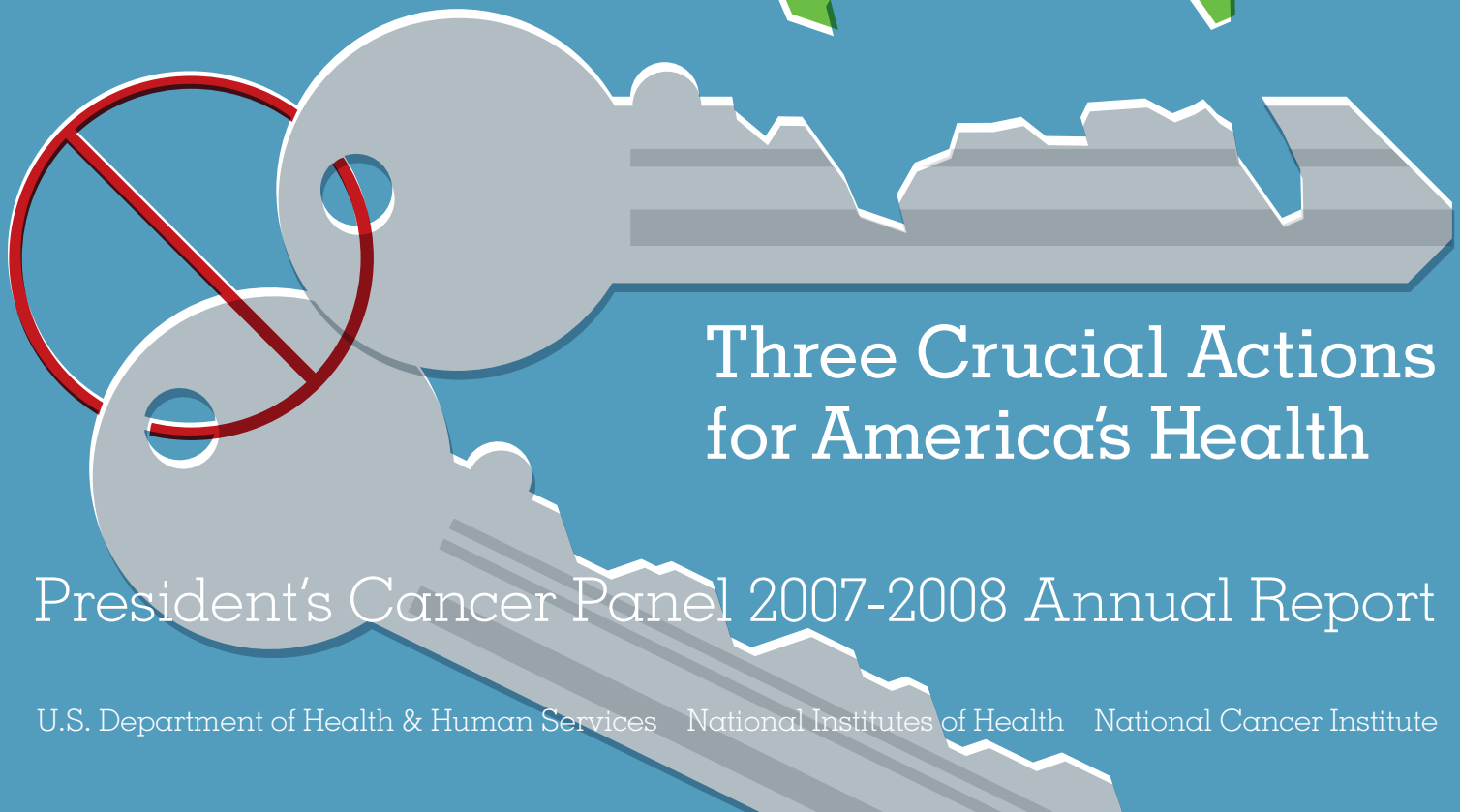
Maximizing Our Nation's Investment in Cancer:



Three Crucial Actions for America's Health

President's Cancer Panel 2007-2008 Annual Report

U.S. Department of Health & Human Services National Institutes of Health National Cancer Institute

The President's Cancer Panel

Chair:
LaSalle D. Leffall, Jr., M.D., F.A.C.S.
Charles R. Drew Professor of Surgery
Howard University College of Medicine
Washington, DC 20059

Members:
Lance Armstrong
Founder
Lance Armstrong Foundation
Austin, TX 78746

Margaret L. Kripke, Ph.D.
Special Advisor to the Provost
The University of Texas M. D. Anderson Cancer Center
Houston, TX 77030

This report is submitted to the President of the United States in fulfillment of the obligations of the President's Cancer Panel to appraise the National Cancer Program as established in accordance with the National Cancer Act of 1971 (P.L. 92-218), the Health Research Extension Act of 1987 (P.L. 99-158), the National Institutes of Health Revitalization Act of 1993 (P.L. 103-43), and Title V, Part A, Public Health Service Act (42 U.S.C. 281 *et seq.*).

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For further information on the President's Cancer Panel or additional copies of this report, please contact:

Abby B. Sandler, Ph.D.
Executive Secretary
President's Cancer Panel
6116 Executive Boulevard
Suite 220, MSC 8349
Bethesda, MD 20814-8349
301-451-9399
pcp-r@mail.nih.gov
http://pcp.cancer.gov

Maximizing Our Nation's Investment in Cancer:

Three Crucial Actions for America's Health

President's Cancer Panel 2007-2008 Annual Report

Suzanne H. Reuben for The President's Cancer Panel

September 2008

U.S. Department of Health & Human Services National Institutes of Health National Cancer Institute

The President
The White House
Washington, DC 20500

Dear Mr. President:

For many in the nation, the ravages of cancer have become simply an awful part of life. Every day, 4,000 people in America learn they have cancer, and their lives are forever changed—marked by suffering, insecurity about the future, and in many cases, dire financial hardship. And each day, another 1,500 Americans lose their lives to cancer.

Few in this country have been untouched by cancer—whether due to their own diagnosis, or that of a relative, friend, or coworker. Yet somehow we have become complacent about this fearsome disease and have lacked the will to change aspects of our cancer-fighting enterprise that are preventing significant and rapid reductions in cancer mortality and morbidity. In effect, we are allowing a "bioterrorist within" to attack almost a million and a half Americans and kill more than 560,000 of us each year. With our population aging, these casualties will increase rapidly in the coming years, despite encouraging but small decreases in cancer mortality and longer survival for some patients.

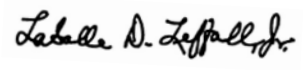
Mr. President, this report recommends three crucial actions to reduce the terrible toll of cancer:

- Make reducing the cancer burden a national priority.
- Ensure that all Americans have timely access to needed health care and disease prevention measures.
- End the scourge of tobacco in the United States.

We already know how to vanquish much of the epidemic of suffering and death caused by cancer. If no one in America used tobacco, we could avoid one-third of all cancer deaths. If all Americans benefited from behavioral, early detection, and treatment interventions we already know are effective, millions would never be faced with a cancer diagnosis and the prospect of premature death. The benefit to our nation in lower health care costs and heightened productivity would be an untold bounty to our economy and our national well-being.

Further, with your leadership and with reinvigorated and appropriately supported cancer research and care programs, we will be able to hasten the day when cancer is a largely preventable and easily treatable malady, and retain our place as the pre-eminent worldwide center for cancer and other biomedical research. The President's Cancer Panel urges you to act rapidly and decisively to save millions of American lives.

Sincerely,



LaSalle D. Leffall, Jr., M.D., F.A.C.S.
Chair

Lance Armstrong

Margaret L. Kripke, Ph.D.

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Executive Summary

Over the past several years, the President's Cancer Panel (the Panel) has noted a troubling confluence of trends, including:

- A cancer research budget declining both in dollars and purchasing power
- Needless inefficiencies in and insufficient collaboration among government, voluntary, industry, and academic components of the cancer research enterprise
- Growing questions about the focus and principal emphases in cancer research given limited declines in mortality and morbidity and increased incidence and mortality from several cancers
- An aging and progressively more sedentary population
- An ever more dysfunctional and unsustainable health care system
- Steady erosion of public and private health care coverage, with rising numbers of uninsured, underinsured, and underserved Americans
- Ongoing tobacco use, shrinking cancer control funding, and intensive tobacco company product development and marketing targeting youth, women, and other vulnerable populations
- An apparent complacency and/or lack of understanding among policymakers, the research and health communities, and the public about the escalating burden of cancer and a lack of urgency to confront the present and looming national cancer crisis

Between September 2007 and January 2008, the Panel convened four roundtable meetings to identify actions that would yield the greatest reductions in cancer mortality and morbidity. The Panel elicited the perspectives of nearly 40 experts from government, industry, the advocacy community, and the fields of clinical medicine, cancer research, health policy analysis, epidemiology, economics, insurance, public health, and journalism. Their diverse views informed the Panel's recommended actions and suggested strategies for realizing them.

The Cancer Burden

By current estimates, approximately one in two men and one in three women—more than 40 percent of the U.S. population—will develop cancer at some point in their lives. In 2008, more than 1.4 million new cases are expected, and more than 565,000 people will die from cancer. Despite declaring a national war on cancer in 1971 and investing many billions of dollars since then to understand and defeat cancer, our success against the disease in its many forms has been uneven and unacceptably slow.

Without question, important gains have been made—in knowledge about the nature of cancers, in early detection and treatment for some cancers, and in cancer survival and quality of life for many patients. At the same time, however, incidence is rising for several cancers and the most intransigent of malignancies remain impervious to treatment. We still lack early detection methods for most cancers, and both proven cancer prevention and absolute cure remain elusive. Lack of more substantive progress in these critical areas is particularly disquieting as we face a rapidly approaching tidal wave of cancer as the population ages, tobacco use continues, and the percentage of Americans who are sedentary and obese rises.

The Cancer Enterprise

Several issues cut across much or all of the cancer enterprise, and are relevant to biomedical research and health care generally. Data systems and data sharing mechanisms—linking research, public health, surveillance, and patient data—are essential both to advance research and care and to enable us to determine if research discoveries and interventions across the care continuum are indeed reducing cancer mortality and morbidity. Such metrics currently are largely absent.

Human capital is arguably the most essential infrastructure component of any complex enterprise. The cancer research workforce is aging, and severely limited research funding is causing young investigators to leave academic cancer research for industry or to pursue other careers. Similarly, the cancer care workforce is aging; significant shortages in the supply of oncologists, primary care providers, nurses, and other providers are projected to coincide with rapidly increasing demand over the next 20 years. Failing to address workforce issues will undercut any other attempts to improve the research and health care systems.

In addition, all of the major stakeholders in the cancer enterprise—the public, cancer patients and survivors, health care providers and payers, academic and industry researchers and administrators, advocates, and policymakers—need clear and unbiased information in order to better understand the cancer crisis in this country and why they must participate and collaborate to meet the challenges of overcoming cancer as a threat to health and life.

Recommendations

The President's Cancer Panel believes three crucial actions must be taken to achieve substantial and more rapid reductions in cancer mortality and morbidity:

Recommendation 1: Preventing and Treating Cancer Must Become a National Priority

The Panel believes that the leadership needed to maximize investments in the cancer enterprise and dramatically reduce cancer mortality and morbidity must come from the President of the United States. Making cancer a national priority will require stronger and more stable support for cancer-related research and progress milestones, to which the research and delivery components of the cancer enterprise are held accountable.

Despite minimal coordination and fragmented, uneven leadership, the National Cancer Program (NCP) has made important strides against some types of cancer. But with our nation at the cusp of transformative approaches to treating cancer, and with an impending upsurge of cancer incidence in our aging population, we dare not wait any longer to make achieving rapid progress in cancer research, prevention, and care an urgent national priority. The NCP must have strong leadership and coordination across the breadth of the cancer enterprise to reorder current research and cancer care funding emphases, provide necessary resources, and catalyze collaborations that will most effectively minimize suffering and death from this disease.

Recommendation 2: All Americans Must Have Timely Access to Needed Health Care and Prevention Measures

Small, incremental health care system and insurance coverage changes—each of which takes years to enact and is fraught with political and ideological entanglements—are not adequately addressing fundamental health care system problems that keep costs spiraling upward and erode Americans' access to care. This approach is a failure and will not markedly reduce morbidity and mortality from cancer either now or in the future as the cancer epidemic mounts.

Despite America's higher health care spending per capita than any other nation, its health outcomes fall short of those in numerous other countries. The number of uninsured, underinsured, and underserved people in the United States continues to grow, and the system remains fragmented and competitive rather than integrated and collaborative. Access to care is eroding, particularly among young adults, non-elderly adults with chronic conditions, and those dependent on publicly funded health services. We do not apply cancer-related interventions known to be of benefit to all, and minorities and the underserved continue to suffer disproportionately from cancer. In large measure, third-party payers and employers decide what types of care will be available to patients and under what circumstances. Recognition of the benefits of promoting wellness and disease prevention is growing, but has yet to be integrated into the standard of care; the system continues to focus principally on the treatment of acute disease.

A new American health care system is urgently needed—one in which patient priorities drive system design. This new system must ensure that all adults and children have a regular and coordinated source of care, reward all participants for adopting and maintaining a wellness orientation, and encourage community members and health care providers to participate in clinical research.

Recommendation 3: The Scourge of Tobacco in America Must End

Ridding the nation of tobacco is the single most important action needed to dramatically reduce cancer mortality and morbidity. There is no substitute for this action if we are to eliminate the sickness and death caused by tobacco use.

Tobacco use is the number one cause of preventable death in the United States. There is no safe level of tobacco use. Smoking is associated with increased risk for at least 15 types of cancer and numerous other diseases, and shortens life expectancy by nearly 15 years. Diseases caused by tobacco use are responsible for an estimated 438,000 premature deaths each year.

Little progress is being made in further reducing smoking rates, particularly among youth, women, and many minority groups. Major factors contributing to this lack of progress include insufficient health provider intervention to help patients quit smoking, meager state tobacco prevention and control investments, and ineffective or absent tobacco control policies at both the state and Federal levels. These failures are particularly glaring given the massive, unrelenting onslaught of tobacco industry marketing and product development targeting susceptible populations.

We know that even if all current smokers cease using tobacco today and no new smokers take up the habit, the latency of tobacco-caused cancer and other diseases dictates that cancer and other morbidity and mortality from tobacco use will continue to affect our population for at least another two decades. For the health and future strength of our nation, this preventable epidemic of disease must be brought to the most rapid end possible.

A Call to Action

For many in the nation, the toll of cancer has become simply an awful part of life—a part each person hopes to avoid. Yet in effect, through our complacency about cancer and a lack of will to change aspects of the cancer enterprise that are preventing significant and much more rapid reductions in cancer mortality and morbidity, we are allowing a "bioterrorist within" to attack almost a million and a half Americans and kill more than 560,000 of us each year. Though few in this country have been untouched by cancer, these attacks and fatalities somehow occur almost quietly, their magnitude virtually

unnoticed except by the families and friends of each stricken individual. Our outrage and sorrow about the suffering and loss caused by cancer seem to be felt individually, but not collectively.

We already have the ability to vanquish much of the epidemic of suffering and death caused by cancer. If no one in America used tobacco, we could avoid one-third of all cancer deaths. If every person with cancer or at risk for cancer—all Americans—benefited from behavioral, early detection, and treatment interventions we know are effective, millions would never be faced with a cancer diagnosis and the prospect of premature death. The reduction in suffering by patients and their families would be incalculable. The benefit to our nation in lower health care costs and heightened productivity would be an untold bounty to our economy and our national well-being. With a reinvigorated, redirected, and appropriately supported cancer research program, we will be able to multiply these benefits for all Americans, hasten the day when cancer is a largely preventable and easily treatable malady, and retain our place as the pre-eminent worldwide center for cancer and other biomedical research.

The Panel challenges our leaders and every individual to consider:

- How much more urgently might we respond to the cancer epidemic if cancers killed quickly, like many communicable diseases?

- How would we reorder our priorities and mobilize our vast resources, talent, and ingenuity if the news reported ***every day*** that another 4,000 had been stricken and another 1,500 had died? If every week, the "faces of the fallen" appeared on television and in newspapers, as do military casualties?

It no longer is acceptable to say that because cancer is complex, disparities in care are entrenched, and the tobacco companies are powerful, we cannot solve the problem of cancer in America. We can. But to do so, cancer must become a national priority—one that is guided by strong leadership; fueled by adequate funding and productive collaboration and compromise among governments, industry, and institutions; and embraced by individuals who understand and accept their personal role in preventing cancer and in demanding meaningful progress.

Preface

With passage of the National Cancer Act (P.L. 92-218) in 1971, the President's Cancer Panel (PCP, the Panel) was created and charged to monitor and appraise the development and execution of the National Cancer Program. At least annually, the Panel reports directly to the President of the United States regarding barriers or impediments to the fullest execution of the Program and provides recommendations for overcoming identified problems.

Over the past several years, the Panel has noted a hastening and troubling confluence of trends, including:

- A declining cancer research budget
- Avoidable inefficiencies in and limited collaboration among governmental, voluntary, industry, and academic components of the cancer research enterprise
- Mounting questions about the focus and principal emphases in cancer research given recent and expected cancer trends
- An aging and progressively more sedentary population
- An increasingly fragmented and unsustainable health care system
- Steady erosion of public and private health care coverage, with rising numbers of uninsured, underinsured, and underserved Americans
- Continuing tobacco use, reduced cancer control funding, and increased tobacco company product development and extensive marketing targeting youth, women, and other vulnerable populations
- An apparent complacency and/or lack of understanding among policymakers, the research and health communities, and the public about the escalating burden of cancer and a lack of urgency to confront the present and looming national cancer crisis

Between September 2007 and January 2008, the Panel held four roundtable meetings entitled, Strategies for Maximizing the Nation's Investment in Cancer. Nearly 40 representatives from government, the advocacy community, and the fields of clinical medicine, cancer research, health policy analysis, epidemiology, economics, insurance, industry, public health, and journalism took part in these meetings. Among the questions explored were:

- What changes to the current system would make the largest impact on cancer morbidity and mortality? How can these changes be achieved? Who must be involved in making these changes and how can they be appropriately engaged?
- How can business models be applied to the cancer research enterprise as a means of optimizing the funding process?

- Why are cancer appropriations not a higher priority? What should be done to raise the priority of appropriations for cancer research and cancer care?

- How do we sustain the momentum of cancer care and research under the current fiscal circumstances?

The roundtable meeting dates and locations were:

September 10, 2007	Atlanta, Georgia
October 22, 2007	San Diego, California
December 3, 2007	San Juan, Puerto Rico
January 28, 2008	New Orleans, Louisiana

The remainder of this report provides:

- A brief overview of the cancer landscape, including the current and projected cancer burden in America, the scope of the cancer enterprise, and cross-cutting concerns

- The Panel's recommendations based on the roundtable discussions and additional data gathering prior to and following the meetings

- A call to action

A roster of roundtable participants is provided in Appendix A.

PART I

The Cancer Landscape

To gain a complete picture of the cancer landscape, it is necessary to consider the extent of the cancer burden in America, the major components comprising the cancer enterprise, and several key issues that affect its operation and effectiveness.

The Cancer Burden

Cancer is not a single disease; it is a multitude of diseases with important, but in many cases undiscovered characteristics that complicate detection, diagnosis, and therapy using available technologies and treatments. What nearly all cancers share, however, is unregulated growth and the ability to spread from their point of origin to distant sites in the body, compromising bodily functions, causing suffering and, too often, death.

Risk of Developing Cancer

By current estimates, approximately one in two men and one in three women—more than 40 percent of the United States' population—will develop cancer at some point in their lives.[1] In 2008, more than 1.4 million new cases are expected, and more than 565,000 people will die from cancer.[2] Despite declaring a national war on cancer in 1971 and investing many billions of dollars since then to understand and defeat cancer, our success against the disease in its many forms has been uneven and unacceptably slow.

