



FRIENDS OF CANCER RESEARCH
Progress in Science & Innovation

ANNUAL REPORT 2009



A Note from Ellen Sigal and Marlene Malek

Two thousand nine was a year of great achievement in biomedical research and innovation. We saw the foundation laid for continued scientific progress through exciting new leadership being chosen for the National Institutes of Health and the Food and Drug Administration, a new Secretary of Health and Human Services named, and a President pledging to “cure cancer in our lifetime.”

Throughout the past year, Friends of Cancer Research (Friends) continued to lead the way in creating constructive dialogue on some of the most significant and timely public health and scientific issues facing the United States.

Friends brought together key communities and thought leaders, producing results, not just talking points. Key events we hosted this year included: a day-long discussion and debate focused on clinical cancer research, which brought together stakeholders from government health agencies, the private sector, and advocacy; a forum on the merits of Comparative Effectiveness Research in conjunction with the release of a white paper on the same topic; and an important public conversation about breast cancer disparities.

We extend our deepest thanks to all of our partners that we had the pleasure of working with in 2009.

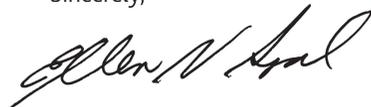
It is through collaboration that true progress continues to be made, and in the year ahead we will remain steadfast in our dedication to science, innovation, and clinical research.

There remains an ever growing need for bipartisanship, to not let political posturing hinder the progress we have made as we strive to discover new life-saving treatments and therapies. We must continue to assure public safety and wellbeing, while not handicapping the drive to bring new medicines to fruition.

This year our country continued to face economic unrest, and in the year ahead there will undoubtedly be difficult financial decisions made by this Administration and Congress. It is vital that all parties keep in mind that these fiscal decisions will directly impact research and the treatment of cancer. It is imperative that funding, both public and private, for life-saving research, not become a victim of this recession.

We at Friends of Cancer Research look forward to working with leaders across all sectors of government, business, and advocacy to ensure that our country continues its leadership in scientific research and innovation, bringing hope to patients and their families battling this horrible disease.

