture of the health information exchange that would be required," Dr. Dalton said.

Dr. Russell Glasgow, deputy director of dissemination and implementation science at the Division of Cancer Control and Population Sciences at the National Cancer Institute (NCI), and Dr. Douglas Lowy, deputy director of the NCI agreed. Dr. Lowy stressed, "The issue of information technology is one of paramount importance. It cuts across all the different aspects of research to the point of implementation. As we try to develop evidence-based research, being able to have platforms that can speak to each other is going to be of critical importance."

Interoperability

Dr. Harold Varmus, director of NCI, noted that a report from the President's Council of Advisors on Science and Technology on the design of health information systems will provide guidelines for how information technology in the healthcare arena might be implemented, including the need for standardization and interoperability of hospital computer systems (PCAST, 2010). He and others at NCI have been consulting with the White House Office of Science and Technology Policy on how to create "in the world of oncology a kind of knowledge repository that could be of immense

benefit to patients, healthcare providers, and the research community. We welcome any advice you want to give for this active process that is currently under development," Dr. Varmus said.

Dr. Ellen Sigal, chairperson and founder of Friends of Cancer Research, also stressed the need for interoperability of health information systems and the data collected by government agencies. "How are we going to synthesize this information and make it useful to make informed decisions?" she asked. "To coordinate all the data collected is a very important opportunity and very daunting responsibility. There is no way that the Patient-Centered Outcomes Research Institute (PCORI)[2] or any of these other initiatives will be meaningful unless we work with one another and figure out the interoperability," she said.

Electronic Medical Records

Drs. Dalton and Glasgow also stressed the importance of having electronic medical records (EMRs) that are complete and implemented within a healthcare information system. Dr. Dalton suggested that researchers and policy makers voice their concerns about the need for EMRs to include information that will be useful for cancer researchers. As he noted, fewer than 10 percent of ambulatory medical practices currently use EMRs with key functionalities identified by the Institute of Medicine (IOM, 2003b; Jha et al., 2006). Given the current push for the implementation of EMRs and the $19 billion in funding that the Health Information Technology for Economic and Clinical Health (HITECH) Act provided to advance health information technology, Dr. Dalton said now is an opportune time to ensure that the architecture of EMRs will be sufficient for the type of research that could be done using the data these records provide. "This community is the one that needs to influence that architecture so that research can be performed," Dr. Dalton said. Dr. Glasgow added that EMRs should

[2] PCORI was established by the Patient Protection and Affordable Care Act of 2010 (P.L. 111-148) for the purpose of "assist[ing] patients, clinicians, purchasers, and policymakers in making informed health decisions by advancing the quality and relevance of evidence concerning the manner in which diseases, disorders, and other health conditions can effectively and appropriately be prevented, diagnosed, treated, monitored, and managed through research and evidence synthesis that considers variations in patient subpopulations, and the dissemination of research findings with respect to the relative health outcomes, clinical effectiveness, and appropriateness of the medical treatments, services, and items." See also Box 2.

include patient-reported quality-of-life measures. "A number of our colleagues could provide you with a list of very practical, well-validated, very reliable quality-of-life measures that could be routinely included as part of quality metrics," Dr. Glasgow said.

Validity of Data and Observational Studies

There was also recognition of the adage "garbage in, garbage out," as Dr. Glasgow put it. That is, the usefulness of the data collected will depend on their quality, lack of bias, and thoroughness. He pointed out that there are methods for ensuring that the type of data collected in healthcare systems is sufficiently complete, accurate, and standardized to be useful for research. The U.S. Department of Veteran's Affairs is an international leader in such data curation and use in research, according to Dr. Glasgow, and the Cancer Research Network, consisting of 14 health maintenance organizations (HMOs) around the country, also has a lot of expertise and publications on this topic.

The usefulness of the data collected in a learning healthcare system also depends on their completeness. Dr. Marcus Plescia, director of the Division of Cancer Prevention and Control at the Centers for Disease Control and Prevention (CDC), pointed out that the biggest challenge the CDC has in ensuring the completeness of cancer registries is not the data coming from hospital systems but the lack of data, or lack of complete data, on people who are diagnosed with cancer in community-based practices. He expects these data to improve when more practices use electronic reporting formats. The CDC also has tried to work out ways to get better electronic reporting from sources, such as pathology laboratories, that do not currently report to it. "If we could get pathology labs to report, that would be an enormous way to pick up on a lot of these cases that are slipping through the cracks," he said. He noted that CDC has also been involved in determining what criteria physicians should have to report on in the electronic records they submit to cancer registries.

Dr. Rachel Ballard-Barbash, associate director of the Applied Research Program of the Division of Cancer Control and Population Sciences at NCI, added that NCI has made an effort to link data systems related to quality of life and patient-reported outcomes to cancer registry data to further their clinical usefulness. "The CDC and the NCI are trying to figure out how to harness the potential for informatics to do this more rapidly. But I think doing it within the context of healthcare delivery systems, where

we are looking at integrating information at the point of care and providing that information back, is probably a model that will be more relevant for immediate clinical interaction," she said. The benefits and challenges of linking patient data from different sources (especially if the data have been de-identified) was described in a recent IOM consensus report (IOM, 2009).

Dr. Plescia added that "it's challenging to make these big state government bureaucratic systems [responsible for the cancer registries] able to respond at the kind of speed that researchers need to be able to do their work." Dr. Patricia Ganz, professor at the University of California, Los Angeles, Schools of Medicine and Public Health, suggested that the cancer registry information collected by states for the CDC be expanded to include information collected by patient insurers. In response, Dr. Plescia noted that information from health insurance systems would be extremely helpful, but it is often difficult to acquire.

There was some debate on how observational studies conducted using the data collected from healthcare information systems should be utilized in addition to the gold standard of randomized, controlled studies. "We probably won't be able to just take an electronic medical record and use it for research because it wasn't created for that purpose, but for the purpose of treating the patient. It's not going to be our savior," said Dr. Kay Dickersin, professor of epidemiology and director of the Center for Clinical Trials and U.S. Cochrane Center at Johns Hopkins Bloomberg School of Public Health. Dr. Dalton agreed that using standardized electronic health records as they now exist will not be sufficient. He stressed that there is an urgent need to incorporate research into the concept of meaningful use as efforts continue to expand the use of electronic health records in clinical practice. There is now a window of opportunity to build the necessary architecture into electronic systems to facilitate research, he said.

Dr. Dickersin added that observational studies are very important for identifying harms associated with treatments and such studies are already commonly included in systematic reviews that focus on harms, but much work remains to develop the methodology for using observational data in systematic reviews more broadly. She noted that a current active area is research on methods related to systematic reviews using observational data to determine, for example, how bias might affect the validity of findings. "I don't think anybody is excluding the idea of observational studies, it's just that we have an awful lot to learn, and it depends on the question you are asking," Dr. Dickersin said.

Although recognizing that observational studies using data collected in healthcare information systems have their limitations, some participants pointed out that there are also limitations of randomized controlled trials. These trials evaluate treatments in relatively small, carefully selected populations, often without the confounding morbidities that would make the results applicable to the general population in real-world settings. "One of the biggest challenges facing cancer right now is the issue of whether the findings we are generating are valid externally for patients that cannot be entered into randomized, controlled trials, because we are not going to test all of our questions in randomized, controlled trials," Dr. Ballard-Barbash said. "We need to think about how to use statistics in our large data systems to really look at this across populations," she added. Dr. Dalton also noted, "The more patients you study that are participating in a real-time learning information system, the more you learn."

Examples of Rapid Learning Healthcare Systems

Dr. Ballard-Barbash cited the HMO Cancer Research Network as an example of a rapid learning healthcare system. This collaboration of HMOs around the country covers 11 million patients and, in one year, diagnoses more than 100,000 cancer patients. The Cancer Research Network has funding from several sources in addition to NCI, such as the Agency for Healthcare Research and Quality (AHRQ) and the CDC, who are interested in its potential to be a "population laboratory," Dr. Ballard-Barbash said, and they have agreed to a centralized approach to institutional review board (IRB) oversight for projects, with the lead institution on a particular research project managing the IRB issues.

Dr. Ballard-Barbash gave this example to illustrate that large healthcare systems already are making progress in learning from the patient data they collect. "While it is true that they are not standardized, there is a lot happening related to natural language processing and other ways to capture data that are currently in many records and are going to evolve over time," she said. Dr. Kirsten Anderson, chief of staff to the chief medical officer and senior medical director at Aetna, added that one-third of Aetna focuses on information technology that generates and stores a tremendous amount of data that is used in meaningful research. "Information technology is going to be key if we are going to make any kind of inroads to efficiency and productivity," Dr. Anderson said.

Dr. Lloyd Everson, vice chair and member of the board of directors of

US Oncology, Inc., agreed that "IT is key to the future," but added, "The question is, Where is the capital going to come from [to pay for IT]? Who can afford this?"

EVIDENCE-BASED MEDICINE

In addition to primary research conducted in randomized clinical trials and observational studies, evidence-based medicine relies upon systematic reviews and comparative effectiveness studies to ascertain which treatments work best for which patients. Dr. Dickersin focused her remarks on how systematic reviews can inform the practice of evidence-based medicine. Dr. Dickersin explained that a systematic review is a review of existing knowledge that uses explicit, scientific methods in a structured and transparent process. Systematic reviews entail a comprehensive search for relevant articles and, unlike other literature reviews, apply explicit scientific methods of appraisal and synthesis of the findings. The IOM has since released a report on standards for systematic reviews (IOM, 2011).