Although anyone can develop cancer, approximately 77 percent of all cancers occur in persons aged 55 years and older.[3] Nearly 68,000 young adults (aged 15 to 39) were diagnosed with cancer in 2002, about eight times more than children under age 15.[4] The average age at diagnosis, now 67 years,[5] continues to fall, due largely to more widespread use of screening tests for prostate, breast, cervical, and colon cancer. Screening rates, however, vary substantially by type of screening and population group. For example, mammography screening among women over age 40 has declined in recent years,[6] and the uninsured tend to have lower cancer screening rates overall compared with people with health insurance.[7]

Overall Cancer Incidence, Mortality, and Survival

The overall cancer incidence rate has declined by about 0.6 percent per year, or about eight percent since the early 1990s.[8] In 1998, the American Cancer Society (ACS) issued a challenge to the cancer research

and care communities, and the nation as a whole, to reduce cancer incidence by 25 percent between its high point in 1992 and 2015. According to a midpoint analysis published in 2007, at the current rate of incidence reduction, that goal is likely to be met only by half.[9]

Cancer is the second leading cause of death across all ages in the United States, but it is the leading cause of death for individuals under age 85 years.[10] Tobacco use is responsible for at least 30 percent of all cancer deaths.[11] Between 1993 and 2002, the overall mortality rate for all cancers combined declined slowly, about one percent per year.[12] Encouragingly, between 2002 and 2004 overall cancer mortality appears to have declined by just over two percent per year, due primarily to fewer deaths from the four most common cancers (prostate, breast, lung, and colorectal).[13,14] These changes primarily reflect decreased male smoking rates and earlier detection of breast and prostate cancers. As with cancer incidence, however, unless progress can be accelerated, mortality reduction is predicted to fall short by half of the ACS challenge to reduce cancer mortality by 50 percent between 1990 and 2015.[15]

In 1971, approximately three million people were cancer survivors. As of 2007, nearly 12 million people were estimated to be living with a history of cancer; some of these individuals were cancer-free, while others still had evidence of disease.[16] The steadily rising number of people surviving cancer is a significant achievement of the National Cancer Program (NCP), although cancer survivors remain at risk for serious, long-term treatment-related side effects, including new cancers. About 66 percent of people diagnosed with cancer (average for all sites combined) now can expect to live five years or longer, compared with 50 percent in 1975-1977.[17] However, survival rates vary markedly by specific cancer type and stage at diagnosis. It is important to note that five-year survival rates are not a measure of cure, since survivors may have recurrent or persistent disease. Five-year survival rates also are not an accurate predictor of an individual's prognosis, but they do provide some measure of progress in diagnosing certain cancers at earlier stages and of treatment advances.

Exceptions to Overall Trends

The hard-won, if less than optimal progress described above is important and represents the dedicated work of thousands of scientists and clinicians. But the recent overall statistics provide an incomplete picture of the national cancer burden since they do not reflect important exceptions to overall trends. Incidence and death rates for some cancers are rising and some forms of cancer remain difficult to diagnose and impervious to treatment. For example, incidence rates among men and women for cancers of the liver, pancreas, kidney, esophagus, and thyroid are rising, as are rates of non-Hodgkin lymphoma, leukemia, myeloma, and childhood cancers. Among women, incidence of brain and bladder cancer and malignant melanoma is increasing; among men, testicular cancer rates are rising.[18] Other important incidence patterns also are being observed; for example, adenocarcinoma of the esophagus is rising rapidly in older white males, which may be related to increasing obesity rates.[19] Breast cancer in African American[20] and other[21] women is being diagnosed at young ages and often is highly aggressive.

We still lack effective early detection tools for most cancers; among the most important of these are lung, pancreas, ovary, liver, and brain cancers, which have high mortality rates and tend to be asymptomatic until they reach advanced stages. Cancers of the pancreas, liver, lung, and esophagus remain almost uniformly fatal, with five-year survival rates of 16 percent or less. Mortality from esophageal, thyroid, and liver cancers is increasing among men; among women, lung

cancer deaths still are rising, but appear to be leveling off due to decreases in smoking rates.[22]

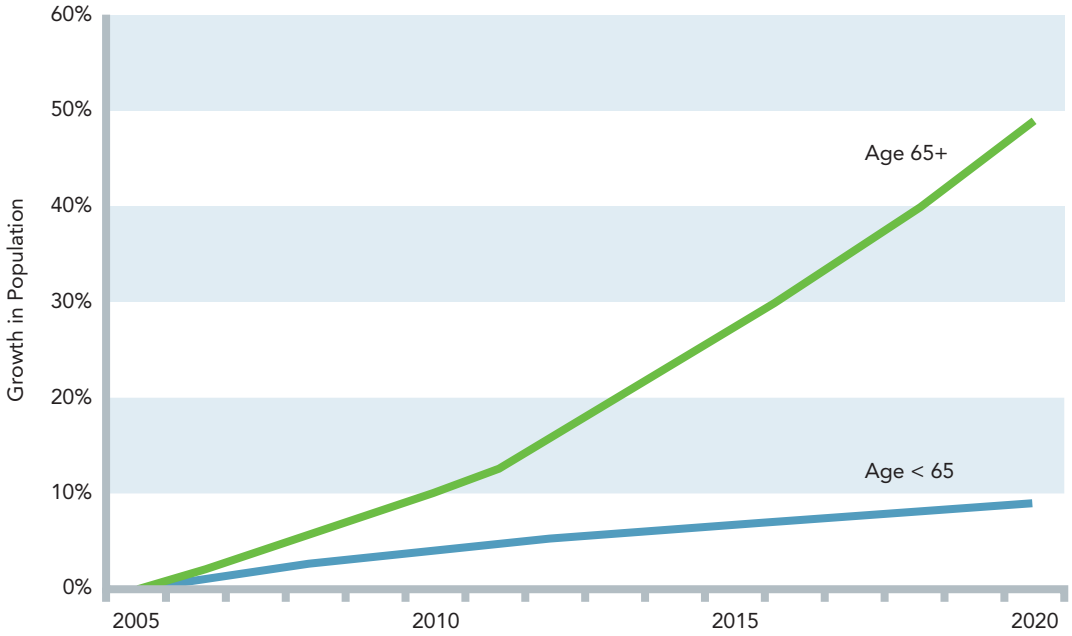
Overall incidence and death rates for most cancers continue to be higher among the poor and among African Americans compared with other parts of the population.[23] In addition, incidence and death rates for specific cancers are significantly higher in some populations (e.g., cervical cancer incidence among Vietnamese American women; prostate cancer in African American men). Many factors may contribute to these disparities, including limited access to care leading to late diagnosis and inadequate treatment; lower screening rates; lifestyle-related risk factors; provider and patient bias based on racial, ethnic, cultural, and socioeconomic differences; lower educational, literacy, and health literacy levels; environmental exposures, including infectious agents; cultural and language differences; and genetic predisposition.

Moreover, current statistics do not yet reflect a rapidly approaching tidal wave of cancer that is expected due to a combination of demographic and lifestyle factors. Specifically, an aging population (Figure 1) with a rising risk for most cancers and increasingly sedentary youth, coupled with poor diets, continued tobacco use, and flat or declining screening rates (e.g., mammography[24]) represent an underestimated emerging cancer crisis.

In its last report, *Promoting Healthy Lifestyles: Policy, Program, and Personal Recommendations for Reducing Cancer Risk*,[25] the Panel reported extensively on our present and expanding understanding of the effects of nutrition, physical activity, and obesity on cancer risk and the impact of tobacco use on cancer incidence and mortality. Since publication of that report, additional research continues to more clearly define and quantify associations between body mass and cancer risk. For

Figure 1

Population Growth, 2000-2020, By Age Group



Source: United States Census Bureau population projections (April 2005 release).

example, a recent meta-analysis of more than 282,000 people with cancer in North America, Europe, Asia, and Australia[26] who were followed for up to 15 years found that in men, a five-point rise in body mass index (BMI, a measure of weight relative to height)—about 33 pounds—was strongly associated with esophageal adenocarcinoma and with thyroid, colon, and renal cancers. In women, a five-point BMI increase (about 29 pounds) was strongly associated with esophageal carcinoma, and endometrial, gallbladder, and renal cancers. Weaker positive associations with numerous other cancers also were found. With few exceptions, these associations were similar across continents and populations.

Recent tobacco-related research has demonstrated the importance of social networks in tobacco use cessation. A study of more than 12,000 people in a densely interconnected social network who were assessed repeatedly over 32 years found discernable clusters of smokers and nonsmokers.[27] Certain relationships among network members were found to influence the smoking behavior of others. For example, smoking cessation by one spouse reduced by 67 percent the chance that the other spouse would smoke. Among siblings, smoking cessation by one increased by 25 percent the chance that another would quit smoking. Similar relationships were found among coworkers in small firms, among friends, and among persons with higher educational attainment. The findings, which have implications for clinical and public health interventions to prevent and reduce smoking, showed that smoking behavior spreads through close and distant social ties, with groups of interconnected people stopping smoking in concert, and increasing social marginalization of smokers over time.

Worldwide Cancer Issues

The global cancer burden needs to be acknowledged as a problem for the United States and other industrialized and developing nations. In 2005, cancer caused 7.6 million deaths—about 13 percent of all deaths worldwide.[28] If current trends continue, cancer deaths will rise to 11.8 million in 2030.[29] Most industrialized nations are experiencing the same demographic and lifestyle trends that are occurring in the U.S. and like this country, are experiencing rising health care costs due to cancer. Cancer in developing nations, especially related to increased smoking and adoption of Western diets and other lifestyle behaviors, is escalating rapidly; by 2030, 70 percent of the global cancer burden will be borne by developing countries.[30] Along with other noncommunicable diseases (e.g., cardiovascular disease, diabetes) that also are increasing in developing countries, cancer can be expected to impose a significant economic and social burden. In a global economy, losses of productivity and resources due to cancer may well have interdependent effects on nations at all stages of development.

The U.S. has invested little to date in the global cancer problem, in part because the direct return on such investment has been perceived to be low. But behavioral and preventive interventions tailored to specific populations and cultures are urgently needed. Similarly, infrastructure is needed to support the delivery of such interventions and improved cancer treatment, particularly in developing nations. The U.S. has established research collaborations and provided consultation in clinical trial and cancer center development in several countries and regions (e.g., Ireland,[31] the Middle East[32]).

The Scope of the Cancer Enterprise

Over the past 10 to 15 years, the cancer enterprise has come to be thought of as encompassing a continuum spanning basic science discovery, the development of discoveries into new interventions and technologies, and the integration of new

Figure 2

Major Components of the Cancer Enterprise and Traditional Businesses

Traditional Business Component	Research and Development	Production and Manufacturing	Marketing and Advertising	Product Distribution and Service Delivery
Equivalent Component of Cancer Enterprise	Basic and Early Translational Research	Late Translational Research, Product Production, and Intervention Development	Education, Training, and Dissemination to the Public, Advocates, Professionals, and Policymakers	Delivery of Care and Adoption of Advances

interventions and technologies into an improved standard of cancer care.[33] This paradigm, sometimes referred to simply as the three Ds—discovery, development, and delivery—has been refined and adapted variously.[34] The Panel's own expansion of the concept[35] to describe the continuum and activities needed to achieve more effective research translation and adoption of new interventions (Appendix B) provided the basis for the National Cancer Institute's (NCI) Translational Research Working Group (TRWG)[36] that was charged to explore how the Institute could improve and expedite research translation (see also pp. 9-10).

Participants in the cancer enterprise include the scientific, health care, and advocacy communities, including public, voluntary, and private sector entities and individuals, cancer patients, and people at risk for cancer. In addition, the Panel considers all entities and individuals (e.g., agriculture system, media, educational system, industry, regulators, legislators) who by their action or inaction affect the national cancer burden, to be part of the National Cancer Program and thus participants in the cancer enterprise.

At the Panel's meetings, roundtable participants drew parallels between the major components of the cancer enterprise and those of a traditional business (Figure 2). They emphasized that in business, if one or more components of the business fails or is seriously compromised, the business itself may fail. In the cancer enterprise, they maintained, the greatest failures are in information dissemination, training and education (for the public, advocates, professionals, and policymakers), and in the delivery of care.

More specifically, our predominant approaches to cancer have placed too great a focus on basic and early translational research (research and development) and relatively little on the other components of the enterprise. The importance of later stage research translation, however, and the team approaches needed to develop new therapies and technologies have become more fully appreciated in recent years.

Research on new treatments is emphasizing tailored ("personalized") therapies based on molecular and genetic markers found in each individual's tumor.[37,38] By contrast, comparatively little research is aimed at developing new preventive interventions or early detection methods, or on improving health system design and processes to make the cancer-related care we know is effective more accessible and affordable for all. Cancer care delivery, it was noted, emphasizes the treatment of diagnosed cases and screening for the few currently screenable cancers. Prevention and

early detection remain the weakest parts of the delivery system, yet have the greatest potential for reducing the national cancer burden.

Research Concerns

Numerous concerns about the research enterprise were explored by roundtable participants, including aspects of the research system that undermine its effectiveness, and problems related to funding, specific structural components, and research focus.

Research Realities

Roundtable participants suggested that a lack of candor about realities of the existing cancer enterprise is an important factor in the apparent national lack of urgency to make faster progress against cancer and the widespread confusion about how to achieve this objective.

Participants generally concurred that the nation's return on investment (ROI) in basic and early translational investigator-initiated cancer research has been good in terms of generating new knowledge,[39] but has been far from optimal in terms of cancer outcomes at the population level (i.e., substantial reductions in cancer mortality and morbidity). Participants noted that in business, if ROI is low, investments are reduced or major strategic changes are made. This observation with regard to cancer research was tempered by the understanding that population-level outcome improvements derived from basic scientific discoveries may be difficult to predict and that the interval between discovery and population-level impact is longer than would be the case in most business environments. In any case, population-level effects of cancer-related discoveries are unlikely if late translation (product and intervention development), education and dissemination (marketing), and delivery (health services research, effective access, and administration) are lacking.

At the same time, roundtable participants emphasized the importance of preserving the essence of basic research—its relatively unfettered exploration of sometimes esoteric topics that may not appear to be directly related to a specific therapeutic goal. Unfortunately, however, the potential clinical benefits of basic science discoveries all too commonly are overexaggerated in media reports. This problem is not entirely the fault of the media, since journalists get the information for their reports from the scientists involved and/or their institution's public relations office. *In vitro,* animal model, and Phase I clinical trial results that are hailed as "breakthroughs" may not reach the public as improved treatments for a decade or longer, if at all. Such overblown reports or intentional vagueness about "promising" discoveries may help individual investigators maintain their funding stream, but adversely affect the funding, operation, and outcomes of the cancer enterprise because they confuse the public and policymakers, create doubt about the value of cancer research, and undermine sound decisionmaking about resource allocation.

Attempts to bring greater efficiencies to the research process have typically been met with resistance. The scientific community historically has been reluctant to apply business models to or think of cancer research and care as a business rather than as a pure quest for knowledge and a calling to help people who are sick. In fact, most of the scientists running research institutions such as cancer centers and the Directors of Institutes within the National Institutes of Health (NIH) do not have business training or experience.

In research, little motivation exists to conduct cost-effectiveness analyses because the prevailing model is that if something is invented, it will be used. Yet this perspective affects research direction significantly and incentivizes higher cost treatment. Desperate patients may expend their only

remaining resources to gain only weeks or months of added survival from such new, exceedingly expensive treatments, often with poor quality of life. Because of skyrocketing health costs, however, the notion of value-based health care identified through comparative and cost-effectiveness analyses is gaining traction among purchasers of care.

Research Funding, System, and Focus

The paragraphs below highlight concerns about current research funding, key components of the research system, and research emphases in the cancer enterprise.

Research Funding

Participants were unanimous in their view that the U.S. biomedical research enterprise as a whole is being starved of funding at a pivotal juncture. We have reached thresholds of discovery and research translation capacity that will enable us to catapult our understanding of cancer as a disease and amplify our ability to turn this knowledge into better interventions and technologies across the cancer prevention and care continuum. Some of these thresholds have been reached as a result of the expanded research capacity and greater ability to fund scientific investigation that became possible during the doubling of the NIH budget between 1998 and 2003.

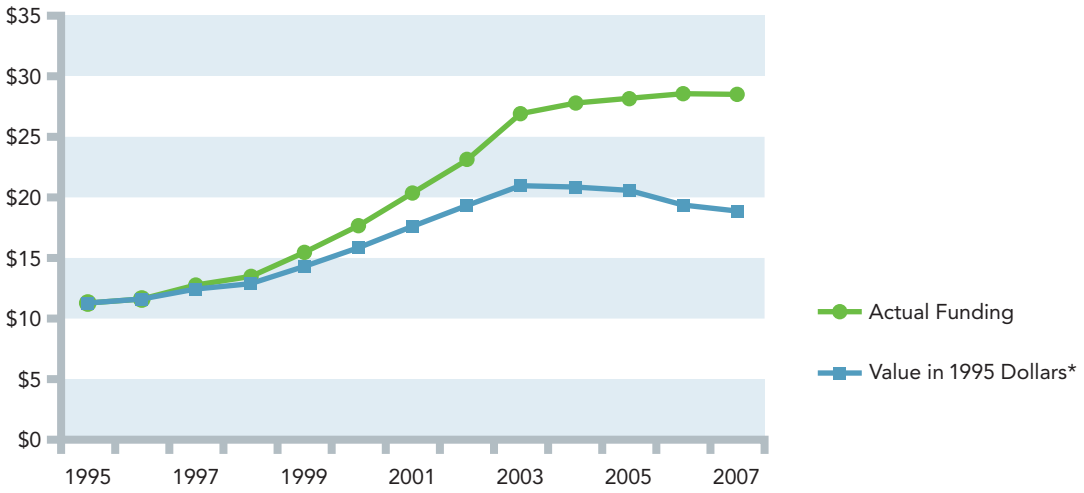
Since then, however, the NIH budget has remained essentially flat. Yet as Figure 3 illustrates, because of inflation in the cost of conducting research (e.g., higher facility, utility, and supply costs), available funds buy far less than previously, such that a flat budget is in fact a declining budget.[40,41]

The result has been little or no growth in the number of grants awarded (Figure 4), curtailed and deferred research projects and clinical trials, closed or unrefurbished laboratories, and reduced staffing at many of the 3,000 institutions that conduct research with NIH grant funds.

At NCI, the percent of new grants and scope of work expansions of existing grants awarded in fiscal year (FY) 2007 was 15 percent combined; this level is expected to drop to 14 percent in FY 2008. NCI anticipates awarding fewer new grants in FY 2008 to minimize the size of budget cuts renewal grants have experienced in recent years. Average grant size grew at less than inflation from $329 thousand in FY 2007 to $333 thousand in FY 2008.[42]

Figure 3

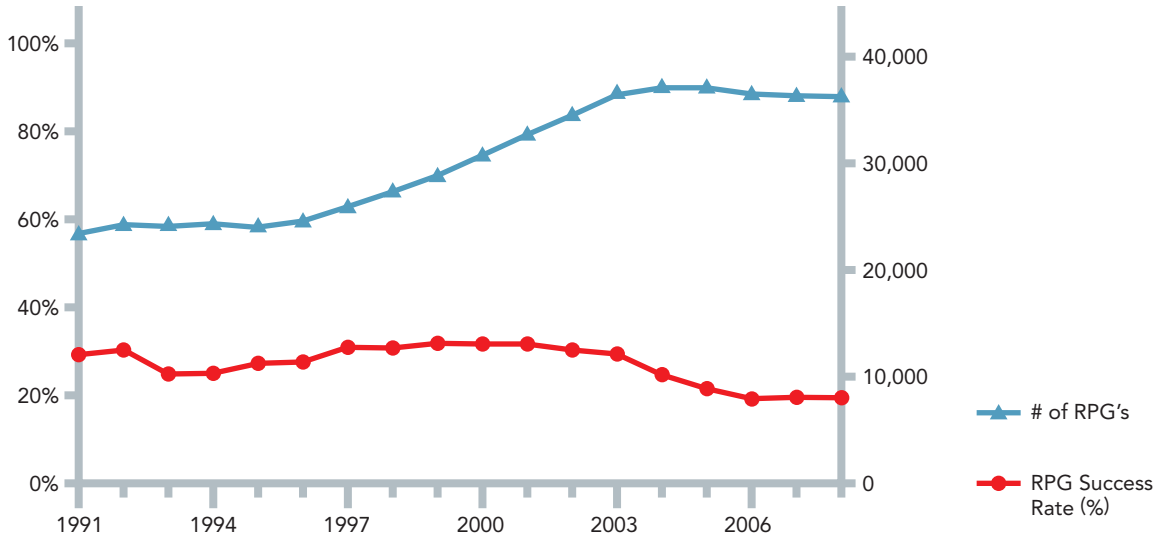
NIH Funding History FYs 1995-2007 (in billions)



*Reflects inflation based on the Biomedical Research and Development Price Index
Source: National Institutes of Health

Figure 4

National Institutes of Health Research Project Grants



Adapted from: NIH agency budget justification for FY 2008.
American Association for the Advancement of Science, February 2007.

Research System and Infrastructure

Several roundtable participants maintained that a principal barrier to achieving more rapid reductions in cancer mortality and morbidity is the nature and operation of the research system itself. The existing system for evaluating and funding research is antiquated and an impediment to the way current and future research needs to be conducted.