Sincerely,



Ellen V. Sigal, Ph.D.
Chair and Founder

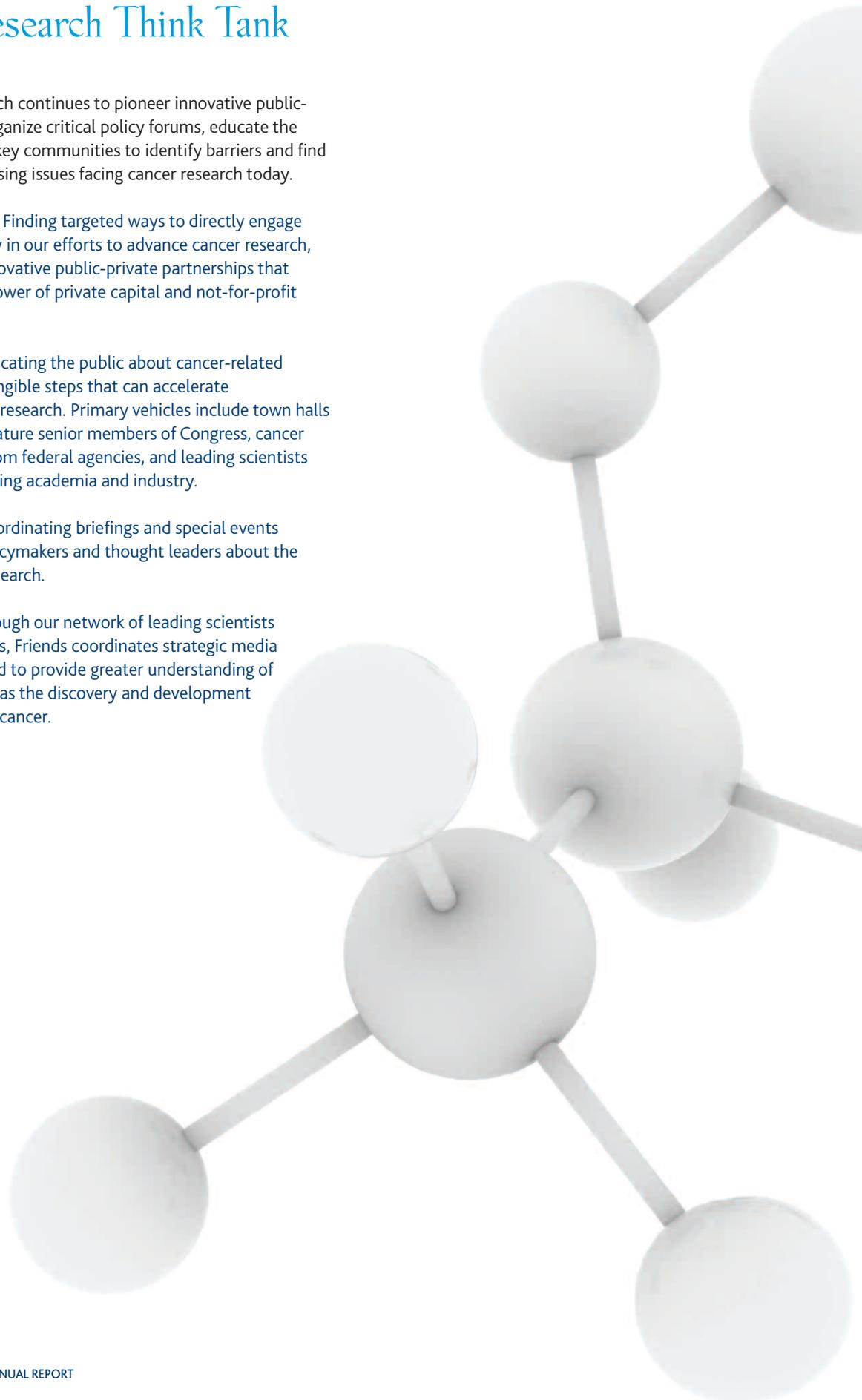


Marlene A. Malek, R.N.
President

A Cancer Research Think Tank

Friends of Cancer Research continues to pioneer innovative public-private partnerships, organize critical policy forums, educate the public, and bring together key communities to identify barriers and find solutions for the most pressing issues facing cancer research today.

- ~ **SCIENTIFIC OUTREACH:** Finding targeted ways to directly engage the scientific community in our efforts to advance cancer research, with an emphasis on innovative public-private partnerships that harness the combined power of private capital and not-for-profit scientific leadership.
- ~ **PUBLIC OUTREACH:** Educating the public about cancer-related issues and identifying tangible steps that can accelerate advancements in cancer research. Primary vehicles include town halls and symposiums that feature senior members of Congress, cancer survivors, top officials from federal agencies, and leading scientists and physicians representing academia and industry.
- ~ **POLICY OUTREACH:** Coordinating briefings and special events designed to educate policymakers and thought leaders about the importance of cancer research.
- ~ **MEDIA OUTREACH:** Through our network of leading scientists and prominent advocates, Friends coordinates strategic media outreach efforts designed to provide greater understanding of complicated issues such as the discovery and development of new tools for fighting cancer.



Improving Medical Decisions Through Comparative Effectiveness Research: Cancer as a Case Study – Forum and White Paper

Experts from HHS, FDA, AHRQ, Congress and Cancer Centers Debate the Future of Comparative Effectiveness at Friends Forum

Friends of Cancer Research hosted a forum on May 13, 2009 on Capitol Hill attended by a large audience of researchers, advocates, House and Senate staff members, employees of the FDA, NIH, NCI and HHS, as well as the general public. This event was held in conjunction with the publication of a white paper authored by an independent committee of 25 leading advocates, researchers and physicians, entitled *Improving Medical Decisions Through Comparative Effectiveness Research: Cancer as a Case Study*. *Full Authoring Committee can be found on page 18.

The report describes the experiences of the clinical and research oncology communities with conducting Comparative Effectiveness Research (CER) in the United States. It includes recommendations for developing a comprehensive CER program, expanding data collection across public and private entities, supporting “personalized” medicine, and integrating CER findings into both standard clinical practice and patient/family decision making.