Practice guidelines are increasingly relying on systematic reviews, according to Dr. Dickersin, who argued these reviews are essential for a well-performing healthcare system. Dr. Dickersin noted that there are a fair number of systematic reviews being conducted at the federal level (including by the AHRQ, CDC, Substance Abuse and Mental Health Services Administration, Centers for Medicare and Medicaid Services, U.S. Department of Veterans Affairs, and U.S. Preventive Services Task Force), but the majority of these reviews are using internal programs or agency or contractual investigators. She said there is little funding for systematic reviews conducted outside of internally supported federal programs. NIH provides the major source of funding for external systematic reviews and funds systematic reviews conducted by the Cochrane Collaboration (Box 1). PCORI will also likely make funding available for systematic reviews.

Dr. Dickersin made several recommendations regarding systematic reviews. One was for NIH to provide more funding for such reviews, so that there is coverage of specific disease-related topics in the reviews that have clinical relevance. AHRQ tends to focus its systematic reviews on broad-based topics that cut across health fields and has done only a few on cancer, for example.

Dr. Dickersin also echoed several IOM recommendations made in its 2008 report *Knowing What Works in Health Care* (IOM, 2008), namely, that there be more investment in advancing the scientific methods used to

BOX 1
The Cochrane Collaboration

The Cochrane Collaboration is an international collaboration with more than 25,000 contributors that prepares, maintains, and promotes the accessibility of systematic reviews of the effects of healthcare interventions. It has done more than 4,000 systematic reviews, 314 of which involve cancer. All of the Cochrane Collaboration's reviews are published in *The Cochrane Library*, which is updated monthly. The Cochrane Collaboration is currently working with other groups, such as the AHRQ and its evidence-based practice centers, to make the data from their systematic reviews publicly available so that other researchers can use these data in their own systematic reviews.

SOURCE: Dickersin presentation (October 25, 2010).

do systematic reviews and that the capacity to conduct systematic reviews be built in the workforce by expanding training opportunities in systematic review and comparative effectiveness research methods. Additional suggestions from Dr. Dickersin included that efforts be made to learn from the methods research that has been done in other countries and that the federal government provide training grants specifically for systematic reviews, as well as infrastructure funds for investigator-initiated systematic reviews. "Let's ensure that these mechanisms are sustained and we don't break down the groups as soon as the funding is over. That's one of the advantages of funding large groups who build infrastructure and hubs of knowledge and activity," Dr. Dickersin said.

Dr. Dickersin's final suggestion was that systematic reviews be required before clinical trials are funded and that the purpose of the trials should be put within the context of a systematic review. "The bottom line is that systematic reviews are very important. I would like to see NIH, AHRQ, and all the federal agencies engaged in a cooperative effort here," she said. Dr. Lowy agreed that it is an appropriate role for NIH to fund systematic reviews and that it should leverage its resources with other agencies in order to create maximum benefit in this regard.

FINANCIALLY SUSTAINABLE MODELS OF CARE

A major focus of comments and discussion at the Summit was on how to provide financially sustainable models of cancer care, given the current economic downturn, healthcare costs that have risen exponentially in recent years, and the current interest in healthcare reform. "The economic crisis in health care is very real and it threatens the delivery of cancer care in our country," stressed Dr. Everson. "Costs are increasing more rapidly than revenue." This is especially true for cancer care, which is particularly complex and thus more costly, he noted. Dr. Allen Lichter, chief executive officer of the American Society of Clinical Oncology, concurred, noting that each oncologist supports, on average, eight staff in their office, which requires a large, reliable revenue stream. Yet he said there has been increasing reluctance of health insurers to reimburse expensive cancer care. This is driving cancer care to be offered only within hospital settings, which further increases the cost of the care, Dr. Lichter noted. "We must address cost. This is the single most poisonous thing that is going on in the field of oncology. If it continues unchecked at the pace it has been going, it will destroy the oncology care delivery system in the United Sates," he said.

Participants made several suggestions for what the elements of a financially sustainable model of cancer care would be, including the following:

- Incentives that are aligned with costs and quality
- Value-added or appropriate care that is indicated by evidence-based medicine
- Quality standards
- Coordinated care that has a team or network approach
- Innovative payment schemes

Appropriate Incentives

Dr. Everson pointed out that incentives drive the use of procedures, and the financial incentives currently in the healthcare system contribute to the fragmentation of care in many settings, with little coordination between the outpatient and inpatient settings or from primary care to specialty care. There also is no real incentive for providing quality care that leads to efficient and effective outcomes, he added. For example, Drs. Ganz and Everson both pointed out that chronic conditions account for more than 75 percent of all healthcare costs, and many chronic conditions can be

attributed to four modifiable behaviors, including the use of tobacco, lack of exercise, poor eating habits, and excessive alcohol consumption (CDC, 2009). Medical care received in the last six months of life also comprises a significant portion of total healthcare costs. Yet physicians do not receive greater payments when they take extra time to provide preventive health care that tackles these health issues or when they have a conversation with the patient and his or her family about choices regarding end-of-life care. As one participant said, "There is no alignment of incentives for the provider of health care to go after the main drivers of cost in the system." Drs. Ganz and Everson called for such alignment of incentives. Dr. Katie Horton, research professor at George Washington University School of Public Health and Health Services, noted that the recent national healthcare reform legislation has preventive health provisions to provide funding for drugs for tobacco cessation, counseling for pregnant women in Medicaid, and a Medicaid demonstration project on obesity.

Mr. Robert Erwin, president of the Marti Nelson Cancer Foundation, suggested preparing formal cancer care protocols. Various institutions and private practices could then be judged on quality, based on how well they adhere to those protocols, with the amount of reimbursement tied to their quality ratings. This would offer an incentive to provide palliative and other forms of cancer care that are currently insufficiently utilized.

Ms. Brenda Nevidjon, past-president of the Oncology Nursing Society and clinical professor of nursing and healthcare leadership at Duke University School of Nursing, added that there also have to be appropriate incentives for healthcare consumers, noting that, despite the recommendations for regular colonoscopies after age 50, many people in this age category do not have colonoscopies routinely. Mr. Steve Miller, executive vice president of regulatory affairs at the National Patient Advocate Foundation, responded that he thinks more education of patients is necessary to encourage them to adopt better cancer screening and other preventive health measures. "You do what you have to do to convince the consumer to get tested," he said.

Dr. Steven Patierno, executive director of the George Washington University Cancer Institute, added that there are other barriers to appropriate health care besides lack of health insurance. He noted that in a study he did, fully insured women of racial and ethnic minorities in Washington, DC, experienced more than a twofold time delay in the diagnosis and onset of treatment for cancer as compared to white women (Hoffman et al., in press). "Coverage alone is not going to solve all of the issues. We really do

need to address the broader sociological context and systemic issues that serve as barriers to health care, particularly for underserved populations," he said.

Dr. Peter Ubel, professor of business administration at Duke University Fuqua School of Business, stressed that there be more application of behavioral economics when determining appropriate incentives, for both healthcare practitioners and their patients. "People like me who work in behavioral economics don't believe that information is sufficient to solve many of these difficult problems. We think that a fuller understanding of human nature is necessary if we are going to develop interventions that improve people's lives," he said. Dr. Ubel pointed out that people's choices are often predictively irrational and are influenced by unconscious biases that can lead them astray and let them make decisions that actually harm their best interests.

Although he advocated a role for behavioral economics in healthcare reform, he also cautioned that behavioral interventions will not work unless basic economic incentives are also given. For example, an intervention to change physicians' behaviors so as to help them control healthcare costs might rely on giving physicians feedback about their relative use of various interventions compared to that of other physicians. However this approach will not counter the basic economic incentive for doctors to order more interventions if they receive payment for each intervention they prescribe. "You first have to line up the more traditional economics—how people are paid and how that will influence behavior—and then behavioral economics added on to that will make such payment more effective," Dr. Ubel said.

Dr. Ubel also asserted that to use behavioral economics effectively to advance cancer care, the following challenges must be met:

- Better definition of what behavioral economics means in the healthcare setting
- Determination of where behavioral economics has the greatest chance of improving medical care and health behavior
- Determination of ways to encourage medical experts to train in behavioral economics and vice versa
- Determination of ways to broaden the behavioral economics research agenda so that interventions are designed to account both for people's rational and for their irrational tendencies

One participant suggested fostering more interaction between the different worlds of laboratory and clinical science and behavioral economics, and use of the latter to devise effective risk communication and decision making tools. Dr. Ballard-Barbash responded that although behavioral research is important, social sciences and economics also "need to be at the table in trying to identify where we are going to make gains in this area."

Appropriate Care

Dr. Ganz pointed out that there are a lot of expensive technologies used in medicine, such as proton beam therapy, that have not been proven to be more effective than less expensive measures (Sher, 2010). "How can we as a community put the lid on things that are not yet ready for prime time without stifling innovation?" she asked. Dr. Scott Ramsey, member of the Fred Hutchinson Cancer Research Center, added that most economists agree that the big driver for healthcare cost increases is unrestrained, uncritical adoption of new medical technologies. "The question is, What's adding value, and what isn't? How [do we] use [technologies] effectively?" said Dr. Sigal, who emphasized the need to differentiate between effective and ineffective healthcare interventions (IOM, 2007, 2008).

As a possible solution, Mr. Alan Weil, executive director of the National Academy for State Health Policy, suggested broader application of Medicare's coverage with evidence policy. With this policy, healthcare provisions of uncertain added benefit are reimbursed with the stipulation that data are collected on the outcomes for patients treated. If those data show a lack of effectiveness, the coverage will be discontinued. In addition, Mr. Weil and other participants again stressed the importance of information technology that enables real-time learning of what medical interventions are effective.