> …I find as I've learned about the scientific enterprise… how long it takes to do everything. It's just astounding. And so I find that very, very frustrating in many, many ways.
>
> *Paula Kim*
> *Translating Research Across Communities*

■ *Peer Review* There was strong consensus that the NIH peer review system has become increasingly risk averse due to funding constraints and career concerns, resulting in unimaginative clinical trial and other research proposals that may get funding but do little or nothing to reduce cancer mortality and morbidity. As one participant noted, the culture of science dictates that one must follow the established process, yet adhering to this approach actually may hold back progress because of the expectation that the process will provide certainty. By contrast, more entrepreneurial approaches found in industry (e.g., venture capital models) encourage more innovative, higher risk research and offer more varied mechanisms for intellectual property licensing and other approaches that have the potential to accelerate progress.

The peer review system, developed in the 1950s, is faltering under a vastly greater, unforeseen, and growing volume of grant applications. Grant application review is time-consuming, requiring reviewers to take time away from their own research to read and evaluate an escalating number of complex applications. This situation has become untenable for some potential reviewers. In addition, as cancer and other biomedical, social, and behavioral sciences further expand and specialize, it has become increasingly difficult to find appropriate reviewers for some types of applications. Although some new study sections have been developed to address this issue,

> I think there has been a massive triumph. Yes, there are huge holes and the system of medical care in this country is a disgrace. I agree with all of that, but we have made great progress in cancer and we are making it again now.
>
> *David Nathan*
> *Dana-Farber Cancer Institute*

investigator-initiated translational, health services, and behavioral research projects still tend to do less well in the traditional, basic science-dominated study group process, unless the applications have been submitted in response to a specific Request for Applications or Program Announcement.

Recognizing that as the scientific and public health landscape continues to evolve, so must the processes used to support science. In June 2007, NIH initiated an internal analysis of the peer review system. In February 2008, a draft report[43] of that analysis was released for comment. Based on extensive feedback from the scientific community, an implementation plan was developed. Phased implementation of selected actions began in June 2008 and will continue for 12 to 18 months.[44] The selected actions reflect four priorities: (1) engaging the best reviewers by increasing service flexibility and compensation, enhancing training, acknowledging reviewer efforts, and reducing administrative burdens on applicants, reviewers, and NIH staff; (2) improving review quality and transparency by shortening and redesigning applications to highlight impact, better aligning applications to explicit review criteria, and modifying the rating system; (3) ensuring balanced and fair reviews across scientific fields and career stages by better supporting young investigators, encouraging transformative research, and reducing the burden associated with multiple application resubmissions; and (4) developing a permanent process for ongoing improvement of peer review. To encourage innovative, high-risk/high-reward research, NIH will commit $1 billion over five years to existing grant mechanisms (e.g., Pioneer, EUREKA, New Innovator) and a new, investigator-initiated Transformative R01 award.

> …we need to link these levels of analysis from the cellular to the population level and do it through health care delivery systems as research platforms; do it through linking surveillance data with biological data; do it through linking behavioral risk factor data with individual clinical data.
>
> *Robert Croyle*
> *National Cancer Institute*

■ *Research Translation* The PCP's June 2005 report, *Translating Research into Cancer Care: Delivering on the Promise,* described the multitude of challenges involved in turning basic science discoveries into new preventive and therapeutic interventions. These challenges include removing barriers to team science erected in large measure by the established research culture; overcoming infrastructure deficits; addressing regulatory barriers; improving dissemination, education, and communication efforts; expanding access to care; and earning and retaining public trust. Most of the challenges elucidated in the report have yet to be addressed substantively.

In Fall 2005, however, NCI convened a Translational Research Working Group (TRWG) to evaluate the status of the Institute's investment in translational research and envision its future. Using the research translation continuum[45] in the Panel's report as a framework, the TRWG elected to focus its efforts on early translational research, including near-term adjustments to NCI programs and a long-term vision for improving this component of the cancer research enterprise. The TRWG's June 2007 report and recommendations[46] to the National Cancer Advisory Board (NCAB) describe 15 initiatives to better coordinate translational research management, tailor funding programs, and enhance operational

effectiveness. The TRWG also produced six developmental pathway diagrams depicting the steps required to move discoveries from the laboratory or clinic to the point at which they can be tested in early-stage clinical trials. An implementation timeline for FY 2008 through FY 2012 has been established. As part of the implementation plan, NCI will initiate a new approach to identifying and supporting translational research projects with potential to meet an important clinical need. Translational research teams may qualify for support through a new funding mechanism, Special Translational Research Acceleration Project (STRAP) awards, to help facilitate handoffs from one group to another along the developmental pathways. STRAP-funded projects will be required to have a management plan for reaching early-stage human studies, specific developmental milestones and a timeline for reaching them, along with a development/commercialization strategy (i.e., a business plan).[47]

> Where we are with cancer therapy is appalling at some level, despite the advances…There is the idea that we have everything we need to know and we just have to make a business model and deliver it. I surely do disagree with that…We don't know enough.
>
> *Craig Thompson*
> *University of Pennsylvania*

■ *Clinical Trials* A recent report[48] notes that the clinical trials system in the United States suffers from: (1) underfunding for publicly supported trials and the infrastructure needed to conduct them; (2) constrained and deteriorating physician practice and institutional finances that limit discretionary spending to support unfunded aspects of clinical trials; (3) workforce shortages in specific subspecialties and physician researchers; (4) limited awareness or priority of clinical trials participation by physicians, patients, and policymakers; (5) insufficient patient participation in cancer clinical trials, including minority populations, and insufficient physician participation in clinical research; (6) reduced numbers of oncology medical residents; and (7) regulatory requirements that unnecessarily impose burdensome financial and personnel requirements on the clinical trials system. Not only do current funding and infrastructure fail to support the existing paradigm of cancer treatment development, they are woefully inadequate to capitalize on a rapidly evolving targeted and personalized treatment paradigm.

PCP roundtable participants emphasized the need to overhaul the clinical trials system to obtain results more quickly, yet safely. Clinical trials are a costly, time-consuming, and failure-prone component of drug development, and cancer drugs have only half the success rate of all new drugs combined—about five percent.[49] By streamlining the system, drug development costs could be reduced, which should result in lower drug costs to consumers and may encourage drug companies to develop more of the agents in their pipeline with potential oncology applications.

In October 2007, the National Cancer Policy Forum (NCPF) of the Institute of Medicine (IOM) conducted a workshop to explore options for improving the quality of cancer clinical trials.[50] Many of the strategies discussed echoed those described by the PCP roundtable participants. In addition, PCP roundtable participants stressed the importance of careful clinical trials patient selection, and urged the development of better ways to study populations (e.g., risk stratification). They noted that randomized clinical trials (RCTs) may idealize populations almost to the point of irrelevance.

> We don't reward people for being in clinical trials…people do not feel their value by being in clinical trials…They don't get thank you letters… This should be a form of national service.
>
> *Greg Simon*
> *FasterCures/The Center for Accelerating Medical Solutions*

NCI and the Food and Drug Administration (FDA) are exploring adaptive and other

(e.g., Phase 0;[51] multi-stage/multi-arm) clinical trial designs that may help answer more clinical questions in a shorter period of time.[52] Validated biomarkers or other surrogate endpoints will be essential to enable clinical trial approaches such as these. But extreme care must be taken in using biomarkers as surrogate endpoints in clinical trials to accelerate the approval process, since biomarkers may not indicate whether the agent under investigation will actually reduce mortality or morbidity, or whether it will have serious long-term side effects or otherwise cause harm.[53,54] In addition, a roundtable participant cautioned against abandoning new agents too hastily; experience has shown that it may take time to find the combination of agents that will have a desired effect. In 2007, a Cancer Biomarkers Collaborative (CBC)[55] was established with broad representation from the government, academic, industry, and advocacy communities to address preclinical biomarker development and related issues.

In 2004, NCI established a Clinical Trials Working Group (CTWG) to determine how best to enhance key components of the clinical trials system. The CTWG's 2005 report[56] provided recommendations for restructuring the clinical trials system and established a five-year timeline for achieving system improvements. As part of the process, a baseline evaluation was conducted. Among other findings, the evaluation identified database upgrades needed to capture information necessary for the evaluation process, inconsistent incentives for collaboration within NCI's clinical trials structures, and wide variation in Phase III trial accrual by Cooperative Group-participating institutions. The implementation plan, which includes specific initiatives related to coordination and cooperation, scientific quality and prioritization, standardization of tools and procedures, and operational efficiency, addresses these and other findings. In addition, NCI has asked the NCPF to assess the Cooperative Group system to determine how it can be improved.

> But the nature of science, of course, is that we don't learn anything from positive experiments. Francis Bacon said, "We learn from negative experiments." That is, we disprove our current belief system, and it's only when you disprove your belief system that you advance knowledge.
>
> *Barnett Kramer*
> *National Institutes of Health*

■ *Research Publication and Coding*
To improve the quality and efficiency of clinical trials and other cancer research and reduce redundancy and unproductive efforts, negative and null results of research studies must be reported and made available to researchers without delay. Negative results are not failures and can be as important as positive results because they document "blind alleys," describe interesting but unsubstantiated theses, and potentially, contradict earlier positive findings.[57] It is the job of medical editors to distinguish between studies that failed because they were poorly designed or carried out and those that were sound but simply did not work or were inconclusive.[58]

The PCP reported previously on efforts to expand publication of negative results and improve access to all research results, as well as on the importance of correctly coding the type and content of research to enable its retrieval and identify gaps in knowledge.[59] In addition to the research community's need for this information, open access is crucial for health care providers and the public to guide intervention choices across the cancer care continuum. Although many medical editors have encouraged researchers to submit papers on negative or null results, some investigators still hesitate to do so for fear of jeopardizing their careers. Similarly, executives and researchers at publicly traded pharmaceutical and biotechnology companies are reluctant to risk endangering their perception by investors and business analysts.

> It's those negative results that often are not reported, so we're redoing studies. The idea sounded good but didn't work before; we don't know that, and it is being done again.
>
> *Sandra Millon Underwood*
> *University of Wisconsin–Milwaukee*

As of April 2008, however, peer-reviewed journal articles based on NIH-funded research (approximately 80,000 per year) must be made available at no cost through the PubMed Central[60] online database administered by the NIH National Library of Medicine. Although articles must be submitted to PubMed Central upon acceptance for publication, authors may still embargo their papers for up to 12 months before they become publicly available.[61] A recent report indicates that open-access publishing is gaining greater acceptance among prestigious research institutions; Harvard University has announced an open-access policy, and it appears that other universities soon may follow suit.[62]

■ *Infrastructure* Essential infrastructure components needed to conduct cancer research in the new century are limited or absent, posing major barriers to progress. For example, roundtable participants urged the expanded use of human tissue studies in pathobiologic research. Uniformly collected, preserved, and annotated human biospecimens are the critical foundation of translational research needed to develop the tailored treatments that are anticipated to transform future cancer care. Without these resources, progress in molecular and genetic research that requires high quality human biospecimens (blood, urine, normal and tumor tissue) will continue to be restricted. Procuring high quality, properly consented, fully annotated specimens requires the cooperation of surgeons, other providers, pathologists, researchers, and patients.

To improve this component of the research infrastructure, numerous legal, ethical, policy, logistical, and technical issues must be addressed. Physicians, investigators, industry representatives, patient advocates, and other stakeholders provided advice that guided development of the NCI Best Practices for Biospecimen Resources,[63] approved by the NCAB in June 2007. To maintain stakeholder input, forums were held to educate the cancer research community about how to implement the best practices. More than 600 researchers, clinicians, industry representatives, hospital administrators, advocates, and members of the general public attended the forums,

and additional such meetings are planned. Other forums will convene researchers and others to address biospecimen quality, custodianship, and ownership issues, and to determine how to achieve open access to specimens through a locator tool compatible with NCI's cancer Bioinformatics Grid (caBIG™).[64] NCI is partnering with the College of American Pathologists to develop evidence-based standard operating procedures for biospecimens, a key foundation for reducing the variability among samples that currently compromises comparability of molecular test results.

Participants consistently underscored the need for integrated, interoperable data systems across the research and care continuum (see pp. 17-18). Improved imaging technologies also were seen as important tools for the future of cancer diagnosis, including genetic diagnosis; treatment selection; and treatment response monitoring.

Some roundtable participants maintained that a separate budget may be needed for infrastructure/capital costs (also called facility and administrative costs, or F&A) and another for conducting scientific studies (direct costs). F&A research costs include items such as electricity, building security, and building mortgage costs. A sometimes politically contentious issue, F&A costs add an average of 50 percent of direct costs onto the total grant amount.[65] One approach to containing F&A costs would be to establish caps on them; the caps might vary by grant type. This approach, either alone or as part of a separate budget for indirect costs, should be studied to assess its feasibility and potential impact on research progress.

Human capital is perhaps the most crucial component of the research infrastructure. Roundtable participants identified several key issues in attracting and retaining the best minds to cancer research careers (see discussion below, pp. 18-20).

Research Models and Focus

At each of the four roundtable meetings, participants discussed issues related to balance within the cancer research portfolio.

■ *Research Models* It was suggested that a shift toward mission-driven research (as opposed to hypothesis-driven research) has considerable potential to produce faster progress in reducing cancer morbidity and mortality. At the same time, discussants agreed that a mission-driven approach still must provide for opportunistic, investigator-initiated research to encourage innovation. In this regard, participants suggested that funding models already supporting high-risk/high-return research, such as the Department of Defense's (DoD) Defense Advanced Research Projects Agency (DARPA)[66] and venture capital models,[67,68] should be explored. Unlike the more risk-averse NIH grant system, these funders fully expect that there will be failures.

> …you don't want to stifle innovation because that really is part of the engine that drives a lot of the new approaches, whether it's prevention or early detection or treatment.
>
> *Lloyd Everson*
> *US Oncology*

Another potential model may be found in the approach adopted by the Howard Hughes Medical Institute (HHMI),[69] in which investigators are funded for five years to explore a specific area of science, but have considerably more leeway than under the NIH grant system to follow leads and change direction if warranted by early results. In 2008, HHMI announced a new $600 million initiative to fund high-risk/high-return medical research at institutions across the country.[70] The need for greater government, academic, and foundation support for high-risk/high-reward funding also was underscored in a June 2008 white paper by the American Academy of Arts and Sciences.[71]

> …we still have to maintain a very balanced portfolio of research so we don't choke off our pipeline when we get beyond the 10-year pipeline where we're translating things that [we find out] don't work.
>
> *William Hait*
> *American Association for Cancer Research*
> *Johnson & Johnson Pharmaceutical Research and Development*

■ *Research Focus* Roundtable participants generally agreed that intensifying research on the mechanisms and pathways involved in cancer development and progression is likely to yield discoveries relevant to many cancers. Similarly, it was suggested that research on correctable causes of cancer—inflammation, infection, addiction, hormonal environment—should be expanded. Participants also identified a need for better biomarkers for identifying predisposition, improving early detection tools, and assessing treatment response. Such biomarkers, they noted, would likely lead to ways of intervening at much earlier (e.g., preinvasive, premalignant) stages of disease. New information and testing technologies are enabling researchers to adopt systems approaches to cancer that previously could not be implemented. However, roundtable participants agreed that while increasing the emphasis on mechanisms and pathways should not preclude organ site-oriented research, investigators conducting cancer site-specific research should perhaps be required to discuss in their grant applications how their findings may be relevant to other cancers.

> A lot of our efforts are on evidence-based practice, but we haven't generated the opposite; that is, practice-based evidence, which is equally important because we don't, in fact, know how the evidence plays out in the community.
>
> *Barnett Kramer*
> *National Institutes of Health*

Numerous discussants emphasized that research on cancer prevention (other than chemoprevention), health communications, human behavior, and health services organization and delivery is grossly underrepresented and underfunded in current public and private research portfolios. The knowledge gap resulting from this extreme imbalance is an important factor in failures of the communication and delivery components of the cancer enterprise to deliver effective, evidence-based behavioral, screening, and treatment interventions to all parts of the population. Participants further noted that while we should practice evidence-based medicine, we also need practice-based evidence. Clinical trials of preventive and behavioral interventions tend to be long and expensive, and success can be difficult to define and measure, but such trials are necessary to know if an intervention is having the desired effect on morbidity and mortality. The Centers for Medicare and Medicaid Services (CMS) is conducting demonstration projects in which certain treatments will be reimbursed only if the patient is participating in a clinical trial.[72] The purpose of these projects is to gather clinical data in a controlled setting to provide evidence to support reimbursement decisions.

Although NCI has a strategic plan,[73] roundtable participants called for more finely honed strategic analyses that set cancer mortality and morbidity reduction objectives, and with which funding should be aligned. It was acknowledged that doing so could result in a major realignment of much of the existing cancer research portfolio.

Intellectual Property (IP), Patent, and Drug Approval Issues

Several interrelated intellectual property, patent, and drug approval issues continue to severely constrain progress in developing preventive and therapeutic interventions that could greatly reduce cancer mortality and morbidity.

Intellectual Property and Patents

IP issues, at their core, are about profit-making. Since single drugs seldom are effective in the long term against cancer due to drug resistance development, the financial aspects of IP and patent issues must be resolved to enable a wider range of combination drug trials. It should be remembered that drug developers' and researchers' willingness to permit and design combination drug protocols has been a major factor in the exceptional progress to date in treating children's cancers.

To me the answer is in these smart drugs because we're going to change the way we [approach] cancer. We have to. We have to go from organ diagnosis to gene diagnosis. We have to use imaging to help us do that and we have to make the drugs. I think that's the biggest challenge, making the drugs that will fit the genetic programs that we are going to identify, and they have to be combinations. We have finally learned that combination treatment is the only way to go....

David Nathan
Dana-Farber Cancer Institute

The PCP discussed processes and problems related to IP and patents in its 2005 report,[74] and most of these issues remain unresolved. One study tracking the movement of publicly funded discoveries into development suggests that the more valuable a patent granted to a researcher is perceived to be, the more likely it is to be diverted to industry rather than remaining at the university where the discovery was made.[75] An earlier study found that 30 percent of researchers funded by NCI do not assign their patents to their universities.[76] It has been suggested that the sale of patents to industry is more likely when the researcher has, or has had, a (usually appropriate) consulting relationship with an outside firm, and that there is a positive correlation between the amount of consulting a researcher does and the likelihood of patent diversion.[77]

The Patent Reform Act of 2007 (H.R.1908/ S.1145) introduced in the 110th Congress attempts to address some of the patent issues that may hinder the potential for patented discoveries to stimulate innovation. These include the current inability to define "inventor" to include a joint or co-inventor, lack of effective provisions for post-grant patent review, and rules regarding infringement litigation and the apportionment of damages awarded in cases where an invention may include many separately patented components. This bill is unlikely to be passed in this Congress, but almost certainly will be reintroduced.[78]

Drug Development Economics

Fostering and retaining expanded private sector interest in cancer drug development poses distinct challenges. According to a recent re-examination of earlier estimates,[79,80] the cost of bringing a compound or biologic from its discovery to its approval by the FDA for use in treating or preventing human disease may vary across a range from approximately $500 million to more than $2 billion, depending on the type of drug and the company developing it. Pharmaceutical companies must choose carefully among the drugs in their pipeline those in which they will make such an investment. These decisions are influenced strongly by company analyses of the potential market for the drug, the likely profit possible during the period of patent protection (i.e., market exclusivity) after development costs have been recouped, and possible competition from other pharmaceutical firms producing drugs for the same medical indication. In addition, drug companies know that in the year following introduction of a generic competitor when a branded drug goes off patent, the brand name drug will lose on average more than half of its market share, and its price will drop with each new generic marketed.[81] An estimated $85 billion of pharmaceutical products face potential loss of patent exclusivity from 2008 through 2012. This amount equals approximately 30 percent of all pharmaceutical sales.[82]

At the same time, a roundtable participant noted, and at least one source confirms,[83] that pharmaceutical companies have among the highest profit margins in all of industry. In fact, for over two decades they were the highest, eclipsed only in 2003 by mining/ crude oil production and commercial banks. Moreover, drug company profits typically substantially exceed their research and development costs.[84]

…I think risk differs depending on the organization or individual who is viewing it. For example, in the pharmaceutical industry there is a lot of research that's considered very high risk when a particular drug that they make a lot of revenue [on] is put up against a different drug, because there's a chance that it will come out inferior… and they have killed it because it's too high risk.