The report received the endorsement of over 25 leading organizations, including the Alliance for Aging Research, Autism Society of America, American Association for Cancer Research, American Cancer Society, American Society of Clinical Oncology, Lance Armstrong Foundation, National Patient Advocate Foundation, and Susan G. Komen for the Cure, among others.

The moderated panel discussion centered on the top-line issue addressed in the publication: how best to improve medical decisions through the use of Comparative Effectiveness Research.

Ellen Sigal, PhD, Chair and Founder of Friends of Cancer Research, welcomed the audience and announced the release of the white paper, capturing its primary conclusion by saying, **“We need a new paradigm for CER.”** She added that although this case study focused on cancer research and care, findings of the report are “ultimately applicable to all diseases.”

Susan Dentzer, Editor-in-Chief of Health Affairs, a policy journal, moderated the panel discussion. The panel included the co-chairs of the committee that authored the report, professional staff from the Senate Finance Committee and the House Committee on Energy and Commerce, and federal leaders from the Agency for Healthcare Research and Quality

(AHRQ), the Food and Drug Administration (FDA), and the Office of the Secretary of Health and Human Services (HHS).

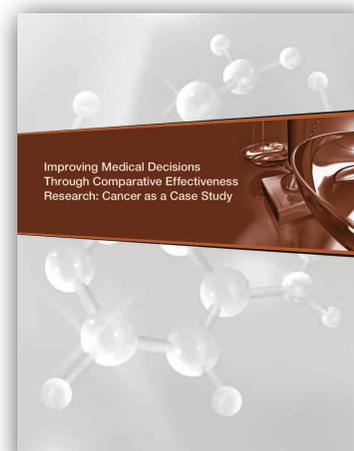
One of the committee co-chairs, **Dr. Al Benson**, Associate Director for Clinical Investigations for the Robert H. Lurie Comprehensive Cancer Center at Northwestern University, discussed the motivation behind the report. “Members of this committee immediately agreed that expanding this research was needed to better understand how different interventions work in a diverse, real world setting”, he said. Dr. Benson described the process of developing profiles of disease, where cancers potentially respond to different treatments based on unique molecular characteristics. **“Understanding these different subpopulations is key to improving medical decision-making.”** By matching patients to the right treatment based on comparative research, Dr. Benson concluded that clinicians “will use health care dollars to the best advantage, sparing patients the cost and potential toxicity of treatments that have no chance of providing benefit”, he said.

Recommendations from the report

“The time is right for us to systematically and methodically review what we’re doing to develop information and guidelines that support and improve outcomes for patients”, said **Kim Lyerly, MD**, Director of the Duke Comprehensive Cancer Center. Dr. Lyerly presented the four consensus recommendations listed in the report for the expansion of CER.

The first recommendation calls for a comprehensive CER program, examining the totality of health care options, the diversity of the patient population, and how differences effect clinical outcomes. The second recommendation, says Dr. Lyerly, involves taking “advantage of the wealth of data that exist throughout the system” to make more timely decisions beyond what’s possible using current published literature and data.

The third recommendation is for CER studies to support the development of “personalized” medicine. Dr. Lyerly cited situations where a population of people treated with a medicine may experience a small survival benefit, but a smaller subgroup may have a dramatic positive response.



"We don't want to eliminate the opportunity for patients in subpopulations based on molecularly-defined characteristics to benefit", he said.

The fourth recommendation from the report is to **"make sure there are mechanisms in place to inform healthcare providers and also citizens."**

Comparison of findings with current government initiatives & priorities

The moderator then asked Carolyn Clancy, MD, Director of AHRQ and member of the Federal Coordinating Council for Comparative Effectiveness Research, if these core recommendations aligned with the federal vision for CER. She responded by invoking the enthusiasm of the Apollo 13 mission: "We're happy, we're proud, we're excited."

Dr. Clancy cited ongoing collaboration since 2005 on the federal vision, with a focus on external stakeholder input. AHRQ's primary focus with CER has concentrated on solving real-world, practical problems through coordination with the National Institutes of Health (NIH) and the National Cancer Institute (NCI). **"What this paper does is inspire us and give us a vision of what's possible and elevate those one-off collaborations to something that's more systematic"**, she said.