Dr. Bruce Chabner, professor of medicine at Harvard Medical School and director of clinical research at Massachusetts General Hospital Cancer Center, noted that there are often a number of effective treatment options, but it is difficult to ascertain which one would provide the greatest good at the least amount of cost. Mr. Thomas Kean, executive director of C-Change, added that both value and cost should be considered in healthcare reform. Dr. Chabner noted that in the recent deliberations of the National Cancer Advisory Board, aimed at thoroughly assessing major NCI programs and projecting priorities for NCI for the future, some people noted "the technology [for diagnosing and treating cancer] may outpace our ability to pay for it," while others argued that dollars could

be saved by using such technology to efficiently tailor therapy to those that actually can benefit from it.

Dr. Lichter suggested that the cost of cancer care can be reduced substantially if more appropriate care is provided. He cited a recent journal article (Sima et al., 2010) documenting that nearly 20 percent of metastatic cancer patients in the Medicare program who had been receiving mammographic screening continue to receive routine mammograms, even though such screening is not appropriate in that population. He suggested that practitioners' reluctance to discuss the limited life expectancy of their patients with metastatic cancer is what is driving this inappropriate use of cancer screening. Such reluctance has led to a lack of end-of-life care planning, even though such planning improves quality of life as well as quantity of life (Kelley and Meier, 2010; Morrison et al., 2008; Temel et al., 2010), in addition to reducing cost (see also the section on palliative care and end-of-life care on page 25). Dr. Julia Rowland, director of the Office of Cancer Survivorship at NCI, added, "When we think about quality, one tenet of that is appropriate care. It's not just access to quality care but to appropriate care."

Quality Standards

Dr. Lichter advocated for quality standards and monitoring to see if practitioners are providing appropriate care, but he was critical of such quality control being fragmented and inconsistent among different parties, especially different insurers. "You are going to be out there practicing oncology and there are going to be 10 programs in so-called quality and they are all going to ask different questions. The irony in some of this is that you are going to get a star for your answer in one program and you are going to get a demerit for the same answer in another program. . . . We must somehow bring the community together and say we are going to focus on quality together as a single community with an electronic-based system," Dr. Lichter said.

As part of the quality standards for cancer, Ms. McCabe suggested making cancer survivorship a formal period of care, providing training and education for it, establishing standard follow-up care for cancer survivors, and applying quality metrics to that care. She suggested having demonstration projects for cancer survivorship care, perhaps within the Cooperative Groups or large-scale healthcare systems, such as Kaiser. She also suggested the establishment of best practices for survivorship care, and how to inte-

grate it within or across specialties and information systems and reach underserved populations.

Dr. Rowland agreed, adding that little is known about the appropriate screening for cancer survivors. "What should those tests look like for the now 13 million in this country and 27 million individuals worldwide who carry a cancer history? That's going to be a lot of money spent on screening tests that we need a better handle on," she said. Ms. McCabe agreed that although cancer survivors have a lot of follow-up visits and testing, there are few data on what effective follow-up of cancer survivors should be.

Dr. Fred Appelbaum, director of the Clinical Research Division at Fred Hutchinson Cancer Research Center, questioned whether it is feasible to have standards and treatment guidelines for the continually multiplying subsets of cancer types that are being discovered each year. Dr. Lichter agreed that the evidence base for such guidelines is lacking, but pointed out that if there were a rapid-learning oncology care system that was collecting patient data in real time about every cancer case, it would be relatively easy to quickly determine appropriate treatment guidelines for new subtypes of cancer shortly after they are identified.

Coordinated, Efficient Care

Dr. Everson suggested that the best way to provide quality, efficient, and coordinated care is to deliver it in large, integrated, and efficient networks that collect long-term data and conduct research to monitor and assess the quality of the care they provide. "Whether you call them medical homes, accountable care organizations, or networks, these organizations have invested in efficiency improvement, have an innovative strategy to deliver better care at lower cost, have access to capital, have aligned incentives with payors and technology suppliers, and are supported by robust electronic medical records and health information technology platforms," he said.

Ms. Mary McCabe, director of the Cancer Survivorship Program at Memorial Sloan-Kettering Cancer Center, suggested determining which cancer survivors are at high risk for recurrence or late effects of their treatment and should be followed by oncologists, versus those that can be adequately followed and cared for by their primary care physicians. She also recommended making increasing use of nurse practitioners, especially for the care of cancer survivors. She noted that that a Memorial Sloan-Kettering Cancer Center analysis of over 8,000 patients indicated that cancer survi-

vors were satisfied with the care they received from nurse practitioners, and preliminary data suggest only 1 to 3 percent of them decided to go back to seeing the treating oncologist after seeing a nurse practitioner.

Ms. McCabe noted that finances drive what healthcare practitioners are able to provide for cancer survivors and suggested thinking about who should be providing survivorship cancer care, as well as how to move cancer patients through a system that is a continuum of care that makes sense and has quality controls. She noted that, financially, it takes about five cancer survivors to be the equivalent of one new patient visit. In a model of cancer care she developed, nurse practitioners provide care to cancer survivors and the salaries of those nurses are recouped through payments from private and government insurers. Yet she noted that payors differ by state in whether nurse practitioner fees are reimbursable for such care. She also pointed out that some postcancer treatment, such as providing information about diet and exercise, does not have to be done via an office visit, but can be provided on a website instead or under the auspices of community groups. "There are innovative ways to think of delivering a core set of services without doing it in exactly the way that we have," she said.

Innovative Payment Schemes

Dr. Ganz pointed out that even if certain care is appropriate and warranted, such as palliative care or hospice care, it is difficult for private practitioners to figure out how to financially support it within their practices. Such care requires personnel that physicians may have to work with for only short periods of time, rather than continuously. "Who is going to bear the cost of the infrastructure for that team? The hospitals say they can't get reimbursed for it and that is really the tragedy of our current payment system," she said.

Dr. Everson agreed that "the hospital and physician get paid for what they do once it is in a certain coding system and unless you change that payment model some way, you are not going to change the cost." However he also noted that there are some experimental payment methods, such as bundled "diagnosis-related groups," used to estimate reimbursement amounts so that the payor and the provider share the risk-reward equation. Dr. Lichter added that UnitedHealthcare has just begun a pilot program in which it pays oncology practices a set amount per cancer episode, regardless of what type of care is given (UnitedHealth Group, 2010). "It makes an attempt to dissociate the procedures and especially the margin on purchase

and reselling of chemotherapy agents, and instead pays you for what you do," he said. He added, "Every system is perfectly designed to get the results it gets. This system that we have [now] is perfectly designed to get the type of care and the continual procedure after procedure that we get. It's the way we set it up and somebody has to try some new things."

One example of an approach to share risk and reward in quality and efficiency strategies is a study conducted by US Oncology, a group of more than 1,300 oncologists affiliated within a network, and Aetna. Utilizing the Level I Pathways guidelines, this study found that evidence-based care for patients with non-small-cell lung cancer resulted in equivalent survival and 35 percent cost savings (Neubauer et al., 2010). "Our experiment with the Aetna program has worked out dramatically well. But, if the cost of this whole program is borne solely by the provider community, it will never work. There has to be a partnership and sharing of risk and reward," Dr. Everson said.

Dr. John Seffrin, chief executive officer of the American Cancer Society, noted that any financially sustainable system for providing cancer care has to control the current high costs of providers. "We use less health care than any other rich nation, yet we pay twice as much for it," he said, adding "We have overuse, but we also have underuse. Some analyses about how to provide access to what you really need when you need it, and have it be affordable—that could be a great contribution."

Dr. Lichter concluded the discussion about new models for cancer care by proposing an exploration of what an ideal cancer care organization for the country would look like. "If we understood what it looks like, we would have some sense of what we need to do to sustain it," he said. He also suggested assessing how cancer care is currently distributed geographically in the United States, including how it is distributed among large cancer centers, hospital-based practices, and community practices. He noted that similar assessments of general surgeon practices revealed that as the population of general surgeons in the country has gone down, there are now areas in the country lacking access to these practitioners (Lynge et al., 2008; Thompson et al., 2005; Williams and Ellison, 2008). This finding led to efforts to ameliorate the shortages of general surgeons in certain locales.

CANCER RISK REDUCTION

Several speakers suggested there was a need for more scientific evidence to guide efforts to reduce the risk of cancer both in the population at large

and in high-risk populations. "How do we improve care, both by treating patients better and also by creating a system that will identify patients at risk and then develop, using new technologies and interventions, ways to actually prevent the disease from occurring in the first place?" asked Dr. Dalton. He noted that more educational efforts will have to be made because most physicians are currently trained to be in the "find it–fix it" mode, rather than in the prevention mode. "At this time, our healthcare delivery does almost nothing related to health behaviors and cancer," Dr. Ballad-Barbash concurred. Dr. Lowy added that "although the bulk of cancer medicine is devoted to the screening and treatment of people who have cancer, we also need to focus on trying to look at the issue of risk reduction and what we can do before cancer actually develops."

Cancer prevention efforts should not be seen as being confined to the realm of the clinic or of public health, Dr. Dalton added, because they also have a huge impact on research discovery, development, and translation, as well as on delivery of care. "It is clearly a continuum, and we can't focus on one without considering the others when we consider the overall goal," he said.