Scott Ramsey
Fred Hutchinson Cancer Research Center

Pharmaceutical companies have learned that more revenue is possible—with far less risk—by making minor alterations in top-selling drugs about to go off patent (thereby gaining another three years of market exclusivity[85]) rather than by developing innovative new drugs. Yet advances in gene-based diagnostics, biomarker identification, imaging technologies, and targeted therapeutics hold the promise of less severe, more effective tailored treatments using various drug combinations. As subsets of major cancer types are identified (making them, by current incidence definitions, "rare" diseases), each with distinct treatment requirements, the market for specific cancer treatment and prevention drugs may shrink. Therefore, financially attractive ways must be found to encourage pharmaceutical companies to continue producing cancer-targeted drugs. The Panel has previously recommended[86] applying the provisions of the Orphan Drug Act of 1983[87] to all cancer drug development, since doing so would provide financial incentives for pharmaceutical companies to develop small-market agents for rare diseases and extend the period of patent protection.

The United States is a market economy. So if you can prove to people that you can make money in drug development in these diseases, you will see results, but it takes a tremendous amount of collaboration to have that happen.

Kathryn Giusti
Multiple Myeloma Research Foundation
Multiple Myeloma Research Consortium

Drug Approval Issues

A recent study[88,89] found that medications (for any indication) approved by FDA within two months of the deadline for deciding on new drug applications are four times more likely to have serious safety issues that later require market withdrawal or a "black box" warning than those not approved near the deadline. The timeframes for drug approval decisions are based on the 1992 agreement between FDA and the pharmaceutical industry[90] in which the industry agreed to pay user fees (to enable FDA to expand its drug review staff and resources) in exchange for faster drug reviews. In practice, this agreement has led to instances in which life-threatening side effects and deaths have resulted from use of rapidly approved medications,[91,92] and the wisdom of this aspect of the drug approval process has come under increasing scrutiny.

Roundtable discussants underscored the importance of conducting post-marketing (Phase IV) drug studies of efficacy and long-term safety. Pharmaceutical companies are required by FDA to conduct Phase IV post-marketing trials to confirm the safety of drugs that receive expedited review and approval, but compliance with this requirement has been uneven at best.[93] Participants suggested that a mechanism (e.g., patent extension) is needed to support Phase IV trials. In addition to addressing safety issues, these trials also may be useful in guiding companies' selection of drugs in their pipeline to develop further.

Crosscutting Concerns

Roundtable discussants explored several important issues that cut across much or all of the cancer enterprise. It should be noted that these issues, including those related to data systems, data sharing, workforce deficits, education and communication needs, and clear measures of success, are not limited to cancer but are relevant to biomedical research and health care in general.

Data Systems and Data Sharing

The PCP reported in depth in its 2005 report on research translation[94] the importance of interoperable electronic data systems, appropriate data sharing, and strong data privacy safeguards to achieve more rapid research progress and improved care across the cancer enterprise. The paragraphs below reflect observations of the roundtable participants and highlight examples of recent efforts toward broader implementation of these systems.

Data Systems

Roundtable participants repeatedly underscored the need for research databases (e.g., caBIG™, cancer surveillance, clinical trials) that are linked to public health data and electronic medical records (EMRs), including claims data and hospital and ambulatory patient records. Achieving the development, installation, and operation of these systems was acknowledged to be a multi-billion dollar project that could take decades. Analyses of other industries suggest that full implementation of complex, networked technology requires approximately 15 years.[95] Estimates of potential annual cost savings from national implementation and appropriate use of a health information technology (HIT) system in the U.S. vary, but general agreement exists that HIT has significant potential to increase efficiency, reduce occurrence of adverse drug events, and improve disease management and preventive care.[96,97] Many questions remain to be resolved, including how interoperability will be established, who will be responsible for maintaining the databases, and how privacy and ethical issues will be addressed. Commercial partnering (e.g., with Microsoft, Google), which is beginning to occur, was suggested as a mechanism for overcoming some of these challenges.

Currently, only 28 percent of U.S. primary care physicians have EMRs, and only 19 percent have advanced HIT capacity.[98] A recent survey of more than 2,700 U.S. physicians[99] found that costs associated with converting to electronic systems and finding suitable HIT systems remain significant barriers to adoption in small ambulatory care practices. The study concludes that new incentives and financing strategies will be essential to support more widespread implementation of EMR systems. In 2008, the CMS will launch a demonstration project that will provide payment incentives to small- and medium-sized primary care physician practices that use certified EMRs, with the goal to reduce medical errors and improve care for an estimated 3.6 million Medicare beneficiaries.[100]

Similarly, electronic prescribing has the potential to expedite transactions and reduce medication errors, but like EMRs, incentives are needed to encourage small practices and pharmacies to adopt the necessary technology; less than 10 percent of physicians now use e-prescribing technology.[101,102]

> We're talking about creating an infrastructure that allows information to move quickly from one place to another and be accessed from everywhere….We need an interstate highway system like Eisenhower built for this country which completely transformed the economy and we need that for biomedicine.
>
> *Clifton Leaf*
> *Journalist*
> *Susan G. Komen for the Cure*

HIT also has the potential to simplify and expedite documentation related to treatment preapproval and reimbursement claims. Many clinicians have severed their "participating provider" relationships with public and private insurers because documentation and justification requirements have become so burdensome. Streamlining this aspect of care may make clinical practice more attractive to new providers and maintain or improve patient access to care.

Data Sharing

For EMRs, e-prescribing, research-patient data linkages, and other technology applications to be useful, appropriate data sharing must become the norm. Incentives must be devised to persuade competitive private insurers, industry, and academia to contribute their data, both initially and on an ongoing basis. Presumably, Federal agencies such as FDA, the Department of Veterans Affairs/Veterans Administration (VA), CMS, and other government entities could be mandated to share their data. As noted, however, data standards and database maintenance are complex issues that remain to be resolved.

Numerous constituencies are concerned about data privacy and discrimination based on personal health information. In May 2008, the Genetic Information Nondiscrimination Act (P.L. 110-233) was enacted to prohibit the use of genetic test information in hiring, promotion, firing, and health coverage decisions. Its provisions will take effect over a 12- to 18-month period. However, if it is not stringently enforced, public fears of discrimination will not be allayed.

At the same time, however, opportunities for individuals to create and share electronic personal health data files are expanding. The Panel has reported previously[103] on Internet-based resources for cancer survivors and caregivers that enable them to access individualized treatment summary and follow-up care plans and enhanced systems for capturing and sharing patient health records. Since then, a number of commercial partnerships have expanded options for individuals to create personal health data files (e.g., GoogleHealth/Cleveland Clinic,[104] Kaiser Permanente/ Microsoft HealthVault[105]).

> We don't train people to share information. We don't reward them for sharing information. We don't pay them for taking risks and failing. We have a lot of incentives that are all geared in the wrong direction....
>
> *Greg Simon FasterCures/The Center for Accelerating Medical Solutions*

Some of the people who develop personal health data files do so because they have complex medical histories and want their health care providers to be able to access this information quickly and easily. The perceived value of being able to consolidate this information at a single source and personally control access to it appears to outweigh whatever data security concern users may have.

Data sharing across the research and care continuum has been hampered by unintended consequences of the Health Insurance Portability and Accountability Act of 1996 (HIPAA).[106] The President's Cancer Panel has described these problems in depth,[107] as have others,[108,109] and recommended a review of HIPAA provisions underlying the problems being experienced by researchers, health care providers, and the public. Such a review is under way at the IOM; a report is expected in late 2008.

Workforce Issues

Human capital is arguably the most essential infrastructure component of any complex enterprise. Roundtable participants identified several pressing issues facing the cancer research and cancer care workforces.

Cancer Research Workforce

Historically, aspiring scientists have trained and established their careers in the laboratories and clinical centers of academic institutions, with the goal of becoming respected, independent researchers who conduct and direct scientific studies in the areas of their greatest interest. Reaching this goal and maintaining a successful career typically require researchers to win grant funding, principally from Federal research funding agencies or to a lesser extent, voluntary sector sources (e.g., American Cancer Society, foundations). Although industry now funds more research than the Federal Government, most cancer and other health scientists still train and work in academic settings and are dependent

on grant funding, regardless of the source. Unlike industry funding, however, support from government or voluntary organizations tends to be unencumbered by any expectation of results that may support a profit motive.

The percentage of scientifically meritorious NIH grant applications that actually are funded each year is at its lowest level since 1991[110] and uncertain Federal research funding trajectories threaten scientists at all stages of their careers. Flat budgets since 2003 (following the five-year period during which the NIH budget approximately doubled) are the primary reason so few high quality applications are being funded. A dramatic increase in grant application submissions contributes significantly to the low percentage of funded grants. A considerable proportion of these applications are from young scientists who entered biomedical research as research capacity expanded nationwide beginning in 1999 when Congress called for more research on pressing health issues.[111] At NCI, the percentage of high quality grants receiving funding also has been flat or declining since 2003; moreover, the majority of awards each year are the next increment of funding for already-awarded grants rather than new grants.[112]

The most worrisome consequence of these cancer research funding shortfalls and uncertainty about future funding is the loss of bright young investigators to other areas of scientific endeavor. Many young basic and clinical scientists who have trained in U.S. academic centers are taking jobs in industry or returning to their country of origin because a career in academic cancer research does not appear viable.[113] Currently, the average age at which a Ph.D.-trained investigator wins his/her first individual (R01) NIH grant is 43; it is even higher for M.D./Ph.D. clinician-scientists.[114]

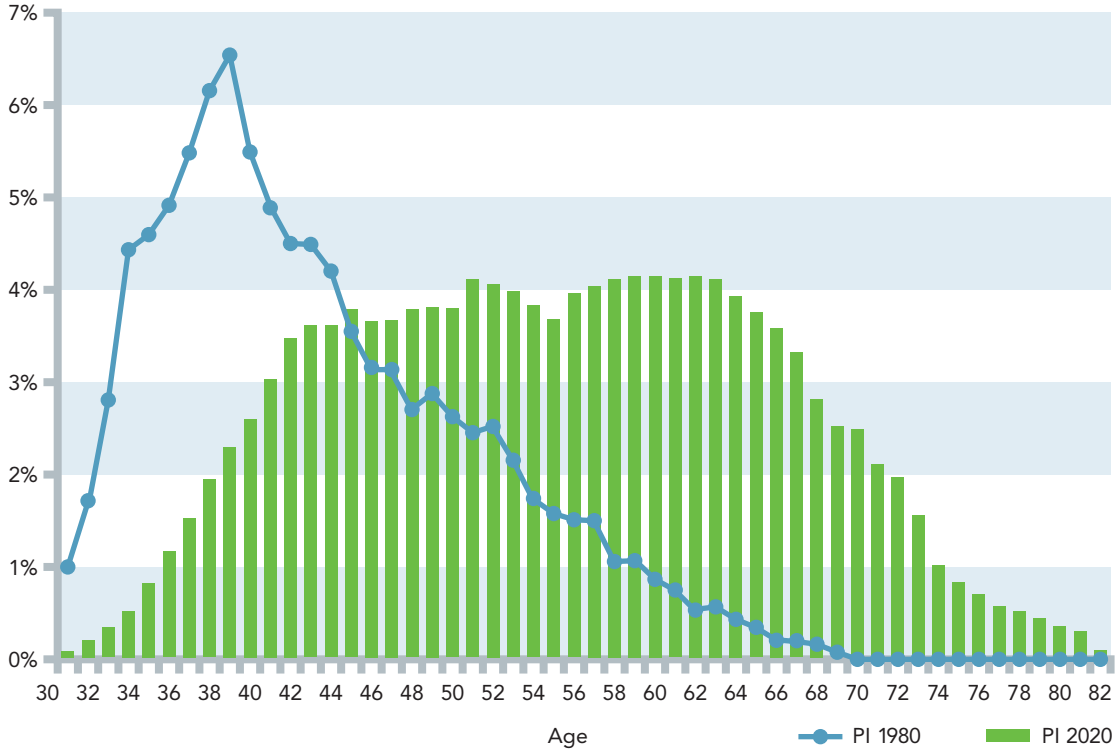
> …a lot of young researchers…spend half their time trying to write grants. They wait a very, very long time. Most of the time at the end of that rainbow there's…just a little sign that says, "Try it again." They deal with their own internal bureaucracies. They don't get to do the kind of important research they want to do. They spend years and years and years just trying to get an independent lab and then find that the science that they're doing is out of favor....they're depressed and they're leaving....some of them are starting biotechs. They're going to industry.
>
> *Clifton Leaf*
> *Journalist*
> *Susan G. Komen for the Cure*

A number of special grant programs sponsored by government, cancer centers, and voluntary organizations have been established to help young investigators secure funding. These were described in detail in the Panel's report on research translation,[115] and though they cannot make up for overall research funding shortfalls, the number of such awards appears to be growing. In June 2008, the American Academy of Arts and Sciences published a white paper[116] recommending specific actions the Federal Government, universities, and foundations should take to nurture early-career scientists of all types. These actions include new and modified funding mechanisms, mentoring programs, and special attention to the needs of primary care providers who are entering faculty roles.

As roundtable participants emphasized, the potential to lose a whole generation of cancer and other biomedical scientists is quite real. Moreover, this potential loss of intellectual capital would be compounded profoundly as much of the current cadre of NIH-funded grantees reach the end of their careers. This has been referred to as the "graying" of NIH grantees,[117] and

Figure 5

Age Distribution of PIs 2020



Source: Zerhouni E. Some observations on demographics of NIH-funded scientists: policy implications for new investigators. Presentation, December 7, 2007.

is illustrated in Figure 5, which compares the age distribution of NIH principal investigators in 1980 and their projected age distribution by 2020.

Roundtable participants also reiterated previous testimony to the Panel regarding the crucial importance of cultivating interest in scientific and medical careers among high school and college students to help ensure that they receive the academic foundations in math and science needed to pursue basic and clinical research curricula at advanced levels.

Cancer Care Workforce

The supply of oncologists, primary care physicians, nurses, technicians, social workers, behavioral specialists, and others who provide cancer care is inadequate to meet current needs in many areas of the country. With projected increases in need for cancer care professionals of all kinds due to the aging population, this situation is likely to worsen and can be expected to impact previously unaffected parts of the nation. Roundtable participants were particularly concerned about shortages of:

■ *Oncologists* Nationally, the current supply of oncologists and the demand for oncology services appear to be in equilibrium, but according to a 2007 study projecting future supply and demand for oncologists, this balance is unlikely to be sustained.[118] Considering a variety of supply-demand scenarios, the study authors project a shortfall by 2020 of 9.4 to 15 million oncology visits, or 2,550 to 4,080 oncologists—approximately one-quarter to one-third of the 2005 supply.[119]

Key factors projected to contribute to this rapidly developing shortage of oncology services include an aging population in whom cancer incidence will increase, growth in the survivor population, an

aging oncology workforce that is retiring in increasing numbers, and too few candidates in the pipeline even for the limited number of oncology fellowship positions.[120] The supply-demand equation also may be influenced by more complex cancer treatments in the future that reduce the number of patients each practicing oncologist can care for, and new generations of oncologists who may work fewer hours per week and/or for fewer years than their predecessors. A combination of strategies addressing these factors will likely be needed to minimize the national oncology workforce shortage. Strategies to close the gap between supply and demand for oncology services are unlikely to help urban and rural populations already experiencing severe oncology service shortages unless incentives are created to attract and retain oncology practices in these geographic areas.

■ *Primary Care Physicians* Primary care providers are crucial to cancer prevention, early detection, and control efforts and for many patients are gatekeepers to cancer treatment, including clinical trials. However, the primary care workforce has long suffered from low reimbursements for services and low status in the medical profession. As a result, a declining number of U.S. medical students are choosing careers in primary care in favor of higher paying specialty fields. According to Health Resources and Services Administration (HRSA) physician supply and demand projections, overall primary care physician supply and need will grow at about the same rate until 2020, at which point need will grow faster than supply.[121] Another analysis estimates that without intervention, a shortfall of 35,000 to 45,000 generalists is likely by 2025.[122] The present relative balance of supply and demand for primary care services is due principally to the large influx of recruited international medical graduates (IMGs).[123] This approach to meeting demand probably is not sustainable and may drain scarce health resources in IMGs' home countries.[124]

As is the case with specialists, some geographic areas have severe shortages of primary care capacity. HRSA notes that national projections mask geographic variations in physician supply; the agency estimates that about 7,000 additional primary care physicians are needed now to alleviate the lack of providers in federally-designated medically underserved areas, where 20 percent of Americans reside.[125,126]

Senate testimony by the Health Care Director, General Accountability Office, notes that "health care workforce projections that are mostly silent on the future supply of and demand for primary care services are symptomatic of an ongoing decline in the nation's financial support for primary care medicine."[127] The Federal Government acknowledges the need to support primary care education to increase the number of available physicians, but Federal funding for physician training programs (e.g., National Health Service Corps) has been flat or declining for years.[128]

In addition to shortages in primary care physicians overall, inadequate training of the current provider workforce to care for the aging population is being recognized. According to an IOM report,[129] the U.S. has just over 7,000 certified geriatricians today; by 2030, an estimated 36,000 will be needed to coordinate the care of the elderly population, who may have multiple comorbidities including cancer and late effects from earlier cancer treatment. In addition to increasing the number of geriatricians, the IOM recommends strengthening geriatric training for all primary care providers, including physicians, nurse practitioners, nurses, and others.

■ *Nurses* The implications of the national nursing shortage tend to be overlooked. The importance of support and education provided by nurses to cancer patients and their families is underappreciated but has

been shown to provide a crucial emotional underpinning, particularly during the treatment phase, and to improve both quality of life and overall survival.[130] Similarly, nursing support is an essential component of care across the health care continuum, and the vital and influential role of nurses in successful hospital quality improvement efforts has been noted.[131]

A recent re-analysis of Current Population Survey data from 1973-2005[132] predicts a significant shortage of registered nurses (R.N.s) by 2012 (projected 2.9 million).[133] The Bureau of Labor Statistics estimates that the U.S. will require 1.2 million new R.N.s by 2014 to meet the nursing needs of the country—500,000 to replace those leaving practice plus 700,000 to meet rising demand for nursing services.[134]

Among several factors influencing these estimates, two are of particular importance. First, the nursing population is aging; the average age of full-time R.N.s in 2005 was 43.5 years, with those in their 40s comprising the largest age group.[135] According to one estimate, approximately half of the R.N. workforce is expected to reach retirement age within the next 10 to 15 years.[136] Second, Federal nursing education and incentives to enter nursing are undersupported. For example, some HRSA-administered nursing education programs are able to fund less than 15 percent of applicants.[137] In 2006, schools of nursing were forced to reject more than 147,000 qualified applicants in large part due to lack of faculty.[138,139] Thus, stronger support for nursing education is essential both to train new nurses and to develop nursing faculty.

> If we're going to make all these great changes—and by the way, the deliverers, if you will, armed with clipboards and protocols are going to be nurses. Physicians are going to be the backup to nurse clinicians because they are the people who really follow a protocol. They don't miss anything. So if we really were going to have a system we'd have the front-line nurses, and by the way, we can't even train nurses now. I don't know if you know that. We have no faculty for nurses because faculty for nurses aren't paid [enough] and so you can't get into nursing school.
>
> *David Nathan*
> *Dana-Farber Cancer Institute*

As the overall number of nurses drops in the coming years, a commensurate decrease in nurses with specialized oncology training also is likely. This deficit is of particular concern as the number of new cancer cases and survivors rises in the coming years; oncology nurses administer chemotherapy, coordinate patient therapies (including clinical trial protocols), manage side effects, and provide counseling to patients and families, among other functions. Their specialized knowledge is vital to effectively deliver the benefits of research across the trajectory of each individual's cancer experience. However, attempts to cut health care costs have included lowering the level of expertise (and wage expense) of nurses who provide care to cancer patients.[140] This trend may discourage general practice nurses from entering this challenging field. Further, to advance oncology nursing research and practice, greater support for master's-and Ph.D.-prepared nurse researchers is needed through the National Institute for Nursing Research, NCI, and HRSA nursing workforce programs.

Other Health Care Providers

Nurse practitioners (N.P.s) and physician assistants (P.A.s) are helping to fill the growing gap between primary care physician supply and demand for primary care services to serve an aging population with complex health problems. These advanced practice professionals are in high demand by many specialty physician practices, including

oncologists, since they can assist with new patient consultations, write prescriptions, and perform invasive procedures, among other tasks.[141] Depending on state law, N.P.s and P.A.s may have independent practices in family medicine, adult care, pediatrics, and oncology. At least one study has shown comparable patient outcomes in patients randomly assigned to N.P.s and primary care physicians.[142]

N.P. and P.A. services are reimbursed by CMS, other public, and some commercial insurers; payments may vary based on level of training and other factors.[143,144] However, reimbursement for the services of many other nonphysician health care providers (e.g., social workers, nutritionists, complementary therapy providers) remains inadequate, inconsistent, or unavailable.