Neera Tanden, J.D., from the Office of the Secretary of Health and Human Services, mentioned a high priority within HHS is stakeholder involvement in determining how to spend the money set aside by Congress. She also spoke of the need to make sure "information gets out effectively to providers." She was encouraged by the common themes in this report compared with forthcoming recommendations from HHS.

When asked about the concerns many people have expressed – that CER might take away care options – Tanden stressed that the Obama Administration's priority is to explain CER and ensure that all involved understand the following: **"We're not rationing care in any way, shape, or form."**

"On the Federal Coordinating Council our discussions are centered on how to make funding most effective — not about rationing care or prescribing that only one treatment will be used", she explained.

The moderator then asked **Janet Woodcock, MD**, the Director of the FDA Center for Drug Evaluation and Research, how continued advances in Comparative Effectiveness Research fit into the work of the agency. Citing past milestones in bringing drugs safely to the marketplace, she said, "We're on another cusp. What CER is about is moving medicine from an art to a science. We should have rigorous information. Patients deserve that."

Dr. Woodcock continued, describing how part of the research will include population-based studies and the other requires basic

biomedical science. "These two things are coming together, and what I'm seeing is a huge blossoming of new science." She anticipates that one practical advance for communicating publicly agreed-upon knowledge is to put the information directly onto drug labels or device labels. Susan Dentzer, the moderator, summarized Dr. Woodcock's statements by saying, "CER is going to be the enabler of personalized medicine, not the enemy of personalized medicine."

Dr. Woodcock responded by saying, "It's not that every person will have a separate treatment. It's that we'll subset people better, we'll be able to identify characteristics of people with their disease and then give treatment based on those markers. You need the big picture that Comparative Effectiveness Research provides. I don't see these in conflict with one another, but I think we need to concentrate on both of them."

How does CER fit into U.S. health reform?

Shawn Bishop, representing the Senate Finance Committee chaired by Senator Max Baucus (D-MT), responded to a question from the moderator about the role of CER in U.S. health reform. "We're in the process of developing legislation for comprehensive health care reform. The President wants to sign a bill this year ... that's what we're pushing for." She cited tremendous interest in CER by committee members at all levels.

"We need to have this as part of the redesign of the health care system. CER is part of the expectation of health care reform. Our goal is to bring a proposal for a permanent approach for CER to the health care system."

"In the Senate we proposed an independent institute with funds from the private and public sector", she added.

The moderator then offered a similar question to **Stephen Cha, MD, MHS**, from the Committee on Energy and Commerce chaired by Representative Henry Waxman (D-CA). Dr. Cha responded that they have initiated a "tri-committee process with the ultimate goal of getting a health care reform bill off the floor by August recess."

"What I'm most encouraged by is that across the board - House, Senate, and Administration – they are all specifically focused on CER." He expressed further optimism by saying, **"I think this is the best opportunity we've had to advance the practice of medicine."**

How can data and technology platforms come together to support CER?

The conversation moved to the subject of data and technology platforms needed to advance CER. Dr. Lyerly commented that leadership is necessary to connect the many repositories of research and clinical data. "There are technology and biotech solutions, but there isn't anything better than vision and leadership to affect this."



*Clockwise from top left:
Ellen Sigal, Neera Tanden, Kim Lyerly,
Janet Woodcock, Stephen Cha*



Dr. Clancy mentioned that AHRQ is working very closely with FDA and other colleagues to build common data definitions rather than a huge centralized repository. In this scenario, data stay with the health care organizations, but common data definitions allow collection of large data sets as needed.

The panel concluded with questions from the audience, and this dialogue generated several additional insights.

On the question of whether or not CER will save money in addition to generating value, Dr. Clancy offered that what's **"most important to patients is effectiveness — Does this work?"** But they want to know about safety and they want to know about cost." She added that CER also might identify effective treatments that are underused. Neera Tanden offered that the most important goal is to ensure effective protocols, but that technology advances may result in more cost-effective treatment.

On the subject of how funds will be spent, Dr. Woodcock highlighted the need to lower barriers for clinicians throughout the country to participate in clinical trials.