Risk reduction is also important for the growing numbers of people who survive cancer, since many of these individuals are at greater risk for developing a new cancer, Dr. Dalton noted (Demark-Wahnefried et al., 2005). These people need adequate follow-up and information about how they can reduce their risk of developing a secondary cancer, he said. To help acquire this information, researchers need to be able to follow cancer patients for the rest of their lives, not just while they are receiving active treatment or shortly thereafter, Dr. Dalton said. He suggested that patients have access to their own health records as well as the ability to contribute to them, perhaps via cancer survivor surveys. "I can't think of any better way to do it than to partner with patients and have them access and follow and contribute throughout their lifetimes," Dr. Dalton said.

The ACA puts a greater emphasis on disease prevention than this area of medicine has received in the past from policy makers, Dr. Horton noted. Once this act is implemented, insurers must reimburse, with no cost sharing, preventive services deemed effective by the U.S. Preventive Services Task Force (as indicated by an "A" [strongly recommended] or "B" [recommended] rating), vaccinations recommended by the Advisory Committee on Immunization Practices of the CDC, and preventive care and screening for women and children both in existing guidelines and in those to be developed for women by the Health Resources and Services Administration. The

ACA also calls for sustained funding for prevention and public health that can be invested in community prevention, core capacity, and building the evidence and allows for the creation of a National Prevention, Health Promotion, and Public Health Council, which will develop a national strategy for prevention and health promotion.

Dr. Seffrin pointed out that about 60 percent of all human cancers are avoidable during a normal human life span by applying what is already known today about cancer risk reduction (IOM, 2003a). He said that because there is now legislation emphasizing prevention and health promotion, suggestions are needed on how to build an effective prevention and health promotion platform as it relates to cancer.

Prevention Areas

Several specific prevention areas were discussed, including efforts related to stemming the adverse effects of tobacco use, obesity, and lack of physical activity on the development or recurrence of cancer. Mr. Danny McGoldrick, vice president for research at the Campaign for Tobacco-Free Kids, stressed that tobacco use continues to be the leading preventable cause of death in the United States, killing more than 440,000 Americans every year, including more than 160,000 from cancer. He said tobacco use is responsible for about one-third of all cancer deaths and almost 90 percent of all lung cancer deaths (ACS, 2010; CDC, 2008). He stressed however that although studies document what tobacco use interventions work, such as reducing exposure to secondhand smoke and smoking cessation programs, our progress in reducing smoking, particularly among adults, has virtually stalled in recent years "because we are not putting in place those evidence-based interventions that we know work. It's time for our actions to meet our words," he said.

Mr. McGoldrick was especially critical of states not spending their tobacco settlement dollars on smoking prevention. He estimated that less than 5 percent of the $25 billion that states receive each year from tobacco settlements is spent on prevention, which is only one-seventh of what the CDC recommends states spend on such efforts. "We have to make tobacco prevention a priority if we want to continue to make progress," he said. Mr. McGoldrick also suggested conducting research on those populations that still are most affected by tobacco use, including people of lower socioeconomic status and people with mental illness. This research may reveal how best to encourage such populations to reduce their tobacco use.

To aid tobacco policy and regulation efforts, Mr. McGoldrick suggested supporting research to document the savings in healthcare costs that successful smoking prevention or cessation programs have generated. This was echoed by another participant later during the discussion. "If we don't do a better job demonstrating not just the health benefits, but the return on investment and economic benefits of preventive health, policy makers will see the economic benefit of raiding preventive health funding as opposed to looking at the long-term benefits of getting the public more aware of the health issues," this participant said, adding that in addition to policy makers, it is important for employers and health insurers to know the economic benefits of supporting preventive health measures.

Mr. McGoldrick suggested doing research to document which substances in tobacco or the packaging of its products are responsible for their addictiveness or their appeal to children or other populations. This is especially important now that the Food and Drug Administration (FDA) has more regulatory authority over tobacco products and packaging. "If we develop the science that says this change in the product will not just reduce harm to an individual smoker, but might reduce initiation of smoking or increase cessation, the FDA has the authority to issue those standards," he said, giving an example of a recent study showing that as much as half of the lung cancer cases caused by smoking are due to changes that tobacco companies have made in the product (Burns et al., 2010, 2011). "We need really strong science for the FDA to be able to take these kinds of steps," Mr. McGoldrick stressed.

Dr. Sigal emphasized that a lot is still not known about how to prevent pancreatic, blood, or other cancers, and research could be done to fill those knowledge gaps. Dr. Ballard-Barbash suggested that such prevention research aim not just at understanding the individual within the context of his or her macroscopic environment at large, but at understanding those environmental effects on a more microscopic level, including understanding environmental effects on specific organs and the microenvironment of tumors.

Dr. Mace Rothenberg, senior vice president of clinical development and medical affairs for the Oncology Business Unit at Pfizer Inc., concurred, adding that "when you think about cancer, it's not just the tumor itself, it's the tumor in its setting—its interaction with the stroma and the microenvironment, the immune system, stem cells, angiogenesis, and countless other different elements of oncology." For example, studies suggest that obesity may influence not only the risk for developing cancer, but also how patients

respond to cancer treatment, by affecting the stromal area around tumor cells. Dr. Rothenberg stressed the need to stimulate interaction between different research areas in oncology. "How often do we see collaborations, using shared models or platforms, between someone who understands the immunology of cancer and someone studying the angiogenesis of cancer or the tumor-stromal microenvironment? That's what really stands [in the way of our] making significant and meaningful advances in some of the most refractory cancers," he said.

The contribution of obesity to cancer risk varies by tumor type. Obesity seems to have no effects on cancer risk for certain tumors, such as head or neck tumors, while increasing the risk of developing mostly hormone-related cancers, including postmenopausal breast cancer, colon cancer, endometrial cancer, pancreatic cancer, thyroid cancer, and kidney cancer, according to Dr. Ballard-Barbash. Similarly, physical exercise seems to have a preventive effect for only certain cancers. More research needs to be done to assess exactly how at the molecular level, certain environmental effects, such as obesity and physical activity, influence the development and growth of tumors, Dr. Ballard-Barbash said.

Dr. Varmus said studies currently suggest that as much as 20 percent of the burden of cancer in this country could be eliminated by eradicating obesity (Wolin et al., 2010). "It always strikes me as odd that when you hear a discussion of the importance of obesity in health, it's almost always linked to heart disease and diabetes. This threat of developing certain kinds of cancers due to obesity could drive people's incentive to get into a healthier weight class," he said.

Yet given the lack of long-term success of many weight reduction programs, Dr. Ballad-Barbash suggested focusing on public health initiatives that make changes in the environment to foster healthier behaviors that decrease the risk of obesity. For example, there are policy efforts under way related to limiting access to sugar-sweetened beverages and fostering the development of "walkable" community designs. The NIH has recently gotten involved in evaluating some of these initiatives to assess what policies work at the population level, and more needs to be done in this regard, Dr. Ballad-Barbash said.

Role of Public Health

Dr. Plescia expanded on the role of public health in cancer screening in the era of health reform. He said that outreach to encourage cancer

screening can be done at the general population level via reminders sent by government programs, as is done in some European countries. Given that a larger population will be enrolled in Medicaid once the healthcare legislation is implemented, there may be more opportunity to reach people through this program and other government programs. Presumably, more people will also be receiving primary care on a regular basis when more of them have health insurance that cover preventive measures like screening, so reminders for screening sent by primary care providers might be more effective in reaching the general population, he said. But there may still be a need to educate patients about the value of regular primary care visits and screening tests. The CDC's Task Force on Community Preventive Services[3] summarizes evidence in cancer-related areas, such as tobacco use, diet and exercise, and interventions to increase use of cancer screening.

Alternatively, there could be more targeted outreach to those at higher risk of developing cancer or of cancer recurrence, by using cancer registries. The media, as well as new communication avenues, such as e-mail and texting, can also be used to educate and encourage people to undergo cancer screening.

For each outreach option, numerous questions have to be answered with research, such as what the costs and benefits of each intervention are and which are more likely to be effective, acceptable, and ethical, Dr. Plescia pointed out. "How do we best provide outreach to the populations and influence people to take advantage of cancer screening services?" he asked. He noted that a big issue currently in public health is how to be more systematic about screening, rather than working through clinical systems. "This is a useful issue we are struggling with," Dr. Plescia said. Dr. Ballard-Barbash agreed, adding that there is increasing emphasis on using modeling and other approaches to develop more risk-based strategies to target screening to those populations that might benefit most and would suffer the fewest negative effects.

Dr. John Mendelsohn, president of the University of Texas M.D. Anderson Cancer Center, pointed out that there currently is no systematic screening for cancer in this country, and it is not clear who should undertake such screening if it is mandated. "Who should do this—the nurses, the primary care doctors, or groups of doctors that are bundled into accountable care organizations?" he asked, pointing out that in the next few years

[3] See http://www.thecommunityguide.org/about/task-force-members.html.

such determinations are going to be made as part of healthcare reform, and it would be helpful to advise the government in this regard.

Mr. McGoldrick noted the importance of involving members of the community when conducting community-based interventions aimed at lowering cancer risk, and another participant stressed the importance of tailoring information to a variety of audiences and needs.

PATIENT-BASED RESEARCH AND CARE

Several speakers and participants at the Summit called for more patient-based research and care. Dr. Betty Ferrell, research scientist at City of Hope National Medical Center, suggested there be more emphasis in health research on outcomes of primary concern to patients, such as quality of life, symptom management, and end-of-life care. Dr. Dickersin pointed out that some groups are involving patients in the peer review, steering committees, and question determinations for research, as well as in preparing lay summaries of the research for other consumers. "Yes, we want to involve patients and consumers in research, but we really don't know much about what works and who those people should be—is it the person who has experienced the disease, or should it also include a family member? We want to do some qualitative research, such as focus groups, about what's important to patients so we can bring that into our analytic studies." She suggested there be more partnerships between doctors and patients when the studies are being planned and priorities are being set, so that the most important patient outcomes are measured.