Over the past several years, patient navigators—trained individuals, usually from the community, who help patients obtain needed care in the fragmented and often confusing health care system—have been gaining recognition as an important addition to the patient support team. Navigators appear to be especially effective in helping individuals with suspicious screening test results obtain crucial diagnostic services, and if needed, treatment and other care in the event of a positive diagnosis. NCI[145] and CMS[146] each sponsor patient navigator research and demonstration programs. The Patient Navigator Outreach and Chronic Disease Prevention Act of 2005 (P.L. 109-18), though minimally funded to date, appears to be providing momentum for public and private initiatives to offer navigation services to newly diagnosed cancer patients in hospital and other settings.

Education and Communication Issues

The Panel has reported previously and made several recommendations[147] addressing the need for better education and communication between and among policymakers, the research and health care communities, advocates, and the public. The paragraphs below highlight related observations of the roundtable participants.

Policymakers, the Research and Health Care Communities, and Advocates

Many policymakers do not understand the complexity of cancer or the need for stable research funding. In addition, many policymakers do not appreciate the impact of the current health care system design and insurance reimbursement structures that prevent us from substantially reducing cancer mortality and morbidity by applying universally what we already know is effective.

In 2006, the Commonwealth Fund published a report[148] that sets out a conceptual framework to support effective use of health services research in state

> …I think we haven't been honest about communicating the [cancer] crisis to the American people....
>
> *Clifton Leaf*
> *Journalist*
> *Susan G. Komen for the Cure*

health policymaking. The framework describes four key stages: understanding the scope and extent of the problem, developing options, implementing a program or policy, and evaluating the program or policy. For each stage, practical lessons and constructive communication strategies for researchers and policymakers are suggested. Among the goals of the framework are to accelerate health system improvement by forging sustainable partnerships between researchers and policymakers based on mutual trust.

The public and private research communities tend to communicate poorly across disciplines, which hampers team science and other collaborative research. Applicability of research findings to patients is a primary focus for relatively few investigators, particularly in basic science. In addition, many have limited understanding of intellectual property and patent laws or regulatory processes related to drug and device development; the Panel has reported previously on the impact of this knowledge deficit on research translation and efforts under way to address this issue.[149]

Roundtable participants also echoed previous testimony heard by the Panel concerning the lack of a prevention orientation in the health care community. Most physicians and other providers receive little training in disease prevention and therefore do not understand its value. Reimbursement structures do not adequately support the provision of preventive health services, adding to their perceived low value among many providers. Similarly, most physicians receive little research training and may not understand the value of clinical trials. They thus are unprepared to participate in community-based clinical cancer research or educate patients about trials from which they may benefit. These educational needs are compounded by the nature of the health care system itself, which is competitive rather than collaborative and integrated, discouraging patient sharing and clinical trials promotion.

Further, roundtable participants cited the need to address counterproductive fragmentation in the advocacy community that has resulted from the cancer site-specific mission of most cancer advocacy organizations. Specifically, advocates need to be informed and persuaded that research on cancer pathways is likely to benefit the prevention and treatment of numerous cancer types, so that they might coalesce around a unified effort to strengthen and sustain cancer research funding as a whole.

The Public

In general, the public has limited health literacy regarding all aspects of health care, and is justifiably confused by conflicting and misleading messages about cancer and cancer prevention, the true importance of reported research discoveries, and the potential benefit of participating in clinical trials. The IOM defines health literacy as the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions.[150] A national literacy study[151] found that about half of the U.S. adult population has difficulty using text to accomplish everyday tasks. Limited health literacy is compounded by equally widespread limited numeracy, the ability to understand and use numeric information in decision making. Numeracy is particularly important in communicating disease risk information and in individuals' perceptions of risk.[152]

These population characteristics must be taken into consideration when developing and delivering cancer and other health information to patients and

the public. In 2007, the Joint Commission[153] published a white paper[154] that provides recommendations for making effective communications an organizational priority, incorporating strategies to address patients' communication needs across the continuum of care, and pursuing policy changes that promote improved practitioner-patient communications. In addition to literacy and numeracy, the white paper emphasizes sociocultural and other factors that affect how patients understand and communicate health-related information.

Roundtable participants suggested that the majority of the population also does not understand the scientific method and thus are unlikely to be strong advocates for cancer research funding. Although the scientific method typically is taught in U.S. middle and high school science courses, it does not seem to have been integrated by most individuals into an understanding of its real-world application in medical and other research to achieve health care advances. Moreover, many Americans are unaware that NIH is the leading source of Federal support for biomedical research in this country. Most also do not recognize how they already benefit, and will benefit in the future, from biomedical research findings.

> …if you ask people what their chances of getting cancer are, they think it's 1 in 100 and 1 in 1,000, and when you ask them how much they're spending on cancer research they usually tell you it's between 10 and 100 times the amount that we really are. So the disease is more common than they think and it's being less well funded than they imagine, so obviously education from both ends needs to take place.
>
> *Geoffrey Wahl*
> *Salk Institute for Biological Studies*

In addition, patients need to be educated as to why their biospecimens are important to advancing cancer research and care. Many refuse to share personal medical information or consent to the research use of their tissues and body fluids for fear of insurance or employment discrimination that may result from genetic or other test results that indicate a possible predisposition to cancer. The recently enacted Genetic Information Nondiscrimination Act of 2008 (P.L. 110-233) should prove an important step toward allaying public concerns but must be coupled with effective communication efforts.

Few people are knowledgeable about cancer until they, a family member, friend, or coworker are diagnosed. Information about cancer as a disease and opportunities to prevent cancer through lifestyle choices typically are not included in school health curricula (except for anti-tobacco messages). In collaboration with the Ad Council, C-Change (a coalition of public and private organizations committed to eliminating cancer as a public health threat)[155] has developed a cancer prevention communications campaign, which was launched nationwide in Summer 2008, that makes available to any employer or other organization an online multimedia toolkit with downloadable products. The four key messages of the campaign—Eat Right, Be Active, Get Screened, and Don't Smoke—have the common theme that cancer prevention is possible.

Roundtable participants emphasized the importance of making more effective use of media and media gatekeepers to deliver cancer-related and other health messages. For example, serialized radio dramas that deliver health messages, a model used successfully for decades in other countries, have been developed to address health problems (e.g., diabetes, hypertension) experienced disproportionately by urban and other populations.[156]

Other topics for public education identified by roundtable discussants included:

- Conveying the urgency of supporting cancer research given changing demographics and the need for more successful therapies
- Fostering understanding that cancer research advances have informed and helped to advance research on other diseases (e.g., HIV/AIDS)
- Improving understanding that ongoing research is essential because cancer is a "moving target," in that it has the capacity to develop drug resistance
- Explaining inherited versus acquired cancer risk and helping individuals accurately assess their personal cancer risk
- Dispelling fatalism about cancer, which is common and particularly entrenched in some cultures
- Dispelling other myths about cancer (e.g., that a cancer cure exists but is being withheld, that cancer surgery causes the disease to spread)
- Conveying that clinical trials offer the possibility of cure and should be considered as first-line treatment rather than as a last desperate choice when standard therapies fail. It was noted that insurers also require clinical trials education to encourage reimbursement for clinical trial participation by everyone eligible, particularly newly diagnosed patients whose disease is not advanced.

Untapped Resources

The advocacy community is able to raise levels of awareness and discourse in ways the scientific community and government cannot. To educate policymakers, researchers, clinicians, and the public about cancer as a disease, the importance of cancer research, personal and policy actions that can reduce cancer mortality and morbidity, and the need to improve and expand cancer care services, we must better appreciate and capitalize on the power of cancer advocates and survivors as educators and communicators.

Likewise, nurses, social workers, trained community health workers, and patient navigators have enormous untapped potential to bring accurate, timely information about cancer to the public, to individuals diagnosed with cancer, and to their loved ones.

Measures of Success

Population-level metrics for gauging success in the cancer enterprise are largely absent, and progress assessment at this level is necessary to determine whether research and interventions actually are reducing cancer mortality and morbidity.

Measures of Success in Research

Current measures of research success (e.g., number of papers published, number of grants won, promotion or tenure achievement, number of patents and drug approvals, revenues from sales of specific medications) do not measure whether research findings result in fewer cancer cases, fewer cancer deaths, substantially improved survival, or improved quality of life. In particular, roundtable participants called for a more robust discussion about research translation, emphasizing that volume of activity is assumed to be a proxy for results, which is not the case. Participants further indicated that while the possible clinical application of basic science discoveries may be difficult to predict, it may be worthwhile to require investigators across the research spectrum to address potential or anticipated clinical benefit in their grant applications.

Measures of Success in Cancer Care

Existing measures for quantifying the quality and impact of interventions across

the cancer care continuum do not clearly demonstrate the effect of specific cancer treatments and other interventions—or the aggregate efforts of the National Cancer Program—on cancer mortality and morbidity at the population level.

Change in cancer mortality (rates per 100,000 population and absolute number of deaths) is the principal quantitative measure of success against cancer at the population level. However, the data sources used to project annual cancer deaths[157] have important limitations (e.g., incomplete data on cancer care provided, racial and ethnic misclassification). Population morbidity due to cancer often is measured as the economic cost of lost productivity. This broad measure of morbidity does not capture the numerous factors that may contribute to lost productivity among people with cancer (or their caregivers), though some researchers have attempted to quantify health limitations and quality of life morbidity related to specific cancers.[158]

Cancer screening data have limited utility for assessing population-level benefits of screening participation. While screening utilization may correlate with earlier stage at diagnosis and be a proxy for decreased morbidity (resulting from less severe disease and treatment), earlier diagnosis does not necessarily correlate with lower mortality rates. Moreover, it currently is possible to screen only for breast, cervical, prostate, skin, and colorectal cancers, and screening is not universal.

Cancer screening, treatment, and supportive care guidelines have been developed by numerous organizations (e.g., NCI,[159] the National Comprehensive Cancer Network,[160] the American Society of Clinical Oncology,[161] U.S. Preventive Services Task Force[162]). These diverse guidelines may be based on scientific evidence of varying rigor and are updated at different intervals. Providers are challenged to know which guidelines are most relevant for specific patients and to remain informed about guideline changes.

Other quality of care measures include: (1) comparative effectiveness analyses, a relatively nascent measurement tool, which may most closely compare elements of care with patient outcomes because they focus directly on whether a treatment or other intervention results in improved outcomes both for individuals and groups of similar patients. These analyses currently are being used to construct health benefit packages and make insurance coverage decisions; (2) pay-for-performance (P4P) initiatives, which are widely used to measure adherence to practice guidelines and efficiency benchmarks for purposes of deciding individual health care provider reimbursement and as a cost control tool; and (3) data sets such as the Healthcare

Effectiveness Data and Information Set (HEDIS)[163] and the Healthcare Cost and Utilization Project (HCUP),[164] which are used by health plans, states, and researchers to assess delivery of specific aspects of care.

Population-level measures of success in cancer care must be improved so that we can know if progress is being made against the disease.

Proposals for Centralizing Efficacy of Care Assessment

A 2008 IOM study[165] concluded that "the nation must significantly expand its capacity to use scientific evidence to assess 'what works' in health care." Several options have been put forward for organizing Federal (and ideally, privately funded) research on the comparative effectiveness of medical treatments.[166,167] These include: (1) expanding the role of an existing agency that already oversees or conducts health services research (e.g., Agency for Healthcare Research and Quality, NIH); (2) creating a new agency either within the U.S. Department of Health and Human Services (HHS) or as an independent body that is part of either the executive or the legislative branch (e.g., Federal Trade Commission); (3) augmenting an existing quasi-governmental organization (e.g., IOM); and (4) establishing a new public-private partnership to oversee and direct these analyses (e.g., a nonprofit, federally funded research and development center). Each of these options might require trade-offs in terms of the entity's independence, credibility with the medical profession, and ability to reach controversial conclusions while maintaining accountability and responsiveness to policymakers and other interested parties.[168] Any initiative to conduct thorough, standardized efficacy assessments will require complete transparency in clinical trials reporting. Media reports and lawsuits alleging that pharmaceutical companies have suppressed negative clinical trial data suggest that this transparency may need to be legislated.[169]

> …studies that move beyond just effectiveness to efficacy to impact…need to be better incorporated into the entire scheme of things so that we can have a sense of whether or not what works in a controlled setting is likely to affect the lives of real communities that are very diverse across the nation.
>
> *Sandra Millon Underwood*
> *University of Wisconsin–Milwaukee*

The IOM report[170] recommends designating a single entity with authority, overarching responsibility, sustained resources, and adequate capacity to ensure production of credible, unbiased information about what is known and not known about clinical efficacy. Accountable to Congress, this entity would be the institutional home of a national organization for clinical guidelines, effectiveness standards, and efficacy reviews. Reviews would be conducted, drawing upon the nation's existing capacity for developing practice guidelines and insurance coverage policy, and providers and purchasers of care would preferentially use recommendations developed according to the established standards.

Critics suggest that an attempt to set rigorous national clinical practice guidelines could slow new treatment technology advances and deny patients timely access to new therapeutic options.[171] Albeit potentially controversial, the President's Cancer Panel believes that such an approach—or a similar one that ensures autonomy, authority, funding support, and accountability—would be an important step toward developing clear measures of success in the cancer care enterprise. Guidelines generated by such a body must, however, be coupled with analyses that demonstrate clearly whether patients treated according to specific guidelines experience significantly reduced mortality and short- and long-term morbidity.

PART II

Recommendations

The President's Cancer Panel recommends three crucial actions to make substantial and rapid reductions in cancer mortality and morbidity:

- Make reducing the cancer burden a national priority.
- Ensure that all Americans have timely access to needed health care and prevention measures.
- End the scourge of tobacco in the United States.

The following sections discuss why these actions are so critical and include suggestions and strategies offered by roundtable participants toward realizing these objectives for the benefit of the American people.

Recommendation

1 Reducing Cancer Mortality and Morbidity Must Become a National Priority

The Panel believes that the leadership needed to maximize investments in the cancer enterprise and dramatically reduce cancer mortality and morbidity must come from the President of the United States. Making cancer a national priority will require stronger and more stable support for cancer-related research and progress milestones, to which the research and delivery components of the cancer enterprise are held accountable.

Our country is struggling to address multiple priorities that compete for finite resources and attention. Yet few priorities should be higher than cancer, which strikes 4,000 Americans and kills another 1,500 every day.

In the war on cancer, begun officially with passage of the National Cancer Act of 1971, our success has been limited in two important ways: inconsistent leadership and little coordination of cancer research and care activities.

History and Barriers Related to National Cancer Program Leadership and Coordination

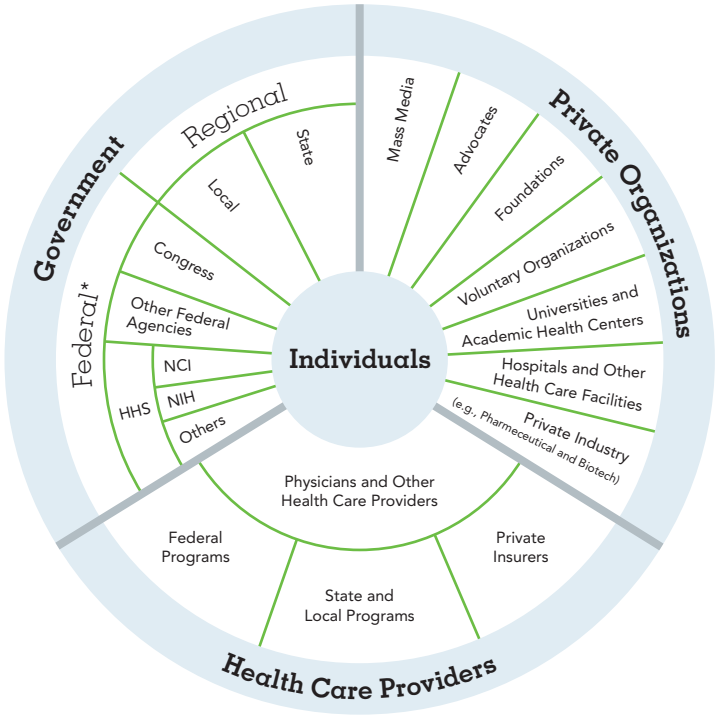
As noted earlier, the National Cancer Program (NCP) involves not just researchers, health care providers, and patient/survivor advocates, but all parts of industry and society that have a role in improving or exacerbating the national cancer problem. As such, the NCP comprises a massive constellation of institutional and individual stakeholders, each with its own set of constituents; ethical, financial, and legal concerns; and organizational, programmatic, and personal objectives. Among virtually all of these stakeholders, relative autonomy in deciding how to conduct their affairs is prized as a right.

The National Cancer Act assigned leadership and coordination of the NCP to the Director of the National Cancer Institute (NCI), although subsequent reauthorizations weakened the language concerning this charge. NCI, however, has always seen itself as a research institution with little or no responsibility for education or health care delivery issues. NCI's Directors have not sought to explicitly direct actions of the multitude of public and private agencies or industries that significantly affect the national cancer burden. NCI maintains advocacy and legislative liaison offices, but not offices dedicated to collaboration and coordination of activities within and outside of NCI.

The issue of overall leadership and coordination of the NCP is far from new; an informative chronology beginning with activities that led to the National Cancer Act documents the ongoing struggle to define clearly both the NCP itself and the seat and bounds of responsibility for managing it.[172] One effort to clarify these and related issues was initiated in 1993 at

Figure 6

Components of the National Cancer Program



*Examples of Federal Agencies Involved in Cancer-Related Research, Care, or Regulation:

- Department of Health and Human Services
  - National Cancer Institute
  - National Institute for Environmental Health Sciences
  - National Center for Human Genome Research
  - Other NIH Institutes and Centers
  - Centers for Disease Control and Prevention
  - National Institute for Occupational Safety and Health
  - Food and Drug Administration
  - Centers for Medicare and Medicaid Services
  - Indian Health Service
  - Health Resources and Services Administration
  - Agency for Healthcare Research and Quality
  - Agency for Toxic Substances and Disease Registry
- Environmental Protection Agency
- Department of Commerce/National Institute of Standards and Technology
- Department of Energy
- Department of Labor
- Department of Defense
- Department of Education
- Department of Housing and Urban Development
- Consumer Product Safety Commission
- Department of Veterans Affairs
- Department of Agriculture

Adapted from: Subcommittee to Evaluate the National Cancer Program. Cancer at a Crossroads: A Report to Congress for the Nation. National Cancer Advisory Board, 1994.

the request of both houses of Congress, which directed the National Cancer Advisory Board (NCAB) to appoint a subcommittee to evaluate the NCP and recommend changes to accelerate progress against cancer. The subcommittee's 1994 report, *Cancer at a Crossroads: A Report for the Nation* states: "The National Cancer Program suffers from an absence of national coordination of cancer-fighting efforts in the public, private, and voluntary sectors."[173] The report recommends establishing "a Presidentially-led plan for overall coordination of the NCP that includes appropriate Cabinet-level representation, criteria for broad participation in Program planning and activities, and re-establishment of the 1971 legislative authority for national coordination of NCP cancer-related research activities of government, industry, and voluntary sectors."[174]

In response to the report, NCI and its advisory committees requested that the National Academy of Sciences establish

a National Cancer Policy Board (NCPB) to "examine the needs of a truly national cancer effort." In October 1996, the NCPB was formed but was charged only to survey current and possible outcomes of the nation's cancer effort and deliberate on issues of broad national significance in the movement of research findings into implementation. At that time, the NCI Director stated that the issues the NCP needed to confront required a forum that could produce useful advice, guidelines, or recommendations, independent of the constraints of a particular Federal agency, advocacy group, or set of interests in the NCP.[175] Thus, although the NCPB (reconfigured in 2005 as the National Cancer Policy Forum) produced a number of useful policy reports, its charge fell short of providing the coordination called for by the Crossroads report.

In 1998, with the issues of NCP leadership and coordination undiminished, the National Dialogue on Cancer (NDC) was established as a forum to bring together key leaders in the public, private, and not-for-profit sectors to initiate an ongoing dialogue on the eradication of cancer as a major public health problem. Championed by former President George H.W. Bush and former First Lady Barbara Bush, the objective of the NDC was to leverage the resources of these three sectors toward this goal. Conceptually, the NDC stemmed from a diagram in the *Crossroads* report depicting the components of the NCP as a set of concentric circles around a hub of individuals affected by cancer (Figure 6).[176]

Although the NDC (renamed C-Change in 2004) has been successful in bringing together broad representation from the public, private, and not-for-profit sectors to consider solutions to specific cancer research and care issues, it has not included coordinating efforts across the cancer enterprise as part of its mission.