Dr. Richard Pazdur, director of the Office of Oncology Drug Products at FDA, concurred that there is a lack of assessment of quality-of-life and symptom issues in clinical trials. He said that attempts to merely add these measures into existing clinical trials have not been that rigorous and instead suggested considering a second trial to look at symptom benefit or other quality-of-life measures, in addition to the original trial, so that these measures are elevated to primary end points of the trial.

Dr. Dickersin mentioned the newly established PCORI, which is an independent institute that will be identifying national priorities for comparative effectiveness research and supporting research through other federal agencies. Dr. Ballard-Barbash also described the PROMISE (Partnership for Responsible Opioid Management through Information, Support, and Edu-

cation[4]) Initiative, which aims to develop and make available for researchers around the world patient-reported outcomes in a web-based system that can develop metrics standardized to different patient populations. NCI is currently making an effort to use some of these measures in improving and systematizing the electronic capture of data through the patient-reported outcomes and clinical trials adverse events reporting system, according to Dr. Ballard-Barbash. "Our next phase and challenge is how to implement those metrics into informatics systems and into routine clinical care," she said.

Several participants stressed the need for better patient-centered cancer care, including the following:

- Better pain management and attention to quality-of-life concerns
- More patient advocacy and caregiver support and standards
- More shared decision making
- Easily portable treatment plans
- Standards for surveillance of cancer survivors

It is important "to try to figure out a way to have patients' voices heard," said Mr. Miller, and Mr. Keane noted in his summary of the conference that "the whole concept of the patient at the center of this came up again and again—the idea of having patient-focused or patient-centered services, and actively trying to gather patient perspectives on what their experiences are like." Dr. Ballard-Barbash also suggested focusing on patient-centered economic issues, such as those tied to patient out-of-pocket expenses and lost productivity due to the chronic, late effects of cancer, which dwarf the healthcare costs related to cancer treatment.

Palliative Care and End-of-Life Care

Palliative care and end-of-life care were a major focus of many comments. Dr. Sigal noted that the Friends of Cancer Research, in conjunction with the Brookings Institution and with the support of the American Association for Cancer Research (AACR), the American Society of Clinical Oncology (ASCO), and Susan G. Komen for the Cure, recently had an informative conference, which involved a panel on pain and metrics for pain measurement, that they plan to build on (Brookings Institution, 2011).

[4] See http://www.endopromise.com/.

"It is a huge issue for patients, and it has been very hard to measure," said Dr. Sigal. Dr. Seffrin suggested that palliative care be part of the essential benefits package offered by a health insurer.

Dr. Diane Meier, director of the Center to Advance Palliative Care and director of the Hertzberg Palliative Care Institute at Mount Sinai School of Medicine, stressed that palliative care is not the same as end-of-life care, but rather is care that focuses on relieving suffering and achieving the best possible quality of life for people with serious and life-threatening illness. This is done by assessing and treating symptoms, supporting families, providing decision support, and helping match treatment to patient and family goals. "We provide a lot of practical support to make sure that people can make it in the community and don't end up back in the ER [emergency room] at 3 a.m. because of a lack of somebody to call," she said.

Dr. Meier emphasized the findings of a recent randomized, controlled clinical trial published in the *New England Journal of Medicine*, in which patients who received early access to palliative care had improved quality of life, less depression, and actually lived 2.7 months longer than patients receiving usual care (Temel, 2010). She remarked that if there were a new drug that demonstrated a three-month survival advantage in metastatic non-small cell lung cancer, people would be rushing to invest in the company making the drug.

Unfortunately, despite an increasing amount of data on the benefits of palliative care, not only in terms of quality of life and cost, but in terms of prolonging life (Kelley and Meier, 2010; Morrison et al., 2008; Temel et al., 2010), the use of this care remains low and it is often initiated late in the course of the disease, according to Dr. Meier. She said this occurs because most physicians wrongly view palliative care as a last-ditch option when there is nothing more they can do to cure a disease or stem its progression. "Palliative care is undergoing and needs to undergo a paradigm shift, particularly in cancer, from a long-held belief that has limited access to palliative care until people are clearly moribund, to a new approach that recognizes that life-threatening illness, whether it can be cured or controlled, carries with it significant burdens of suffering for patients and families, and that this suffering can effectively be relieved with modern interdisciplinary palliative care teams," Dr. Meier said. "There clearly is a need for policy-focused examination on this. The timing could not be better because of the opportunities in the health reform act," she added.

Dr. Meier suggested focusing on how to increase access to palliative care in the essential benefits package of nationally approved health insurance

plans. She also suggested that meaningful-use criteria for electronic health records should mandate documentation that the healthcare provider has determined the patient's goals and identified who the decision maker is. The National Quality Forum has called for palliative care as a high priority in standard healthcare packages, Dr. Meier said, and stressed the importance of "bringing that to implementation and reality for cancer patients in this country." Dr. Meier said palliative care consistently and markedly improves quality of life and also prolongs life. It does so at little cost because palliative care is not a procedural specialty, but rather reduces spending, making it one of the highest values in health care in this country.

Dr. Meier noted that there is a need to educate and train oncologists, as well as practitioners in all other disciplines involving the care of people with chronic disease, in palliative care. Dr. Meier called for palliative care being a competency requirement for medical and nursing schools and graduate medical education. "You can get out of a three- or four-year oncology fellowship today without knowing how to manage pain. That has to change," Dr. Meier argued. Patients and families also need to be educated about what good chronic disease management is and not view palliative care as euthanasia, she said.

Every institution that cares for patients, such as nursing homes, hospitals, and home care agencies, should also be required to have a palliative care program that meets quality guidelines as part of its accreditation or condition of participation in Medicare or as a preferred provider in a commercial healthcare system, Dr. Meier stated. In addition, she said there needs to be more of an investment in the evidence base for palliative care. Between 2003 and 2005, the total extramural NIH funding for palliative care was less than 0.01 percent of the total funding from NIH, according to Dr. Meier.

Several participants at the conference expressed concern that the most money is spent on patients during the last few weeks of their life when it has the least effect and that standards for appropriate end-of-life care are lacking. Dr. Ferrell pointed out that a huge barrier to cancer patients' receiving quality care is that they are often forced to choose between continuing their chemotherapy and other disease-focused care or opting to have hospice, so she argued that the hospice Medicare benefit in this country needs to change. Dr. Anderson responded in favor of that suggestion and added that Aetna has data to back up its policy of not requiring patients to choose between hospice care and active treatment (Spettell et al., 2009).

Caregiver Support

Participants at the Summit called for more standards for support of caregivers of cancer patients. Pointing out the time, financial, and emotional pressures involved with cancer caregiving, Mr. Miller suggested that "families be educated up front to know what the future is going to hold, at least the immediate future, and not by a physician, but by someone who can really take the time to tell them and who can be in touch with them on a periodic basis to give them support." Mr. Miller also suggested that families be engaged in discussion with either nurses, nurse practitioners, or social workers on an ongoing basis and that those professionals have the responsibility to contact the family regularly. Ms. Walsh noted that the National Association of Social Workers has developed standards for social work practice with family caregivers of older adults, which can be found on its website.[5]

Dr. Rowland added that cancer care has largely become outpatient care, with the bulk of the caregiving done by family members, "yet we do not systematically assess how they are functioning or how we can help them be better caregivers in the setting of cancer. For the growing population of those who are going to be diagnosed and live with cancer, we have to be thinking about their caregivers and what standards should be in place or how we can move that along," he said. Dr. Ferrell added that she is the principal investigator of a new training grant funded by NCI that will be exploring oncology family caregivers. The project will bring together about 400 professionals from 200 cancer centers to present what evidence there is about family caregiving and ways to improve it. She noted that the bulk of evidence in this area is in regard to family caregivers of Alzheimer's disease patients and that "there really has been very little attention to caregiving in oncology."

Some family members take the role of patient advocate, which is another role that needs support in cancer care, some participants suggested. "Physicians can't be the patient's advocate. They are too busy and they are not with the patient 24 hours a day. There needs to be some understanding on the part of government that advocacy for a particular patient is important, and families have to be better informed," said Mr. Miller. Dr. Plescia also noted the importance of what he called "patient navigation care management." Mr. Miller added that data collected by the Patient Advocate Foundation suggest patients and their advocates have multiple problems

[5] See http://www.socialworkers.org/practice/standards/NASWFamilyCaregiverStandards.pdf.

that are not sufficiently addressed by their healthcare providers, including pharmaceutical access, debt crises, and job discrimination.

Shared Decision Making

Dr. Ubel discussed the notion of shared decision making, which grew in large part out of the recognition that the right medical decision often depends on patients' values, and only an individual patient knows which values are most important in making a given decision, he said. The field of shared decision-making has promoted the development of decision aids designed to educate patients about their treatment alternatives, including the risks, benefits, and likelihood of success for each alternative. "The idea here is that patients trying to decide between chemo and radiation and surgery can integrate their own values with the information about how each of these treatments affects specific outcomes, and thereby help the clinician figure out which decision maximizes their best interests as they see them," Dr. Ubel said.

He noted however that simply giving patients information in a comprehensible manner will not necessarily lead to a rational decision by either patients or physicians. For example, patients told of a treatment having a side effect that occurs in 30 out of 1,000 people will tend to judge it more negatively than if told it has a side effect that occurs in 3 out of 100 people, because 30 out of 1,000 seems larger, even though it is not. "The research I have done in this field has shown that when you look at a decision aid, if you can find out what kinds of biases it creates, what kinds of psychological forces will be created by the decision aid, you can design the decision aid in a way that will overcome these biases," said Dr. Ubel.