In 2008, leadership and coordination remains one of the most significant weaknesses of the National Cancer Program. Beyond the representation in Figure 6 above, we lack a clear picture of the cancer enterprise as a whole (e.g., dollar flow, information flow, realms of authority, relationships among entities). This central problem stymies efforts to coalesce around a shared vision and coordinate research, educational, and service delivery efforts. It also impedes the collaborative decisionmaking needed across the cancer enterprise continuum (e.g., National Institutes of Health and the pharmaceutical and biotechnology industries; research and advocacy; intra- and extramural researchers; payers, providers, and advocates; media, government, and industry).

Suggested Strategies for Addressing Leadership and Coordination Issue

Agreement was unanimous among roundtable participants that the scientific, health care, and advocacy communities need to unite in messages to policymakers to restore a sense of urgency about the cancer problem (including tobacco policy) and improve funding levels. Roundtable participants indicated that some government agencies, including those listed in Figure 6, and nonprofits (e.g., American Cancer Society, Lance Armstrong Foundation, American Society of Clinical Oncology, other

> …whatever the President's job is—whether it's to protect the American public, the economy, educate our youth, take care of our elderly—curing cancer is a central part of that job….if we don't make this a national priority for whoever is President, then we are going to suffer those consequences for 50 years….
>
> *Greg Simon*
> *FasterCures/The Center for Accelerating Medical Solutions*

I think all of us would balk at the idea of having an entirely centralized research infrastructure enterprise where some small group of people make the choices for everybody, but there does seem to be a need for some sort of oversight structure where group A knows what group B is doing, which doesn't seem to be the case.

Deborah Banker
Leukemia and Lymphoma Society

professional and philanthropic organizations) can and should play larger roles in the areas of education, training, and service delivery. There was, however, no consensus on how NCI's role should change as a research institution, a research funding source, or a coordinator of research activities, or the extent to which NCI should become more involved in health care delivery issues.

Roundtable participants discussed the possibility that designating an individual within the White House Office of Domestic Policy to coordinate the activities of a coalition of cancer enterprise participants may be useful to assist the President in ensuring that necessary progress is being achieved. Some participants echoed previous testimony before the Panel suggesting that while stronger leadership and coordination are critically needed across the cancer enterprise, appointing a "cancer czar" would not be desirable or effective. Resistance to centralization is strong among many stakeholders, and some believe that an unproductive layer of bureaucracy would be created. Other roundtable participants maintained, however, that an individual or office (e.g., a Cabinet-level position) established to facilitate coordination could be beneficial, but agreed that any such person or office would be ineffective without sufficient resources and authority.

Examples of public/voluntary/private coordinating bodies include the HIV/AIDS Network Coordination project,[177] the Diabetes Mellitus Interagency Coordinating Committee,[178] the Interagency Committee on Disability Research,[179] and the Autoimmune Diseases Coordinating Committee.[180] Though none of these groups appear to have authority to direct the activities of participating agencies and some do not include nongovernmental organizations, examining the structure, challenges, failures, and successes of these organizations may offer lessons for constructing a coalition of stakeholders committed to coordinating the research and care activities of the national cancer enterprise.

Despite minimal coordination and fragmented, uneven leadership, the NCP has made important strides against some types of cancer. But with our nation at the cusp of transformative approaches to treating cancer, and with an approaching storm of cancer incidence in our aging population, we dare not wait any longer to make achieving rapid progress in cancer research, prevention, and care an urgent national priority. The NCP must have strong leadership and coordination across the breadth of the cancer enterprise to reorder current research and cancer care funding emphases, provide necessary resources, and catalyze collaborations that will most effectively minimize suffering and death from this disease.

…there is enough money in the system if moving the cancer story quicker becomes a priority. I'm convinced of that, so whether it's one war, two wars, or three wars, or wherever you want to spend our money, when cancer becomes enough of a priority, there is enough money there to make a huge difference.

John Seffrin
American Cancer Society

Recommendation

2 All Americans Must Have Timely Access to Needed Health Care and Prevention Measures

Small, incremental health care system and insurance coverage changes—each of which takes years to enact and is fraught with political and ideological entanglements—are not adequately addressing fundamental health care system problems that keep costs spiraling upward and erode Americans' access to care. This approach is a failure and will not markedly reduce morbidity and mortality from cancer either now or in the future as the cancer epidemic mounts.

In each of its reports since 2001, the President's Cancer Panel has recommended significant health care system reform to ensure that all Americans receive adequate preventive, acute, and chronic disease care to reduce the burden of cancer and bring the benefits of research to all segments of the population. Similarly, an Institute of Medicine report on public health in the 21st century maintains that "adequate population health cannot be achieved without making comprehensive and affordable health care available to every person residing in the United States."[181]

Americans have not benefited fully or equally from available evidence-based cancer prevention and treatment interventions. Not delivering what we know to be effective is a major reason for our failure to achieve more rapid reductions in cancer mortality and morbidity. The current health care system suffers from critical weaknesses that require comprehensive system reforms.

Health Care Spending

Health care spending in the United States surpassed $2 trillion in 2006, or $7,026 per person per year. This level exceeds spending in any other country in the world, and is more than double the average among Organization for Economic Cooperation and Development industrialized nations.[182]

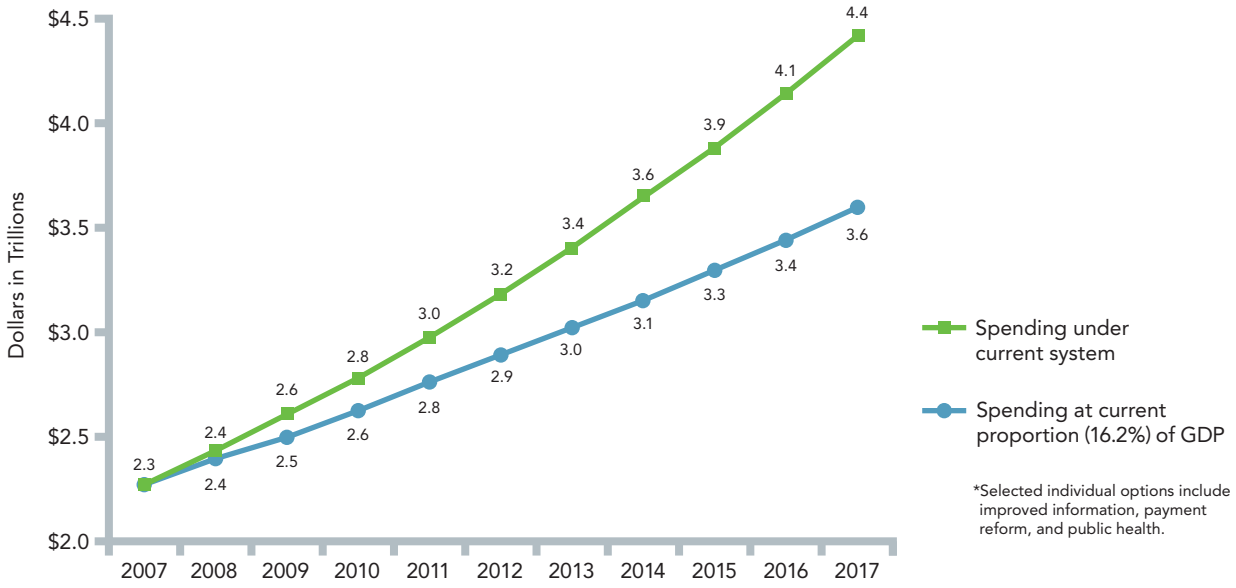
As Figure 7 shows, U.S. health care spending could reach $4.4 trillion by 2017 if the current system remains unchanged, given demographic and other trends. Even if spending could be held to its current percentage of Gross Domestic Product (GDP), expenditures could reach $3.6 trillion by 2017.

The National Institutes of Health estimates that in 2007, the overall costs of cancer reached $219.2 billion. Of this amount, $89 billion was spent for direct medical costs, $18.2 billion was spent on indirect morbidity costs (the cost of lost productivity due to illness), and $112 billion in cost was due to indirect mortality costs (the cost of lost productivity due to premature death).[183]

The acceleration of health care costs at the rates experienced over the past decade is unsustainable. One roundtable participant suggested that people are neither speaking frankly about the impending cancer treatment cost burden that may threaten

Figure 7

Projected Total National Health Expenditures, 2008-2017



Adapted from: Schoen C, Guterman S, Shih A, Lau J, Kasimow S, Gauthier A, and Davis K. *Bending the curve: options for achieving savings and improving value in U.S. health spending.* Commonwealth Fund Commission on a High Performance Health System, December 2007.

the country in the coming years, nor recognizing that the overall cost of medical care will affect our ability to deliver on the promise of cancer research advances.

Delivery System Realities

The private health care delivery system is competitive rather than collaborative; it is revenue- and cost control-driven rather than patient-driven. Likewise, the pharmaceutical industry is highly revenue-driven. The chronically underfunded, publicly supported delivery system is of necessity oriented more toward cost control than patient outcomes. To varying degrees, all of these principal players lack the perspective that they are part of a total system whose purpose is to maintain and improve population health. This lack of a system orientation and shared patient-centered goals is a major barrier to improving efficiency and quality of care. Arguments for major changes in how the system operates have been hampered by limited actual data (as opposed to models or other projections) that persuasively demonstrate that financial viability and improved patient outcomes are possible and worth (both economically and societally) the temporary upheaval that would accompany large-scale system changes.

Another underacknowledged reality of the cancer enterprise is the extent to

> …from a pathway and mechanism perspective, it's also going to require a huge amount of education on the payer side…the power that they wield with whether they're going to pay for certain drugs in certain situations and it takes forever sometimes when an application is discovered to get it up to regional coverage and to national coverage.
>
> *Sandra Murdock*
> *Nevada Cancer Institute*

which third-party payer systems influence resource allocation in research and delivery. Access to interventions across the cancer care continuum depends largely on payer reimbursements. If insurers refuse to reimburse expensive new interventions, their refinement will be stunted, access will be limited, and researchers and providers will explore other approaches, even if the new interventions and technologies produce better patient outcomes. In that regard, it must be acknowledged that while "personalized" cancer care based on genetic and other profiles of each person's tumor eventually may fundamentally transform our approach to cancer, these costly treatments will likely benefit only the affluent and well-insured for many years. Disadvantaged populations may not have access to this sophisticated care for decades; the potential exists to exacerbate existing cancer health disparities.

Roundtable participants noted that business models designed to lower overall health care costs will be difficult to implement if intervention (e.g., prevention, prophylactic vaccines) is pushed earlier in the disease process. The long-term value of preventive interventions (e.g., lower total health care costs per individual) has been estimated.[184] Currently, however, consumer demand for preventive interventions (e.g., tobacco use cessation assistance to reduce risk of cancer and other tobacco-related diseases) is low, even with insurance coverage; as a result, the cost savings that might accrue from illness avoided are not being realized. Demand is low in part due to ineffective patient and provider incentives and short-term cost control objectives of private and public payers that cause many to resist expanding access to preventive interventions (e.g., prophylactic vaccines, nutrition and weight control counseling) or informing patients of such services when they are available.

Employer appreciation of the benefit of wellness programs, however, may be increasing. At least one recent survey suggests that more large employers are offering or contemplating premium discounts, cash payments, gift cards, and other enticements for employees to participate in employer-sponsored health and wellness programs. Of those that have measured the return on this investment, more than 80 percent are seeing returns of better than break-even.[185] A recent report concludes that an investment of $10 per person per year in proven community-based programs to increase physical activity, improve nutrition, and prevent smoking and other tobacco use could save the country more than $16 billion within five years—a return of $5.60 for every dollar invested.[186]

Major changes in the way research and health care are financed and delivered—and changes in the focus of each (e.g., toward wellness and prevention)—almost certainly will bring changes in funding, practice patterns, and incentives. This shift may well endanger the careers of some individuals or the viability of organizations whose success is defined by the status quo, since it is unlikely that redirected incentives will be able to replace all lost revenue for every practitioner and institution.

Critical Weaknesses of the U.S. Health Care System

The United States continues to compare unfavorably with other industrialized countries in terms of deaths from treatable conditions, including cancer.[187] This measure is considered a reflection of access to timely and effective health care and overall health care system quality. An update of an earlier 19-country analysis of deaths before age 75 from causes that would be responsive to appropriate health care found that the decline in "amenable mortality" in all countries averaged 17 percent between 1997-98 and 2002-03. In the United States, however, the decline over that period was only four percent.[188] The analysis suggests that if the United States could reduce

amenable mortality to the average rate achieved in the three top-performing countries, 101,000 fewer deaths would have occurred during the study period.

Infrastructure Distribution and Fragmentation of Care

Perhaps the most fundamental weakness of the current health care system is the longstanding and ongoing maldistribution of cancer-related infrastructure, including facilities; providers; and treatment, supportive, and survivor services. Without question, many factors in addition to access to care contribute to cancer mortality, but lack of geographically, financially, and culturally accessible services and providers is at the root of many of the entrenched disparities in cancer care and outcomes suffered by poor, minority, immigrant, and other disadvantaged populations.

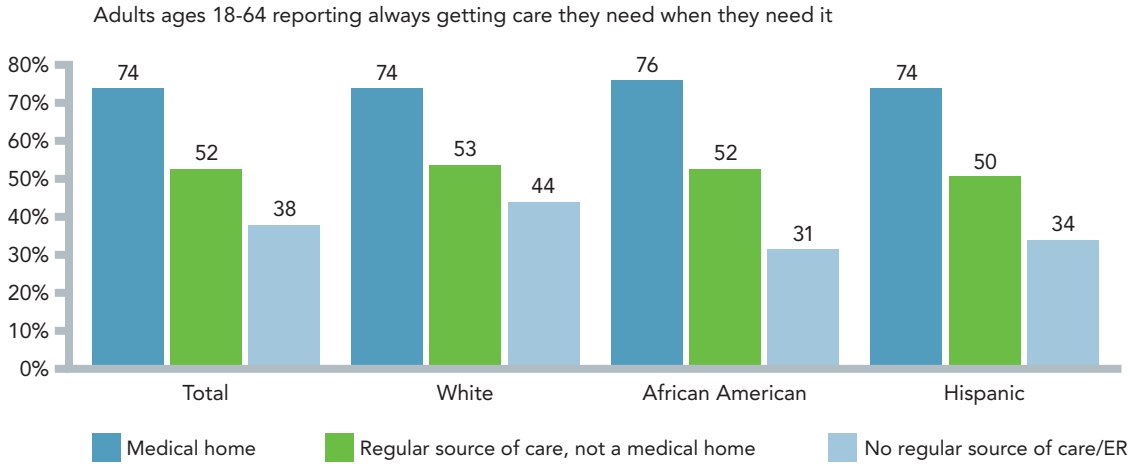
These persistent disparities, at times exacerbated by overt or unintentional provider bias,[189] are being documented with increasing frequency and clarity. Unfortunately, however, these reports show that despite greater awareness of the problem and implementation of diverse initiatives, little progress is being made in narrowing treatment disparities.[190,191]

> …if you get a mammogram and you're an indigent person in Houston, it takes six months to get an appointment to see the doctor. If you get a mammogram and you're a wealthy person in Houston, you're in the next morning....
>
> *John Mendelsohn*
> *M. D. Anderson Cancer Center*

As the 2007 National Health Care Disparities report[192] again indicates, disparities persist among minority groups compared with whites, and between low and higher income populations. Published annually by the Agency for Healthcare Research and Quality, the report examines disparities by tracking core measures such as mammography rates. For 16 core measures, more than half of disparities in quality of care have not gotten smaller between 2000-2001 and 2004-2005 and have worsened particularly among American Indians, Alaska Natives, and those living in poverty. Yet as Figure 8

Figure 8

Racial and Ethnic Differences in Getting Needed Medical Care Are Eliminated When Adults Have Medical Homes



Note: Medical home includes having a regular provider of care, reporting no difficulty contacting provider by phone or getting advice and medical care on weekends or evenings, and always or often finding office visits well organized and running on time.

Source: Commonwealth Fund 2006 Health Care Quality Survey.

We have a case study project right now that's looking at oncology care in the United States and it found that the most problematical phase of that coordination and communication takes place in the period between initial suspicion and final diagnosis of cancer.

Martin Brown
National Cancer Institute

shows, racial and ethnic differences in getting needed medical care are eliminated when adults have a consistent source of care (a "medical home").

Specific to cancer, an analysis of more than 143,000 Medicare patients with breast, colorectal, lung, and prostate cancer shows that from 1992-2002, treatment disparities persisted, as did their magnitude.[193] Research demonstrates, however, that with equal treatment, patients experience equal outcomes.[194] In 2004, a Cancer Health Disparities Progress Review Group convened by the U.S. Department of Health and Human Services provided recommendations[195] for reducing these disparities, but to date, implementation of the recommendations has been disappointing.

Health care fragmentation due to payers' arrangements with specific providers based on cost often force sick and frightened patients into a maze of rules, paperwork, disparate sources of care, and inadequate provider communication. Too often, gaps or lapses in care occur at a time when patients are least able to cope with the stress such a situation engenders. Only a fortunate few patients have the help of a knowledgeable loved one or a trained professional to steer them through the health care labyrinth.

According to a 2006 Commonwealth Fund Survey of public views of the U.S. health care system,[196] an overwhelming majority of Americans are eager for a more coordinated approach to care in which a single place or doctor is responsible for coordinating an individual's care and both the patient and his/her doctors have easy access to medical records.

Acute Care Orientation

The Panel's 2006-2007 report, *Promoting Healthy Lifestyles: Policy, Program, and Personal Recommendations for Reducing Cancer Risk*, discusses in detail the impact of the health care system's acute care orientation and failure to support increased emphasis on cancer and other disease prevention interventions (e.g., dietary and physical activity counseling and monitoring, tobacco use prevention). Resistance to integrating and reimbursing preventive health services as an accepted and important component of the standard of quality care remains a critical weakness of the health care system.

Reliance on Employer-sponsored Health Coverage

Another critical weakness of the American health care system is its continued reliance on employment as the primary gateway to health insurance. Health care premium increases continue to outpace income gains for most individuals (78 percent premium increases compared with 19 percent wage increases between 2001 and 2007[197]) and consume a higher percentage of employers' payroll costs, with significant variations in share of hourly wage and total payroll depending on size of employer, industry, and employee wage rate.[198] Among workers with access to health benefits, the average employer cost for health insurance per employee per hour rose 62 percent between 1999 and 2005, far exceeding the 23 percent increase in average employer payroll costs per hour for these employees.

…a lot of what we know in terms of prevention, early detection, and treatment just never gets materialized in terms of access, reach, and so on.

Janet Collins
Centers for Disease Control and Prevention

> …we define failure now [as] not increasing the lives or decreasing morbidity and mortality of invasive cancer....I think we will in the future define failure as not decreasing the incidence of invasive or established cancer.
>
> *William Hait*
> *American Association for Cancer Research*
> *Johnson & Johnson Pharmaceutical Research & Development*

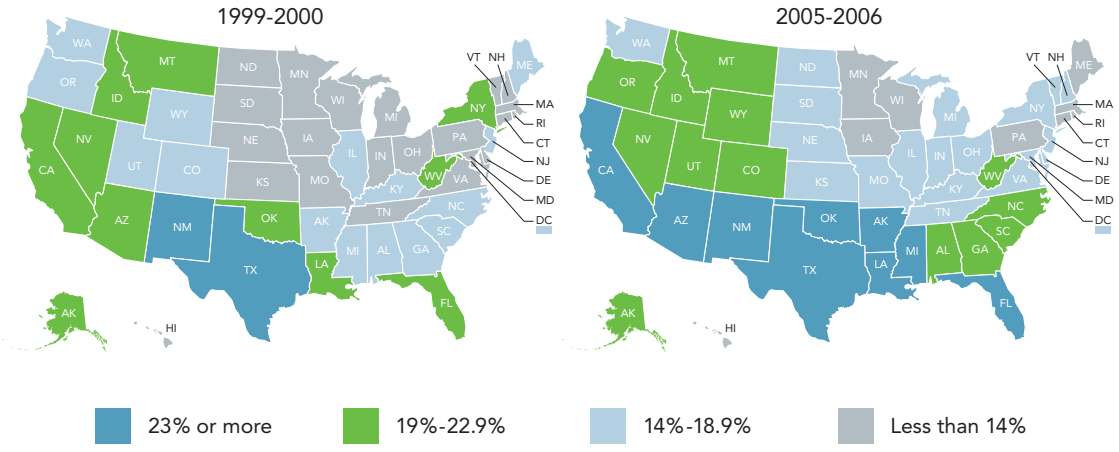
An incisive assessment of this situation[199] suggests that spiraling health care costs, which in turn lead to higher health insurance premiums, are the cause of the gap between health insurance costs and wage increases. The authors maintain that increased health premiums are an element of total employee compensation and not a separate cost paid by the employer. Paying a greater share of total compensation for health premiums has resulted in depressed wage rates, thus widening the premium-wage gap. The authors recommend taking employers out of the health insurance equation so that health care costs will no longer have this effect on wages.