The National Cancer Policy Forum will further explore the concept of shared decision-making and examine current models for how to improve it at a workshop on "Patient-Centered Cancer Treatment Planning" in February 2011.[6]

Survivorship Care

Given the growing numbers of cancer survivors, some participants called for focusing on standards of care for cancer survivors. "Some patients tell us that we do a poor job transitioning them out of active care and that

[6] See http://iom.edu/Activities/Disease/NCPF/2011-FEB-28.aspx.

it was the second worst day of their lives when they finished treatment and were shoveled off," said Dr. Patierno. He noted that some oncologists are trying to develop survivorship programs with support from grants, and he raised the question of how to work toward sustainable survivorship initiatives that address the growing population of cancer survivors.

One participant noted that not only are there more cancer survivors, but these survivors are likely to shift to different insurers and healthcare providers over time. He suggested empowering individual patients with treatment summary plans for their future care so that patients are able to easily move through different systems during the course of their care while still undergoing proper surveillance and screening. Another participant noted that there currently is no system in place for the surveillance of cancer recurrence, saying that "it's very difficult to figure out how we would go about doing that, but it's certainly something we should consider taking on." Dr. Ballard-Barbash noted that at a recent International Cancer Screening Network meeting, there was discussion of whether predictive biomarkers of cancer recurrence might indicate a differential approach to screening.

Dr. Ballard-Barbash also stressed the need to support research identifying the mechanisms that may underlie the influence of physical activity, weight control, and diet on survival for different types and subtypes of cancers. She noted that in the past 5 years, several observational studies have shown a correlation between physical activity and improved survival for breast and colon cancer. She recommended more studies, including randomized, controlled trials related to physical activity, weight control, and cancer survivorship to assess the effects of these health behaviors on various tumor subtypes, including molecular subtypes if that molecular information is known. She also suggested pooling existing cancer cohorts to gather large enough numbers of individuals with each tumor subtype to assess whether there is a significant effect of health behaviors on cancer survival.

NCI STRUCTURE AND PROGRAMS

Research continues to show that certain molecular markers are linked to greater likelihood of response to treatment, recurrence, survival, or other outcomes, such that they may help determine which treatments and post-treatment surveillance are most appropriate. This paradigm shift in viewing cancer is triggering efforts to reorganize the way cancer research is done and the way new cancer drugs and diagnostics are tested and regulated.

Several participants stressed these advances in molecularly targeted

therapies and how they point to the need for systematic changes. Dr. Chabner noted, "The growth of molecular science and targeted therapies and targeted risk assessment is rapidly transforming everything, and has to pervade everything that happens at NCI from Cooperative Groups to preventive research, to early diagnosis. The issue here is, do the NCI's structure and its programs really address the need to fully exploit this molecular science and targeted therapies?"

Recognizing the importance of genomics to cancer research, NCI recently created a new Center for Cancer Genomics, Dr. Varmus pointed out. "The creation of the center reflects not only the emphasis I see the NCI placing on genomics over the next decade in the research arena, but also the centrality of genomics in practice, with the need to incorporate education in genetics into the training of oncologists," he said. Dr. Varmus also noted that the genomic revolution is creating the need for interagency interactions—especially with CDC and FDA—and more oversight, including the need for regulations that govern the use of diagnostics and other biomarkers and new ways to conduct clinical trials.

NCI is also exploring how best to further translational research within NIH's Clinical Center, according to Dr. Varmus. He noted that NCI also plans to play a significant role in the Cures Acceleration Network called for in the healthcare reform legislation (Bruckbauer et al., 2010).

Dr. Chabner reported that the National Cancer Advisory Board would soon be releasing its report that assesses the major NCI programs and recommends future priorities for the institute. This report suggests changes for NCI that are responsive to the advent of molecularly targeted therapies, new investment by industry in the cancer drug and diagnostic discovery and development field, and fiscal restraints on the NCI budget (NCAB, 2010).

FDA REGULATION OF CANCER DRUGS AND DIAGNOSTICS

The FDA is also reorganizing the way in which it reviews oncology products, Dr. Pazdur noted. The original structure of the Office of Oncology Drug Products (OODP) included three divisions that evaluated oncology products—Biologics, Drugs, and Imaging. In 2011, the name will be changed to the Office of Hematology and Oncology Products (OHOP), with a new structure encompassing four divisions (Goldberg, 2010):

1. The Division of Hematology Products (DHP)
2. The Division of Hematology Oncology Toxicology (DHOT)

3. The Division of Oncology Products 1 (DOP 1)
4. The Division of Oncology Products 2 (DOP 2)

Review staff within the two divisions of oncology products will specialize in specific oncologic diseases (e.g., breast cancer, gastrointestinal cancer, melanoma), an approach that Dr. Pazdur noted mirrors what is currently being done in academic comprehensive cancer centers. The motivation for this restructuring was to encourage more consistency of review and improved career building of the FDA staff through increased interaction among FDA staff and outside academic investigators, he said. In addition, recognizing the growing need to combine unapproved drugs, the agency has created the DHOT, a toxicology-pharmacology division that will focus not just on routine toxicology, but on mechanisms of action. The agency also is hiring people to become thematic leaders, including leaders with expertise in clinical pharmacology or biomarkers. Dr. Pazdur also mentioned the Oncology Program at FDA, which helps to coordinate activities within the agency, such as meetings with CBER (Center for Biologics Evaluation and Research) on tumor vaccines and cellular therapies or meetings with CDRH (Center for Devices and Radiologic Health) focused on in vitro diagnostics and other cancer-related products, as well as cross-center meetings to discuss oncology drug development.

Dr. Wagner noted that a current major problem for drug development in oncology is how to handle the multiple possible drug combinations in a rational way and, from a regulatory standpoint, gaining approval of the combination of nonlicensed candidate drugs. He discussed a related issue, which is drug-diagnostic combinations, and how to validate biomarkers that predict response to specific treatments with the aim of providing targeted therapeutics. He also suggested that biomarkers be increasingly used to predict and reduce the toxicity of cancer drugs.

Dr. Pazdur responded that the FDA is currently developing a guidance on testing multiple, unapproved drugs (FDA, 2010). A major emphasis of that guidance is the need to have mechanism-of-action information before the FDA allows the candidates to be tested in combination. FDA is also considering how best to evaluate drug-diagnostic combinations, he said, and recently held a workshop on the topic. How these combinations will be regulated depends on the purpose of the diagnostic. "If someone is using the diagnostic to make a critical decision, for example, denying somebody [a particular] therapy, one may need to have a very accurate depiction of the sensitivity and specificity. If somebody is simply using the diagnostic

to identify a population that is more likely to benefit, where there is no standard therapy, one might have a much lower tolerance of what goes on in the evaluation of that drug," he said, adding that the FDA is currently developing guidance on this topic.

Dr. Pazdur raised two questions related to FDA regulation of cancer drugs that he thought would be worth exploring further. One is whether the safety oversight of oncology drugs needs to be different than that for other drugs. In particular, he questioned whether the REMS program (Risk Evaluation and Mitigation Strategies) should be applied in the same way across different therapeutic areas. He noted that there already is a restricted distribution of cancer drugs, which are used primarily by medical oncologists with specialized training, and there are mechanisms in place to monitor cancer drug toxicities. "We have investigators, as well as nursing staffs, that are quite familiar with drug safety issues. So when one takes a look at the issue of drug safety that is occupying a considerable amount of time for the drug regulatory point of view, I think we have to step back and ask the question, What is the purpose of these programs when it comes to oncology drugs?" he said. He added that the FDA plans to have a workshop with the American Society of Clinical Oncology in the near future to examine the issue of drug safety and mitigation strategies as they relate to oncology products. He stressed that the risk-benefit decisions for a drug that might be used for diabetes are much different than those for oncology drugs, which tend to be inherently unsafe, and for which there are already measures in place to deal with any drug toxicities that do arise.

The other question he raised is how to best evaluate drugs that have impressive activity in oncology (i.e., drugs that target specific molecular pathways and have initial response rates in excess of 50 percent, suggesting "home runs" in the treatment of patients). Unique study designs that could more quickly determine safety and effectiveness in clinical trials might be appropriate for these types of drugs. Such study designs could include the use of surrogate end points or early randomization right after Phase 1 studies that could detect a major improvement in overall survival.

Dr. Rothenberg suggested that traditional end points for cancer clinical trials, such as overall survival, may not be adequate, especially for assessing the value of newer targeted therapies, and should perhaps be supplanted by other end points that are biologically significant and predictive of outcome but have not served as a basis for regulatory review or approval. These innovative end points could include pathologic complete response. "We might be able to look to some of these biological end points and really understand

their clinical significance in ways that can bring new drugs forward in a more expeditious manner," Dr. Rothenberg said. Dr. Lowy responded that "what we actually need are validated surrogate end points. Clearly biomarkers end up being of critical importance." He noted that in the HPV (human papilloma virus) vaccine trials, there was sufficient understanding of the pathogenesis of cervical cancer that researchers could use moderate and high-grade dysplasia as an end point. "Because this was a prevention trial, it would have been unethical to wait until cancer developed in these patients," Dr. Lowy added.

PRECOMPETITIVE COLLABORATION

As researchers continue to uncover the molecular complexity of the network of pathways that foster various cancers, there is increasing interest in combining multiple drugs, each of which targets a key player in the network. Such combination therapy will likely require precompetitive (i.e., premarket) collaboration if these therapeutic agents are not already on the market and are sponsored by different drug companies. Dr. Rothenberg noted that there are four major obstacles to developing combination therapy: determining targets, validating those targets, determining how those targets interact, and clinically validating the drugs aimed at those targets when used in combination. Each of these tasks can be more effectively addressed by collaboration, Dr. Rothenberg said.