Under the current system, employers are attempting to control the cost of employee health benefits by shifting more of the costs to employees and changing health plans frequently. Cost shifting is particularly burdensome to lower wage employees, for whom higher premium contributions, copayments, and other out-of-pocket costs consume a larger percentage of income than for higher wage employees. Insured employees faced with rising costs may defer screening and other disease management services, or opt for less robust health coverage that will reduce premiums but leave them more vulnerable to out-of-pocket costs in the event of a serious illness. Some may drop their employer-sponsored coverage entirely. According to an analysis of consumer costs between 2000 and 2007,[200] spending on health care now takes up more of consumers' income than housing, food, or clothing. As the economy slows and food, fuel, and medical costs continue to rise, millions of people may be unable to afford care.

In addition, when employers change health plans, employees often are forced to change health care providers. This situation may contribute to lapses and inconsistencies in care, as well as the loss of a trusted and regular source of care. Moreover, as health benefit costs continue to rise, some

Figure 9

The Rate of Uninsured Nonelderly Adults Rose from 17 Percent to 20 Percent in Six Years



Source: Commonwealth Fund State Scorecard on Health System Performance, 2007.
Updated data: Two-year averages 1999-2000, updated with 2007 Current Population Surveys correction, and 2005-2006 from the Census Bureau's March 200, 2001 and 2006, 2007 Current Population Surveys.

employers are reaching a crossroads—when they feel they cannot cost-shift any further, some simply opt to eliminate health coverage rather than deny wage increases or reduce the workforce.

The Uninsured and Underinsured

In 2006, 47 million Americans were uninsured, an increase of 2.1 million from the year before,[201] and 8.6 million (more than 18 percent) since 2000.[202] The rate of uninsured nonelderly adults rose from 17 percent to 20 percent in six years (Figure 9). As in previous years, the majority of these people were employed; in 2006, nearly two-thirds were employed full time throughout the year; only 17 percent were not employed.[203] Moreover, lack of insurance is not restricted to the working poor. In 2006, 36.5 percent of the uninsured nonelderly had family incomes between $30,000 and $74,999. Another 14 percent had family incomes of $75,000 and over.[204]

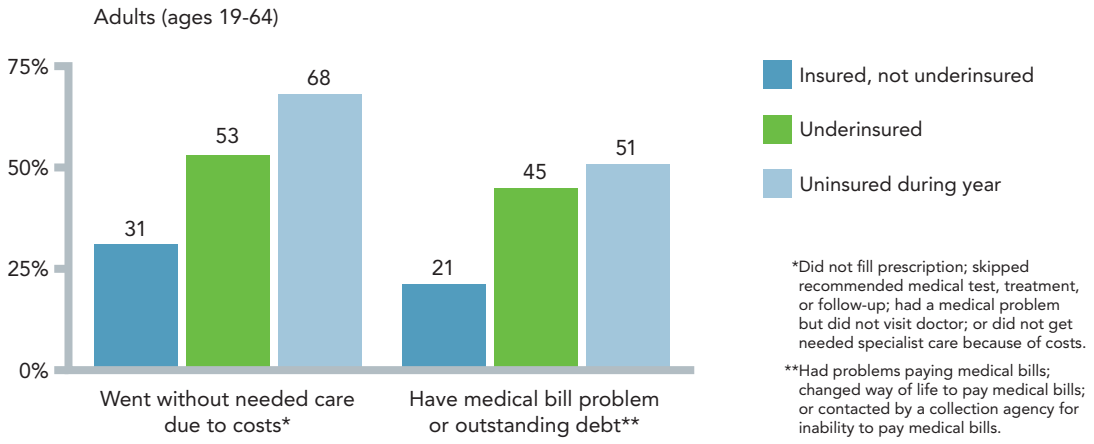
In addition to those without insurance, approximately 25 million American adults (aged 19-64 years) are underinsured—an increase of 60 percent since 2003.[205] Among those with family incomes above $40,000, the underinsured rate nearly tripled since 2003. The population segments most likely to be underinsured in 2007 were young adults aged 19-29 years and those aged 50-64. The underinsured are defined as those who were insured all year but experienced one of the following: medical expenses equaling 10 percent or more of income; medical expenses equaling five percent or more of income among low-income persons (income <200 percent of the poverty level), or deductibles equaling five percent or more of income.[206]

As Figure 10 demonstrates, lack of insurance and underinsurance leave workers and their families at risk of significant medical debt,[207] which has been shown to be a major cause of personal bankruptcies.[208]

Avoidance of medical debt leads to deferred preventive and acute care, inappropriate use of emergency room services for primary and other nonemergency care, and importantly, delayed diagnosis and management of chronic and life-threatening diseases such

Figure 10

Underinsured and Uninsured Adults at High Risk of Going Without Needed Care and Experiencing Financial Stress



Adapted from: Schoen C, Collins S, Kriss J, Doty M. How Many Are Uninsured? Trends Among U.S. Adults, 2003 and 2007, *Health Affairs* Web Exclusive, June 10, 2008.
Data: 2007 Commonwealth Fund Biennial Health Insurance Survey.

as cancer. A 2005 Commonwealth Fund survey found that compared with people in five other industrialized countries that have universal coverage, Americans with medical problems are more likely (51 percent vs. 13-38 percent) to skip recommended medical tests, treatment, or follow-up care; not fill a prescription; or forgo a doctor or clinic visit due to cost.[209]

> …we need to go back to reimbursement… how do we take that worry away from patients, because that's what they worry about every day when they go for treatment or they have to go for a CT scan: How am I going to pay for this?
>
> *Peggy Anthony*
> *Director's Consumer Liaison Group, NCI*

For cancer patients and others with certain chronic diseases—both insured and uninsured—the cost of expensive but life-saving medications and drugs that slow disease progression is skyrocketing. Insurers have used a three-tiered system of copayments for prescription drugs for some time, with inexpensive generic medications comprising the first tier and those in the third tier having the highest copayments. In recent years, however, a growing number of payers (including the Federal Government) have instituted a fourth tier with much higher copayments; patients most affected by this change include those using new cancer drugs, and those with conditions such as rheumatoid arthritis, hemophilia, and multiple sclerosis.[210]

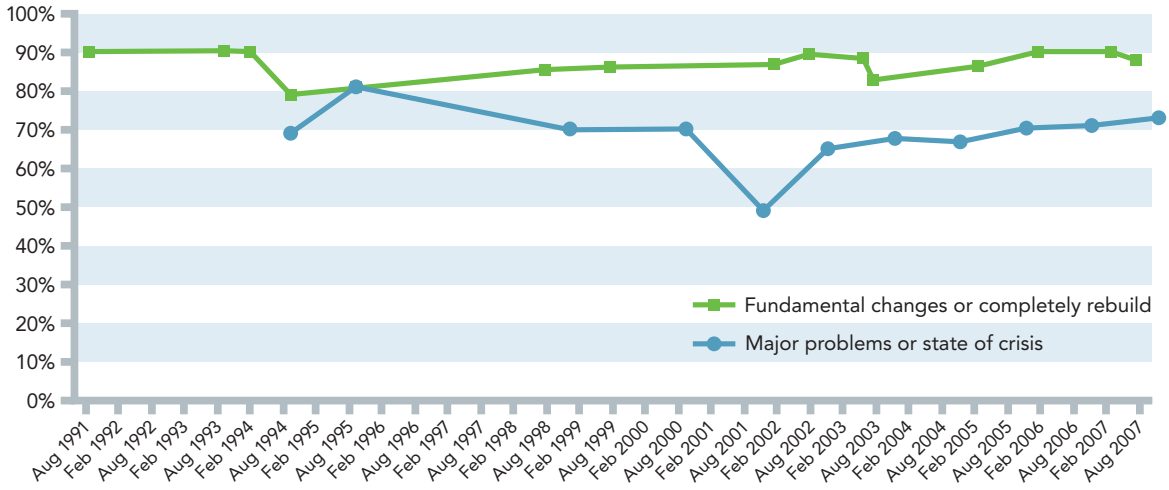
Limited Access to Care

All of the health care system weaknesses described above contribute to limitations in access to needed care. Individuals who rely on publicly funded programs are at particular risk. For example, continuing constraints on Medicare services and provider reimbursements block access to needed care due to lack of coverage and because some providers refuse to accept new Medicare and Medicaid patients. State budget issues have forced new limits on Medicaid services and eligibility (even as some states look for ways to expand coverage with limited funds), and efforts at the Federal level to cut payments to hospitals serving predominantly Medicaid and other low-income populations (so called "safety net" hospitals) further threaten access to care.[211] Community health centers (CHCs), the largest primary care network in the nation, serve primarily low-income or uninsured individuals. These facilities are being stressed as the number of uninsured swells. Pending legislation to reauthorize the Community Health Centers Program[212] through FY 2012 would double the number of people who could be served by CHCs, but the impending shortage of primary care providers (see p. 21) raises concern that even with higher funding levels, CHCs may not be able to attract and retain a workforce sufficient to meet demand. Moreover, linkages to appropriate cancer care remain tenuous for these patients. As the PCP has reported previously,[213] Federal support for Indian health has been shamefully meager; this population suffers from inadequate primary care and cancer-specific care. Legislation to reauthorize the National Indian Health Improvement Act is pending; if signed into law and adequately funded, it would improve access for many American Indians, including those living in urban areas.

> …access to state-of-the-art cancer care in our country, I think, will be the greatest determinant of mortality that we will face over the next decade. We'll have great progress in the science, but I can tell you right now we have zero way of getting that state-of-the-art science to people in this country [in] the communities where they live.
>
> *John Niederhuber*
> *National Cancer Institute*

Negative Public Attitudes toward the U.S. Health Care System, 1991-2007

Figure 11



Source: Jacobs LR. 1994 all over again? Public opinion and health care. New England Journal of Medicine. 2008;358(18):1881-3.

Health Care System Reform

The paragraphs above highlight the grinding costs to personal health and well-being and national productivity under the current health care system; the following paragraphs suggest potential strategies for improving health care delivery.

Need for a New Delivery System Design and Focus

As Figure 11 indicates, a large majority of the public believe that the U.S. health care system has major problems or is in crisis, and an even greater percentage believe that the system requires fundamental changes, or that it must be completely rebuilt.

Roundtable participants maintained that we need to adopt a national health and cancer care system in which patient priorities drive system design—a coordinated research and care continuum across the lifespan with feedback loops among clinicians, cancer patients/survivors, and investigators.This new system must reward all participants for adopting and maintaining a wellness orientation. For example, providers must be encouraged to become more active in assessing patient smoking status at each medical encounter (currently, only 23 percent of patients in primary care offices are screened for tobacco use[214]) and to offer, arrange, or provide quit assistance as needed; but reimbursement is required for the time spent in these potentially time-consuming activities. At this time, little reimbursement exists for preventive services.

The value of a "medical home" for all adults is recognized for its capacity to improve continuity of care, reduce inappropriate health service (e.g., emergency room) utilization, manage risk-promoting conditions and behaviors, increase the likelihood of consistent cancer screening and earlier detection of new cases,[215] and as noted on p. 43, eliminate health disparities. The generalist physician specialties (e.g., pediatrics, internal medicine, family medicine) are experimenting with various medical home models based on teams of physicians, nurse practitioners, and physician assistants who

> If the patient were the center… we wouldn't need patient navigation; we wouldn't need connectivity because we would all be focused on the patient and we would be connected through the patient.
>
> *Deborah Banker*
> *The Leukemia and Lymphoma Society*

I'm always struck that you would never allow a patient to leave a clinical setting with a systolic blood pressure of 250, but day after day smokers leave clinics without treatment for their tobacco dependence.

Michael Fiore
University of Wisconsin

provide acute care, chronic disease management, and preventive and educational interventions through in-person visits, telephone and email consultations, and electronic medical records. The success of these models, however, will depend on reimbursement changes that foster their development.[216]

In cancer, critical lapses in the current system of care often occur during the period between suspicion of disease and a definitive diagnosis, and between diagnosis and the start of treatment. Factors underlying these problems include lack of follow-up of suspicious screening findings and insurance status. Roundtable participants emphasized the need to institutionalize patient navigation to ensure that patients do not "fall through the cracks" and are assisted to receive effective, timely care throughout the cancer care process.

Participants also maintained that the health care system should spend the most on wellness, not on the last six weeks of life. This should not be misconstrued to mean that effective palliative and end of life care should be withheld, but rather refers to costly therapies with curative intent that almost certainly will be futile. In other words, we need to change the focus of care for patients with advanced disease from "extended life" care to palliative and/or end of life care, as needed. To do so, it will be necessary to fully integrate hospice/end of life care into the standard of cancer care—improving and expanding services, making them universally available, and increasing understanding among patients, families, and providers of their benefit to patient quality of life. Many patients and providers alike still view palliative and hospice care as "giving up" or as a personal failure.

…in our institution five years ago it took a breast cancer patient somewhere between 25 and 35 phone calls to set up all the diagnostic appointments, get all the tests, arrange for hospitalization, or whatever it was. And it wasn't 25 to 35 phone calls; it was 25 to 35 different people they spoke to. And we realized that we were the problem....[Now] once you become a cancer patient in our cancer center you have a phone number and no matter what you need, you call that phone number.

Mark Israel
Dartmouth-Hitchcock Medical Center

Adequate provider reimbursement is needed to encourage adult clinical trials participation (incentives to inform and refer; payment tied to protocol adherence). However, the infrastructure necessary to support significantly increased clinical trials participation must be in place before implementing incentives to increase enrollment.

Roundtable participants acknowledged that significant change in the cancer care delivery enterprise is unlikely unless an alliance can be forged among patients, professionals, employers, and payers to develop a system upon which they agree and which could form a basis for Congressional action. Because governments are the largest health care payers and purchasers and are responsible for oversight, to revolutionize the delivery system we must start with government policies and programs.

Evidence-based Care, Comparative Effectiveness Analysis, Guidelines, and Pay for Performance

Numerous roundtable discussants called for better consistency and transparency across the delivery continuum—care consistent with evidence-based guidelines that is compensated based on improved patient outcomes rather than on the quantity of

> …we should strive to have a cancer health care system that can prevent what can be prevented, detect early what can be detected, cure what can be cured, and do more research.
>
> *Elmer Huerta*
> *American Cancer Society*
> *Washington Cancer Institute*

care (e.g., number of procedures) provided. The procedure-based compensation system is deeply entrenched, and a change to compensation based on demonstrated outcome improvements also is being slowed by a lack of accepted guidelines and patient outcome measures on which to base the system.

Steps Being Taken to Improve Health Care

The serious deficiencies in the current health care system described above are almost universally acknowledged. Diverse efforts are under way to address access, system emphasis, and organization problems in the health care system both generally and specific to cancer care. For example:

- The Patient Centered Primary Care Collaborative (PCPCC) was formed in late 2006 and has become one of the major developers and advocates of the patient-centered medical home (PCMH) model in the United States.[217] PCPCC's membership of more than 40 organizations includes a number of major employers, most of the major primary care physician associations, health benefits companies, trade associations, academic centers, consumer groups, and health care quality improvement associations. The Collaborative believes that the PCMH model improves the health of patients and the health care delivery system. In addition, the Collaborative has established centers to study and promote: (1) a physician payment system based on the medical home model, (2) implementation of the PCMH model among public payers, (3) implementation of local PCMH multi-stakeholder demonstrations, and (4) expanded use of e-health information exchange and adoption. PCPCC also released guidelines for health care purchasers that offer strategies for advancing the PCMH model.[218]

- The National Business Group on Health formed a workgroup to develop strategies aimed at increasing employer support for primary care. Its priorities are to promote PCMHs, employ health information technology to transform primary care practice, promote payment policies that recognize the value of primary care services, and encourage educational and loan programs to attract physicians and other health professionals to careers in primary care.[219]

- The National Cancer Institute is piloting a National Community Cancer Centers Program (NCCCP)[220] at 16 hospitals nationwide. The NCCCP program was developed in recognition of the need to extend state-of-the-art cancer care beyond the NCI-designated Cancer Centers and into the community, where more than 80 percent of cancer patients receive their treatment and follow-up care. By networking community hospitals, community oncology practices, and the Cancer Centers, the NCCCP aims to improve the level of cancer care in the community and increase community physician and patient participation in clinical research.

- The CEO Roundtable is promoting cancer prevention-oriented insurance coverage among large employers through an initiative called the Cancer Gold Standard that emphasizes cancer screening, tobacco control, cancer education, lifestyle modification, and access to cancer treatment when needed. A representative of the CEO Roundtable who participated in the Panel's meetings indicated that within the next two years,

approximately 30 million Americans will receive health benefits through entities with Cancer Gold Standard accreditation.

- Numerous bills addressing various aspects of the health care system are under consideration by Congress. One specific to cancer care is the Comprehensive Cancer Care Improvement Act (H.R.1078/S.2790). If signed into law, this legislation would improve cancer care by ensuring that cancer survivors receive cancer treatment and survivorship plans that will enhance their decisionmaking about treatment and assist them in managing all elements of their care.

- Some states are taking steps to improve the health care of their populations. For example:

  - A new Delaware program covers the full cost of cancer care for two years for all persons diagnosed with the disease who have incomes (for a family of four) up to $122,525. Patients are assigned a nurse navigator to ensure that they receive timely, coordinated care. Since 2004, the program has paid for cancer treatment for over 350 patients. The program is supported through state and Federal funding. In addition, tobacco control measures have reduced smoking to below the national average. Delaware also implemented a statewide colorectal screening initiative; in 2007, 74 percent of all state residents over age 50 had had at least one colonoscopy,[221] well above national colonoscopy rates.

  - In April 2006, Massachusetts enacted legislation intended to achieve near-universal health coverage within three years and improve access to affordable, high-quality care. In the first year under these reforms, uninsurance among working-age adults was reduced by almost half, to seven percent. Access to care improved, and the share of adults with high out-of-pocket costs and difficulty paying medical bills declined. Although costs have been higher than anticipated, public support for the reforms remains strong.[222]

  - In Wisconsin, a physician-led health care quality collaborative has achieved voluntary public reporting of comparative performance information in both ambulatory and hospital settings across the state. Data now are being reported by more than half of Wisconsin primary care physicians, with 75 percent physician participation anticipated by 2010.[223]

These are examples of important efforts to improve cancer and other health care. However, these and similar initiatives are not a substitute for a national health care plan. Efforts such as these must be expanded and melded into a comprehensive system of health reform. Each offers lessons for crafting a new American health system that puts the patient first, ensuring that every individual receives competent, affordable care in a coordinated, more efficient manner that promotes disease prevention, chronic disease management, and improved outcomes for cancer and other acute and chronic conditions.

Recommendation

3 The Scourge of Tobacco in America Must End

Ridding the nation of tobacco is the single most important action needed to dramatically reduce cancer mortality and morbidity. There is no substitute for this action if we are to eliminate the sickness and death caused by tobacco use.

Tobacco use is the number one cause of preventable death in the United States. Smoking accounts for at least 30 percent of all cancer deaths and 87 percent of lung cancer deaths.[224,225] Of the more than one billion smokers alive today worldwide, approximately half will be killed by tobacco.[226] Smoking is associated with increased risk of at least 15 types of cancer and a host of other illnesses (e.g., heart disease, emphysema).[227]

The Panel's 2006-2007 report[228] describes in detail the many interrelated issues that enable continued access to and use of tobacco. These issues include the addictive properties of tobacco, tobacco company marketing practices, insufficient tobacco control efforts at the state and Federal levels, failure to use proven reduction strategies (e.g., raising tobacco taxes to levels that discourage purchases by youth), tobacco import and export policies that continue to support tobacco use, failure of the U.S. to ratify the Framework Convention for Tobacco Control (FCTC),[229] continued reliance of policymakers on tobacco company funding, and states' dependence on tobacco settlement[230] funds and tobacco tax revenue.

The Panel's recommendations regarding tobacco are consistent with conclusions of the United States Surgeon General,[231,232,233] the Institute of Medicine,[234,235] the International Union Against Cancer (UICC),[236] and the World Health Organization (WHO),[237] among others,[238,239] and are supported by an incontrovertible body of research on the harm caused by tobacco use and environmental tobacco smoke exposure.