Dr. Dalton added that "there are definite synergisms between what different technologies, different companies, can bring. Companies are also realizing that by partnering, they actually increase their market considerably. So some strategic collaborations and partnerships are developing."

Dr. Pazdur suggested such collaborations could be fostered with appropriate incentives, such as increased market exclusivity. FDA successfully used incentives to encourage drug companies to test their adult drugs in pediatric populations, he said. The incentive FDA gave companies was increased exclusivity for six months for the entire drug moiety when it was used for a pediatric indication. "From a regulatory point of view, it is a suboptimal situation if we have to make somebody do something. . . . When you have a program that has incentives—the only thing we have, from an FDA point of view, is exclusivity—then that means something." The NCPF recently held a workshop on precompetitive collaboration (IOM, 2010a).

GLOBALIZED HEALTH RESEARCH AND REGULATION

Increasing globalization of biomedical research, especially drug development, testing, and regulation was also raised as an important issue among participants. Dr. Pazdur noted the international scope of oncology and the globalization of clinical trials, and stressed "our need to embrace it rather than flee from it."

The vast majority of clinical trials accrue patients internationally, not only from Western Europe but from Eastern Europe and Asia. "Is this a good thing? Yes. It provides answers more quickly. It provides information on subpopulations in the United States, as we are a nation of immigrants with an ever-increasing presence of Hispanic and Asian populations. So to have representation of these people in clinical trials is extremely important," Dr. Pazdur said. Dr. Lowy agreed with this statement, adding that the HPV vaccine he was involved with was tested internationally, which he thought was important given that the vaccine is destined to go to different populations, and "it is critical to be sure that your intervention is going to work across populations, and not just be useful for a particular population," he said.

Dr. Pazdur added that "it doesn't work in the economics sphere to be a protectionist, nor does it work in the scientific sphere." He suggested that the Cooperative Groups, which are responsible for running many of the major clinical trials of oncology drugs in this country, coordinate their efforts with international studies. He noted that there have been international clinical trials in which Cooperative Group trials have participated, with pharmaceutical companies running the European components of the trials. Dr. Pazdur encouraged more of these collaborations, rather than viewing the Cooperative Group trials as being in competition with international clinical trials. He said the quality of data emanating from these international trials is generally good, and the trials represent the standard of care in the United Sates. "For us to try to cast doubt on these trials by implying that they are inferior really kind of smacks of a protectionism that probably doesn't benefit anybody in the long run," Dr. Pazdur said.

Dr. Rothenberg pointed out, however, that international trials can have their own set of complications. For example, in a crossover trial, patients whose disease progresses on an experimental therapy are allowed to cross over to another therapy. Yet the type of subsequent therapy given to patients may vary from country to country, so "how will the selection of regions in

which you choose to do the trial impact the subsequent therapies of those patients, and therefore impact the outcomes of the trials?" he asked.

Dr. Pazdur also pointed out the need for consistent international regulation of drugs. He noted that the innovative regulation FDA is currently devising in relation to combinations of unapproved drugs and drug-diagnostic combinations has to harmonize with international regulations, especially with the European Medicines Agency. The FDA has regular discussions with this agency about these topics, he said.

Recognizing the rising importance of global health, the NCI is creating a new center for global health that will bring together several existing international programs of NCI and will pave the way to better partnership in research with developing countries, Dr. Varmus reported. "I believe quite strongly that, while it's difficult to bring sophisticated radiotherapy, complicated surgery, and highly expensive drugs to poor countries, there are many things we can do to lower the burden of cancer in the low- and middle-income populations of poor countries by better prevention practices, especially vaccinations against HPV and HBV (hepatitis B virus), smoking cessation programs, pain management, early detection, and using therapies that are inexpensive because they are off-patent," Dr. Varmus said.

Dr. Seffrin pointed out that the United Nations (UN) is having its first-ever, high-level meeting on noncommunicable diseases in September 2011. There have only been 28 high-level UN meetings since World War II, he noted, and only one so far has dealt with a health problem (HIV/AIDS). "This is not only our first time to get up to bat, but it's probably our only time to get up to bat, about what we might be able to do to change the fact that noncommunicable diseases are not on the global health agenda," he said. He noted that the Millennium Development Goals of the UN are silent about cancer, even though it is the number one cause of death in the world and the single greatest economic burden on the world economy—three times more costly than HIV/AIDS, tuberculosis, and malaria combined (John and Ross, 2010). He added that "if we just were able to provide what we know works today to everyone when they need it and as they need it, by 2030, we could be talking about averting . . . over 15,000 deaths per day globally."

HEALTHCARE REFORM—AFFORDABLE CARE ACT

Dr. Horton gave a presentation on the major provisions of the recently passed ACA, which are summarized in Box 2. Dr. Horton noted that much

of the implementation of the ACA will be occurring within the next four years. Mr. Weil pointed out that states will be instrumental in implementing many of the provisions in the legislation, including those to expand coverage and preventive health measures. Dr. Horton, Mr. Weil, and others then pointed out ways in which oncology stakeholders can monitor and influence the implementation of the ACA, especially in regard to determining the essential benefits that will have to be offered by qualified health insurance plans, the funding that is allocated to carry out some of its provisions, and gaps in coverage that need to be closed.

Essential Health Benefits

Dr. Horton noted the importance of defining the essential health benefits package of qualified plans. "What do you get as part of this minimal package or standardized package? How do you influence that at the federal level? That's very important," Dr. Horton said. Both she and Dr. Seffrin noted that such a package could specify palliative care, for example. Dr. Horton added that there is opportunity to inform and influence the National Prevention and Health Promotion Strategy that will be developed and its advisory council. Mr. Joseph Glick, founder of Expertool Software, suggested developing standards for risk-benefit analysis and cost calculation. These standards could perhaps be required on both the provider and the payor side and considered when determining essential benefits. "Neither the payors nor the providers are looking at cost-benefit in a standardized way," he said.

Funding and Implementation

"There is a lot of authorization language in [the ACA], but not many appropriations. So if Congress makes an effort to defund, most of these provisions are out of luck," Dr. Horton pointed out. She added that the legislation could potentially be repealed or deemed unconstitutional at some point in the future. Dr. Seffrin doubted that the legislation would be repealed, although he acknowledged that it is likely to undergo changes and that "the important point is that we will be dealing with a new platform for delivery and we have to make sure that we build a better platform than what we have—that we get it right."

Dr. Seffrin noted that the American Cancer Society is focusing more than three-quarters of its advocacy activities for the next four years on

BOX 2
AFFORDABLE CARE ACT (ACA)

The main goals of the ACA are to provide broad health insurance coverage and improve the fairness, quality, and affordability of that coverage, improve healthcare value and efficiency, strengthen primary care access, and invest in public health. The ACA establishes a health plan exchange marketplace for insurance products that meet certain federal and state standards, which are called qualified health benefit plans. These plans are required to cover "essential benefits," which have yet to be fully defined.

The stipulations of the ACA that are especially relevant to cancer patients and providers include the following:

- Children up to age 26 can enroll on a parent's plan, and exclusion based on preexisting conditions is prohibited for children, effective July 1, 2010.
- Adults with preexisting conditions, beginning in 2014, cannot be denied coverage or be forced to pay more based on their health status or gender.
- Insurers cannot drop coverage because of an individual's participation in a clinical trial. The legislation prohibits the denial of coverage of routine care costs of participants in certain clinical trials, including FDA-approved drug trials and federally funded clinical trials that treat cancer or other life-threatening diseases. However as currently devised, it does not mandate coverage of routine care costs of Medicaid participants in clinical trials, although that is an option for states, if they are willing to fund it.
- Medicaid will be expanded to cover all nonelderly, nondisabled citizens and legal U.S. residents with family incomes below 133 percent of the poverty level and will provide preventive care for those individuals. However, coverage of preventive screening

efforts to ensure that the many regulations related to ACA implementation meet the needs of cancer patients. Dr. Seffrin said there is a need for scientifically based recommendations in the areas of cancer prevention, palliation, quality of life, cost containment, and appropriate care. Dr. Glasgow suggested conducting mathematical modeling of healthcare reform so as to see the effects of different policy options. He suggested that such modeling

benefits for adults in "traditional" Medicaid eligibility categories is not required.

- Medicare benefits will be expanded to include preventive measures deemed effective by the United States Preventive Services Task Force, and screening for women and children recommended by the Health Resources and Services Administration. There will be no cost sharing for these preventive measures. Another new Medicare benefit will be an annual wellness visit and the development of a personal prevention plan.
- A multipayor national quality improvement strategy will be offered, as well as continued movement toward provider reimbursement tied to quality outcomes.
- Demonstration projects will be done on medical homes, gain sharing, medical liability, bundling, geographic payment variation, and accountable care organizations.
- The Patient-Centered Outcomes Research Institute will be established.
- The Center for Medicare and Medicaid Innovation will align payment incentives in areas of treatment planning and follow-up care planning with nationally recognized evidence-based guidelines for cancer care.
- There will be increased scrutiny and control over health insurer cost increases.
- The act calls for sustained funding for prevention and public health and the establishment of a National Prevention and Health Promotion Strategy and Council, and provides a new grant program for community prevention.
- Lifetime and certain annual coverage limits will be banned. Such caps have been a prominent reason for underinsurance and delays in seeking tests and treatment.