An Update on Trends

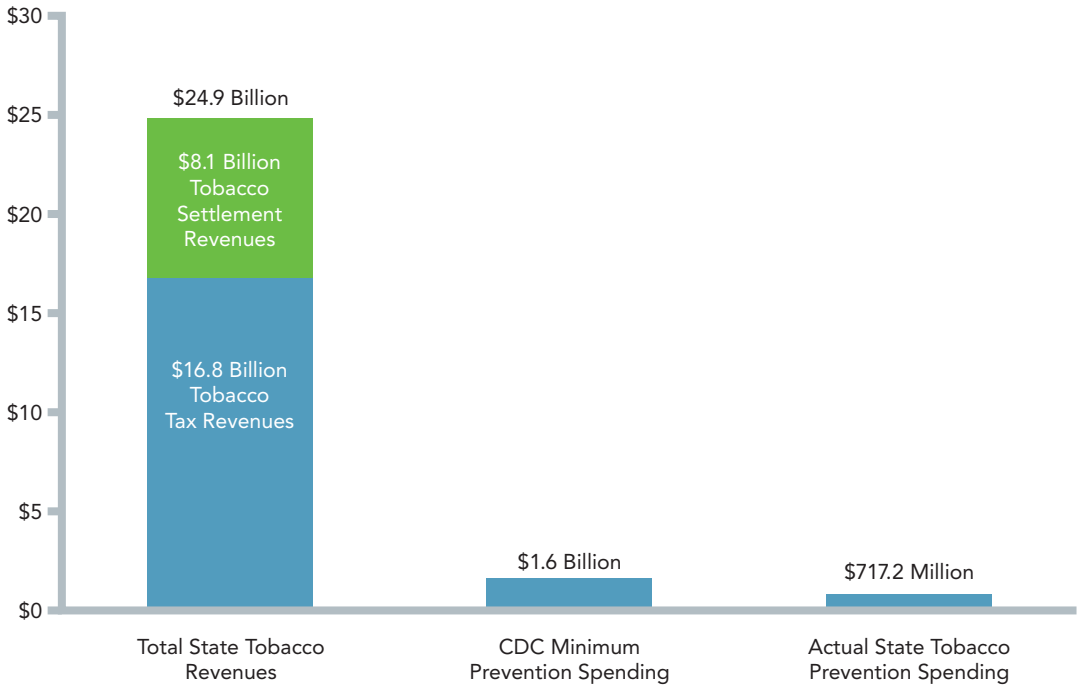
Since the Panel's 2006-2007 report, approximately 112 additional smoke-free ordinances have been passed in the United States;[240] and tobacco taxes have been raised in 14 states since mid-2007.[241] Echoing the Panel's findings, roundtable participants underscored that tobacco control efforts tend to be most effective at the state level, and emphasized the need for adequate tobacco control program funding. A comprehensive analysis published since the Panel's last report again demonstrates that state tobacco control expenditures are independently associated with overall reductions in adult smoking prevalence.[242]

However, the most recent data from the Youth Risk Behavior Survey indicate that smoking prevalence (current cigarette use) among U.S. teens, which dropped significantly from 1997 to 2003, has not declined further since then.[243] The flattening of the decline in youth smoking prevalence coincided with sharp decreases in, and even elimination of many state tobacco-control programs. Concomitantly, tobacco company marketing (particularly targeting youth, women, and minorities) intensified greatly; this increase in marketing was accompanied by the introduction of numerous new flavored cigarettes and smokeless products.

The most current assessment of state tobacco control funding[244] indicates little progress in the past year toward the level needed for effective, comprehensive state tobacco control efforts, as recommended by the Centers for Disease Control and Prevention.[245] Although state spending for tobacco control increased to $717.2 million for FY 2008 from $597.5 million in FY 2007, this amount is less than 2.9 percent of total tobacco revenues (i.e., funds from the Master Settlement Agreement of 1998[246] plus tobacco taxes), an increase of 0.3 percent over the 2.6 percent committed annually over the period FY 2005-FY 2007 (Figure 12).[247] Further, this funding level remains miniscule compared with the $13.11 billion (2005 Federal Trade Commission estimate) tobacco companies spent on product marketing in 2005, the most current year for which data are available.[248]

Figure **12**

FY 2008 Tobacco Money for Tobacco Prevention (in Billions)



Source: Campaign for Tobacco-Free Kids, American Heart Association, American Lung Association, American Cancer Society. A Broken Promise to Our Children: The 1998 State Tobacco Settlement Nine Years Later, Executive Summary, 2007.

Nonetheless, efforts to counter aggressive tobacco company marketing despite limited tobacco control funding are continuing through collaborative efforts designed to leverage available resources. For example, in March 2008, the National Alliance for Tobacco Cessation (NATC), a coalition of the nation's leading governmental, voluntary, private, and public health organizations launched a national tobacco use cessation campaign entitled *EX*.[249] Participants include the National Cancer Institute, American Cancer Society, the American Heart Association, the American Legacy Foundation, the Robert Wood Johnson Foundation, the Association of State and Territorial Health Officials, the Mayo Clinic, C-Change, and 14 state health organizations. The campaign's goal is to guide smokers to existing cessation resources and build their confidence about quitting. In addition to multimedia outreach, *EX* provides a free quit plan book to help smokers approach quitting as a manageable process. The program also includes a research component; survey data gathered via telephone interviews with adult smokers will be collected over a two-year period.

In addition to efforts such as the NATC campaign, numerous researchers continue to clarify individual and social factors[250,251] and health system changes[252] that predict smoking cessation success. Others are monitoring the influence of advertising on tobacco use initiation,[253] and developing other interventions to improve tobacco use prevention and cessation. As the Panel has noted, this work is important and should be more fully supported; however, it will not be sufficient to eradicate the scourge of tobacco without the underpinning of policy that supports efforts to reduce demand and eliminate the supply of tobacco.

At the Federal level, legislation still is pending to raise the Federal tobacco tax and authorize the Food and Drug Administration (FDA) to regulate tobacco products and tobacco marketing. Illustrative of the tobacco industry's tenacity in opposing restrictions to its operations, Reynolds American, one of the largest tobacco conglomerates, has launched a media campaign maintaining that the FDA already is overextended and unable to perform its oversight responsibilities and

therefore should not be burdened further with tobacco regulation.[254]

> …there's almost universal agreement that if we could get rid of the tobacco problem, for lack of a [better] way of saying it, cancer rates would plummet and the cost of health care would plummet.
>
> *Mark Israel*
> *Dartmouth-Hitchcock Medical Center*

The Panel reported previously[255] on the 2005 dismantling of the tobacco quota (license to grow) and price support system established during the Depression. The Tobacco Transition Payment Program, commonly referred to as the tobacco "buyout,"[256] was intended to entice small tobacco farmers to give up their quotas and reduce the acreage devoted to tobacco growing. The program was successful in this regard. However, recent data indicate that the program's removal of previous restrictions on where and how much tobacco could be grown, coupled with rising world market prices for American tobacco due to turmoil in other tobacco-producing nations, has contributed to increasing U.S. tobacco acreage (albeit on fewer, larger farms) and export. Since 2005, U.S. tobacco acreage has risen 20 percent (Figure 13), and U.S. tobacco exports have grown to 150 million kilograms (Figure 14). For some farmers, net revenue per acre of tobacco may exceed that of corn by sevenfold or more.[257] With financial assistance from tobacco companies that want to ensure a stable supply of domestic tobacco, farmers now are expanding their tobacco-growing operations.[258]

The Global Tobacco Problem

Since the Panel's August 2007 report, nine more countries have ratified the FCTC, bringing the total as of September 2008 to 157 nations.[259] Discouragingly, however, a recent WHO assessment[260] indicates that no country comes close to fully implementing the major provisions of the treaty, although governments around the world collect 500 times more money in tobacco taxes annually than they spend on anti-tobacco efforts. As in the United States, other nations appear to have become dependent on tobacco tax revenues to fund diverse domestic infrastructure and other needs.

At the same time, tobacco companies continue to increase global marketing activities in conjunction with the introduction of flavored and other tobacco products, targeting in particular youth and young women in developing nations. If tobacco use trends continue, by 2030 approximately 11.8 million tobacco-related deaths will occur each year, with more than a billion deaths in the 21st century.[261] Most of these deaths will occur in developing countries. In 2008, the Bill and Melinda Gates Foundation and Bloomberg Philanthropies committed a combined total of $550 million to global tobacco programs. This contribution is particularly noteworthy because of the decision to direct the funds toward tobacco prevention and control efforts in Africa, where the tobacco epidemic has yet to become full-blown and an opportunity exists for primary prevention and early intervention.[262]

The UICC has launched a four-year initiative[263] targeting environmental (secondhand) smoke exposure among children. A key outcome is to raise awareness that there is no safe level of secondhand smoke exposure and establish a global movement in support of smoke-free environments for children. Year 1 activities will focus on mobilizing media at the global, regional, and national levels and encouraging local initiatives by UICC members worldwide. Years 2 and 3 will focus on sustainable educational pilot projects that mobilize local cancer societies and the communities they serve. Participating projects will be presented at the World Cancer Congress in 2010 in China. UICC will develop and disseminate fact sheets in multiple languages targeting health professionals, community leaders, and policymakers; tips to help cancer societies mobilize communities; model approaches for smoke-free homes and cars; smoking cessation resources for parents; a campaign

Web site with toolkits in multiple languages; and numerous other materials.

The Bottom Line: No Level of Tobacco Use is Safe

Without question, tobacco use exacts a terrible price in human suffering and economic costs. Smoking reduces life expectancy by approximately 14 years, and costs our nation more than $167 billion annually in health-related economic costs, including adult mortality-related productivity costs, adult medical expenditures, and medical expenditures for tobacco-affected newborns.[264]

There is no safe level of tobacco use. Moreover, we now know that former smokers never reduce their risk of lung cancer to the level of never-smokers.[265] The extent to which risk for other tobacco-related cancers is reduced in former smokers compared with never-smokers has been less well studied. Because of the long latency period of lung (20 years or more) and many other tobacco-related cancers, health care providers need to actively encourage and support quit attempts by patients who smoke and be aware of their patients' status as former smokers in order to properly monitor them for tobacco-related illnesses throughout life. Yet even if all current smokers cease using tobacco today and no new smokers take up the habit, the latency of tobacco-caused cancer and other diseases dictates that cancer and other morbidity and mortality from tobacco will still be affecting our population for at least another two decades. This preventable epidemic of disease must be brought to the most rapid end possible.

> Seventy percent of smokers see a primary care doctor every year. Few of them leave that encounter with evidence-based treatments that can result in the individuals—most of whom want to quit—having a high likelihood of succeeding and preventing the one-third of cancer we have that's directly caused by tobacco use.
>
> *Michael Fiore*
> *University of Wisconsin*

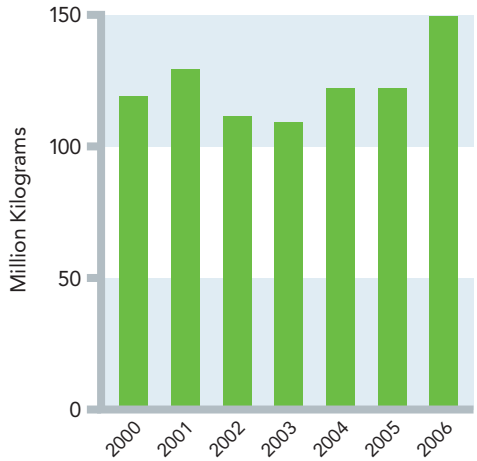
Figure 13

Total U.S. Tobacco Crop Harvested

Source: USDA

Figure 14

U.S. Tobacco Exports



Source: U.S. Census Bureau

PART III

A Call to Action

For many in the nation, the toll of cancer has become simply an awful part of life—a part each person hopes to avoid. Yet in effect, through our complacency about cancer and a lack of will to change aspects of the cancer enterprise that are preventing significant and rapid reductions in cancer mortality and morbidity, we are allowing a "bioterrorist within" to attack almost a million and a half Americans and kill more than 560,000 of us each year. Though few in this country have been untouched by cancer, these attacks and fatalities somehow occur almost quietly, their magnitude virtually unnoticed except by the families and friends of each stricken individual. Our outrage and sorrow about the suffering and loss caused by cancer seem to be felt individually, but not collectively.

We already have the ability to vanquish much of the epidemic of suffering and death caused by cancer. If no one in America used tobacco, we could avoid one-third of all cancer deaths. If every person with cancer or at risk for cancer—all Americans—benefited from behavioral, early detection, and treatment interventions we know are effective, millions would never be faced with a cancer diagnosis and the prospect of premature death. The reduction in suffering by patients and their families would be incalculable. The benefit to our nation in lower health care costs and heightened productivity would be an untold bounty to our economy and our national well-being. With a reinvigorated, redirected, and appropriately supported cancer research program, we will be able to multiply these benefits for all Americans, hasten the day when cancer is a largely preventable and easily treatable malady, and retain our place as the pre-eminent worldwide center for cancer and other biomedical research.

The three crucial recommendations contained in this report, and suggested strategies for realizing them, reflect those of the nearly 40 experts who contributed their diverse knowledge to the Panel's discussions in 2007 and early 2008. The Panel challenges our leaders and every individual to consider:

- How much more urgently might we respond to the cancer epidemic if cancers killed quickly, like many communicable diseases?

- How would we reorder our priorities and mobilize our vast resources, talent, and ingenuity if the news reported ***every day*** that another 4,000 had been stricken and another 1,500 had died? If every week, the "faces of the fallen" appeared on television and in newspapers, as do military casualties?

It no longer is acceptable to say that because cancer is complex, disparities in care are entrenched, and tobacco companies are powerful, we cannot solve the problem of cancer in America. We can. But to do so, cancer must become a national priority, one that is guided by strong leadership; fueled by adequate funding and productive collaboration and compromise among governments, industry, and institutions; and embraced by individuals who understand and accept their personal role in preventing cancer and in demanding meaningful progress.

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Appendix A

Participants: President's Cancer Panel Meetings

Strategies for Maximizing the Nation's Investment in Cancer

Meeting Dates and Locations:

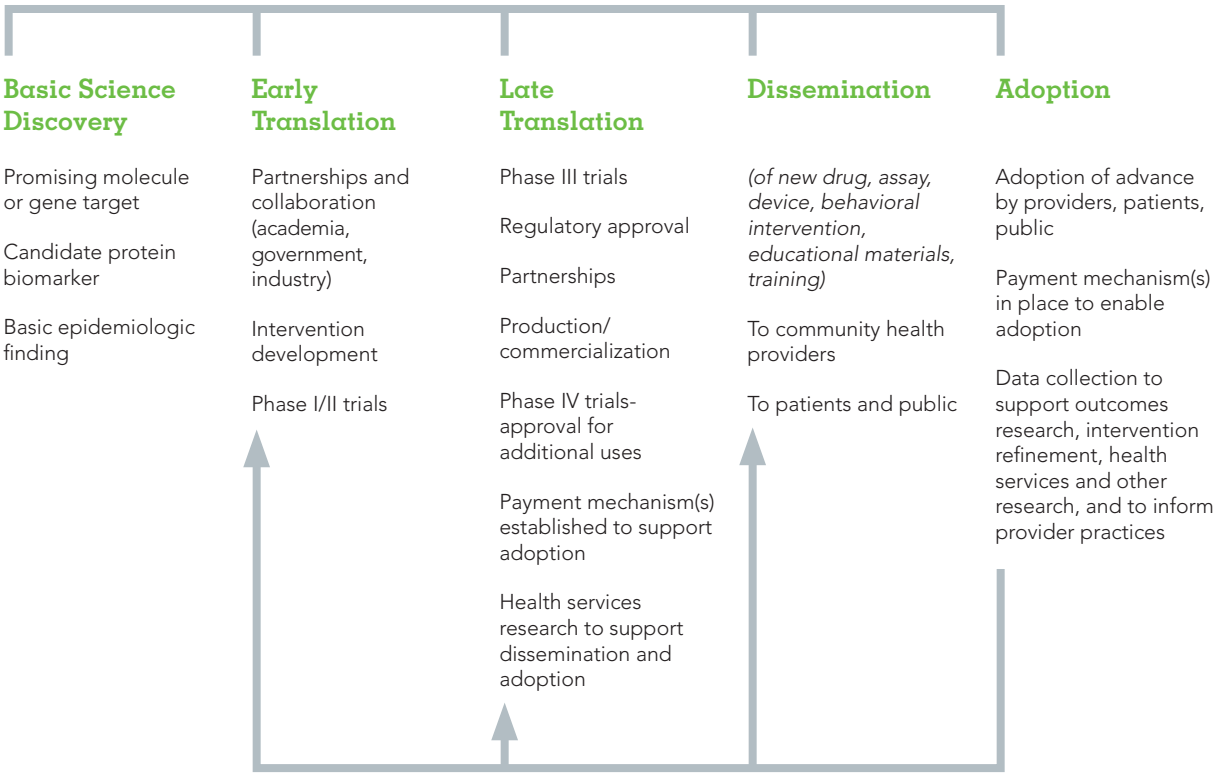
September 10, 2007	Atlanta, GA
October 22, 2007	San Diego, CA
December 3, 2007	San Juan, PR
January 28, 2008	New Orleans, LA

Name	Affiliation
Peggy L. Anthony, R.N., M.H.S., C.N.O.R.	Director's Consumer Liaison Group, National Cancer Institute
Lance Armstrong	President's Cancer Panel
Peter B. Bach, M.D., M.A.P.P.	Memorial Sloan-Kettering Cancer Center
Deborah E. Banker, Ph.D.	The Leukemia and Lymphoma Society
Edward J. Benz, Jr., M.D.	Dana-Farber Cancer Institute
Martin L. Brown, Ph.D.	National Cancer Institute
Moon S. Chen, Ph.D., M.P.H.	University of California, Davis Cancer Center
Janet L. Collins, Ph.D.	Centers for Disease Control and Prevention
Robert T. Croyle, Ph.D.	National Cancer Institute
Nancy E. Davidson, M.D.	American Society of Clinical Oncology Johns Hopkins University School of Medicine
James H. Doroshow, M.D.	National Cancer Institute
Lloyd K. Everson, M.D.	US Oncology
Michael C. Fiore, M.D., M.P.H.	University of Wisconsin
Judith C. Gasson, Ph.D.	University of California, Los Angeles Jonsson Comprehensive Cancer Center
Kathryn Giusti, M.B.A.	Multiple Myeloma Research Foundation Multiple Myeloma Research Consortium
Kevin P. Guidry, M.H.A.	Our Lady of the Lake Cancer Center
William N. Hait, M.D., Ph.D.	American Association for Cancer Research Johnson & Johnson Pharmaceutical Research & Development
Elmer E. Huerta, M.D., M.P.H.	American Cancer Society Washington Cancer Institute

Mark A. Israel, M.D.	Dartmouth-Hitchcock Medical Center
Stephen Albert Johnston, Ph.D.	The Biodesign Institute at Arizona State University
Paula Kim	Translating Research Across Communities
Barnett Kramer, M.D., M.P.H.	National Institutes of Health
Margaret L. Kripke, Ph.D.	President's Cancer Panel
Beverly Laird, Ph.D.	Director's Consumer Liaison Group National Cancer Institute
Clifton Leaf, M.F.A.	Journalist Susan G. Komen for the Cure
LaSalle D. Leffall, Jr., M.D., F.A.C.S.	President's Cancer Panel
Reynold E. López Enríquez, M.D.	University of Puerto Rico Puerto Rico Cancer Center
John Mendelsohn, M.D.	The University of Texas M. D. Anderson Cancer Center
Sandra S. Murdock, Dr.P.H., F.A.C.H.E.	Nevada Cancer Institute
Martin J. Murphy, Jr., Ph.D.	CEO Roundtable on Cancer
David G. Nathan, M.D.	Dana-Farber Cancer Institute
Lee Newcomer, M.D.	United Healthcare
John Niederhuber, M.D.	National Cancer Institute
Scott Ramsey, M.D., Ph.D.	Fred Hutchinson Cancer Research Center
Jonathan M. Samet, M.D., M.S.	The Johns Hopkins University Bloomberg School of Public Health
Abby B. Sandler, Ph.D.	President's Cancer Panel National Cancer Institute
John R. Seffrin, Ph.D.	American Cancer Society
Greg Simon, J.D.	FasterCures/The Center for Accelerating Medical Solutions
Michael B. Sporn, M.D.	Dartmouth Medical School
Craig B. Thompson, M.D.	University of Pennsylvania
Robert H. Topel, Ph.D.	The University of Chicago Graduate School of Business
Doug Ulman	Director's Consumer Liaison Group, National Cancer Institute
Sandra Millon Underwood, Ph.D., R.N., F.A.A.N.	University of Wisconsin-Milwaukee
Geoffrey M. Wahl, Ph.D.	The Salk Institute for Biological Studies

Appendix B

The Translation Continuum



Source: Reuben SH. Translating research into cancer care: delivering on the promise [2004-2005 Annual Report, President's Cancer Panel]. Bethesda (MD): National Institutes of Health; 2005 Jun, Figure 1.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