SOURCE: Horton presentation (October 25, 2010).

could detect unanticipated outcomes "before we have to go through the pain of a large clinical trial to find that out."

Mr. Weil noted that states could hamper effective implementation of ACA by not providing sufficient funding or by further limiting coverage. "All roads to implementation run through the states. If we are going to get this right, it's not just a matter of rules at the federal level, but also imple-

mentation choices at the state level," Mr. Weil said. For example, half the expansions in coverage that the legislation stipulates are in the Medicaid program, which states administer. "We know that, for cost containment reasons, states often set up administrative barriers that go beyond the eligibility criteria, and outreach is done at the state and local levels," Mr. Weil said. This means that federal eligibility expansions essentially will not be implemented unless states make their eligibility systems work effectively, Mr. Weil said.

States can also influence the continuity of care as low- to middle-income patients move from being covered by the Children's Health Insurance Program or Medicaid to participating in a qualified insurance plan. States may or may not put continuity rules in those programs that specify benefit design and actual providers. "Continuity is going to be a huge issue, largely determined at the state level," Mr. Weil said.

He also pointed out that although the federal law changes how insurance is regulated, for example, by eliminating preexisting condition exclusions and by rating changes, it is up to the states to enforce those rules. "If states take those changes seriously and have the resources to do the oversight with health plans, we will see improvements. If they don't have the resources, those changes will be on paper, but they won't be in reality," Mr. Weil said.

State budgets and rules will also determine implementation of many of the public health measures the ACA stipulates, as well as quality standards and pay-for-performance rates. States are also responsible for the risk adjustment systems within the insurance exchange, which will ensure that health plans have appropriate incentives to cover people with higher costs. "We have tremendous potential for improvement in cancer care associated with the implementation of the Affordable Care Act, but effective implementation is going to rely heavily on the states. So as you are thinking about how to make a difference, how to achieve the potential, do not just look at the federal government, but also support the efforts going on within your states," Mr. Weil said.

One participant pointed out the lack of capacity and sophistication of some state health departments and legislatures and the need for strategies to influence implementation of the ACA at the state level. Yet as Dr. Glasgow and Mr. Weil both pointed out, an advantage of the state implementation process is that states often take the lead in public healthcare innovations with their experimental programs, whose results pave the way for universal implementation nationwide.

Mr. Weil noted that although many of the provisions of the legislation will be implemented by 2014, some will not be in effect until as late as 2021, so there is still the opportunity to engage in workshops or studies that would influence the implementation of the bill. "Think about the time line that health reform is under. Some things are already out of the chute, and other things have yet to happen," Mr. Weil said. Dr. Ferrell added that "health reform is more than just shifting of the funding. . . . In each of these provisions there is also an opportunity for us to really rethink the quality of care that's delivered to real patients and families."

Coverage Gaps

There will be several potential gaps in coverage with the advent of the ACA that Dr. Horton pointed out. She noted that the National Breast and Cervical Cancer Early Detection program and similar existing programs will expire within several years. It is not clear if the ACA will be sufficient to extend the preventive care those programs provide in an environment of tight discretionary dollars. "How do you begin to make the case to continue other programs like this as needed?" Dr. Horton asked.

While the ACA provides coverage of routine care costs related to clinical trial participation for state-regulated insurance and employer-sponsored plans, this provision is not applicable to Medicaid, although states may cover the routine costs associated with clinical trial participation through their own funding initiatives (Rosenbaum et al., in press). Dr. John Hohneker, senior vice president and head, Global Development and Integrated Hospital Care at Novartis Pharma AG, asked how to achieve uniform implementation of the legislation in this regard at the state level so that "cancer patients in California are treated the same as cancer patients in Iowa," he said. Mr. Weil agreed that attention to this is warranted.

Dr. Horton also pointed out that Medicaid will be expanded to cover all nonelderly, nondisabled citizens and legal U.S. residents with family incomes below 133 percent of the poverty level and will provide preventive care for those individuals. However, the ACA doesn't require coverage of preventive screening benefits for adults in "traditional" Medicaid eligibility categories, which tends to comprise the poorest women who are caretakers of minor children and disabled nonelderly adults, creating a gap in coverage for this vulnerable population.

CLOSING REMARKS

At the conclusion of the Summit, Mr. Kean provided a wrap-up of the day's discussions and offered some thoughts for consideration. He noted that the concept of keeping the patient at the center of focus came up again and again. Many participants spoke about patient-focused or patient-centered services, about gathering patient perspectives on their experiences, and about patient empowerment. With regard to cancer prevention, there were some provocative ideas around diet, weight control, physical activity, and reducing tobacco use, he said.

Many discussions focused on research opportunities, but there was also frequent mention of a lack of metrics, methodologic and analytic tools, and technologies needed to accomplish the goals identified. For example, health IT is often looked upon as the solution to many ongoing challenges in cancer research and care, but there are also many challenges associated with implementing effective, integrated IT systems.

Many participants emphasized the need to both increase the quality and lower the cost of cancer care. In some ways, these goals may seem at odds with each other, but aligning incentives of patients, physicians, and payors could help to achieve both goals, Mr. Kean observed. At the same time, impending workforce shortages in oncology care and continuing disparities in access to health care among various populations and geographical regions will have to be considered as well, he noted. The ACA aims to address such disparities, but implementation of many provisions remains uncertain and will likely vary among the states.

Mr. Kean noted that several participants suggested that the cancer field is in a position to lead the charge in trying to solve some of these difficult challenges, because of the infrastructure and mechanisms that are in place. At the same time, he noted that the cancer community is under incredible pressure to do more with fewer resources. Acknowledging these challenges, he called on Summit participants to work on concrete ideas to improve the quality of cancer research and care.

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Appendix

Summit Agenda

October 25, 2010
St. Gregory Hotel & Suites
2033 M Street, N.W.
Washington, DC 20036

Purpose The National Cancer Policy Summit, held by the National Cancer Policy Forum (NCPF), will convene key thought leaders in the cancer community to identify and discuss the most pressing policy issues in cancer research and cancer care. Discussions between invited panelists and NCPF members will guide the Forum's strategic planning and ensure that NCPF activities are responsive to priorities in the cancer community.

8:00 am Welcome, Objectives of the Meeting
Harold Moses, Chair, National Cancer Policy Forum

8:10 am **Panel Discussion 1: Science of Cancer Research**
Moderator: Ed Benz, Jr., Dana-Farber Cancer Institute
Panelists will identify policy issues surrounding the opportunities and challenges in the various stages of cancer research and discuss ways to advance the field. Topics may include the following:

- Basic, translational, and clinical research
- Synthesis of evidence and addressing research gaps
- Economic issues

William Dalton, H. Lee Moffitt Cancer Center & Research Institute
Kay Dickersin, Johns Hopkins University
Douglas Lowy, National Cancer Institute
Richard Pazdur, Food and Drug Administration
Mace Rothenberg, Pfizer

9:55 am **Perspectives from the National Cancer Institute**
Harold Varmus, Director, National Cancer Institute

10:35 am **Break**

10:45 am **Panel Discussion 2: Implementation of Healthcare Reform**
Moderator: Tom Kean, C-Change
Panelists will discuss how the intent and timing of healthcare reform will impact oncology care. The goal will be to identify topics that would benefit from a Forum evaluation prior to the implementation of different provisions of healthcare reform. Topics may include the following:

- Impact on healthcare services and cancer care
- Implementation at the federal, state, and local levels
- Center for Medicare and Medicaid Innovation, and payment reform
- Patient-Centered Outcomes Research Institute
- Economic issues

Overview of healthcare reform implementation
Katie Horton, George Washington University

John Seffrin, American Cancer Society
Ellen Sigal, Friends of Cancer Research
Alan Weil, National Academy for State Health Policy

12:30 pm **Lunch (please pick up lunch and return for presentation)**

12:50 pm **Report from the National Cancer Advisory Board (NCAB) Working Group**
Bruce Chabner, Dana-Farber/Harvard Cancer Center

1:30 pm **Panel Discussion 3: Delivery of Cancer Care**

Moderator: Betty Ferrell, City of Hope

Panelists will focus on important policy issues in the delivery of cancer care, with consideration of perspectives from patients and families, the cancer workforce, and payors, with the goal of improving care. Topics may include the following:

- Disparities and access issues in cancer care
- The impact of demographics on cancer care
- Patient and family caregiving issues
- Palliative care
- Cancer survivorship
- Cancer workforce issues
- Models of care delivery
- Economic issues in care delivery

Kirsten Anderson, Aetna
Lloyd Everson, US Oncology
Allen Lichter, American Society of Clinical Oncology
Mary McCabe, Memorial Sloan-Kettering Cancer Center
Diane Meier, Mount Sinai School of Medicine
Steve Miller, National Patient Advocate Foundation

3:25 pm Break

3:35 pm Panel Discussion 4: Cancer Control and Public Health Needs

Moderator: Peter Bach, Memorial Sloan-Kettering Cancer Center

Panelists will address policy issues in the prioritization of public health research needs in cancer and population-based cancer control activities, both internationally and in the United States. Topics could include the following:

- Global initiatives in cancer
- Tobacco control
- The obesity epidemic and its impact on cancer
- Cancer communication and public education
- Surveillance system needs and opportunities in cancer
- Economic issues

Rachel Ballard-Barbash, National Cancer Institute
Daniel McGoldrick, Campaign for Tobacco-Free Kids
Marcus Plescia, Centers for Disease Control and Prevention
Peter Ubel, Duke University

5:15 pm **Closing Comments, Wrap-up**
Tom Kean, C-Change

5:30 pm Adjourn