Finally, the panel discussed how to integrate CER guidelines into daily clinical practice. Dr. Benson said it's going to take "ongoing education, integrated into medical training programs." Dr. Woodcock added that it is essential to "not just educate folks, but enlist them. If people have a stake in the research and results, you have much more of a stake in the guidelines that come out."

The moderator closed the discussion by echoing an earlier statement by Dr. Clancy. "We have a lot more to do."

To download the full report please visit:
www.focr.org/comparative-effectiveness

Friends & Lombardi Hold Cancer Health Disparities Forum

At a town hall hosted by Friends of Cancer Research (Friends), Georgetown-Lombardi Comprehensive Cancer Center, and Lombardi's Capital Breast Care Center, leaders from academia, advocacy, industry and the federal government explored current research and policy initiatives on breast cancer health disparities.

During the forum, held on October 28th 2009, at Georgetown University Medical Center, special focus was given to the issues of breast cancer disparities, the high rates of triple negative breast cancer and the disproportionate cancer incidence and death rates among minorities.

President of Friends, Marlene Malek, opened the discussion welcoming everyone and stressed the importance of collaboration between academic medical centers, industry, government researchers, regulators and patients, all working together to "eliminate the burden of cancer, and advance research." Malek, a former oncology nurse at Georgetown, also shared with the audience the many personal reasons that influenced her entry into cancer advocacy.

Chair and Founder of Friends, Dr. Ellen Sigal, discussed the importance of cancer research, especially peer review and translational research. She thanked all the panelists for their contributions and she praised the Lombardi Center, which she called "a jewel in Washington D.C."

Deputy Director of the National Cancer Institute (NCI), Dr. Anna Barker, in her keynote address, focused on the staggeringly disproportionate rates of cancer incidence and mortality among minorities, especially African Americans. She shared with the audience her grave concerns that the numbers will only go up if more resources and focus are not given to this issue. She emphasized the role of entities such as community hospitals and cancer centers in reaching out to under-served populations to educate them and thus help alleviate the crisis.

The panel discussion, moderated by Susan Dentzer, Editor-in-chief of Health Affairs, included topics such as the many factors that lead to health disparities, promising emerging therapies and the need for continued and sustained federal funding for biomedical and cancer research.

Head of the Molecular Oncology Unit at NCI, Dr. Lee Helman discussed the burden of triple negative breast cancer, a type of breast cancer that is more common among African American women as compared to Caucasian women. Triple negative breast cancer is characterized by tumors that lack the expression of the estrogen receptor, progesterone receptor, and the HER2 protein.

Helman mentioned that although this is one of the most lethal types of cancer, like most breast cancer outcomes are best if caught early. Researchers are currently working on targeted treatments that have showed early promise for triple negative breast cancer patients.

Dr. Barry Childs, Associate Vice President of Oncology for Sanofi-Aventis, agreed that triple negative breast cancer is the "worst type of cancer." He described Sanofi's efforts at developing targeted therapies including a treatment specifically targeted toward triple negative breast cancer that is currently in Phase III clinical trial.

Associate Director for Minority Health & Health Disparities at Georgetown-Lombardi Dr. Lucile L. Adams-Campbell, highlighted the role of the Capital Breast Cancer Center (CBCC) in serving uninsured and under-insured populations of women across Washington, DC by providing critical mammograms, follow-up screenings and treatment for breast cancer. Dr. Adams-Campbell emphasized that "if we can't get to the population that needs education and access, then we will always have disparities."

A former patient of the CBCC and now a breast cancer survivor, Tovia M. Miner shared her personal experience with CBCC. She explained how although she was uninsured, she was able to get free screenings at CBCC and how her cancer was detected early and treated through their vigilance. Ms. Miner said, "CBCC made it easy for me to create a relationship with medical staff and pursue medical care when I needed it."

Director of Lombardi, Dr. Louis M. Weiner, reiterated that "early detection of cancer, especially breast cancer, is the best way to prevent death." He spoke of the central role that Lombardi cancer center and CBCC play in not only serving the cancer patient community of DC, but also as a leading research facility.

Dr. Dora Hughes, Counselor for Science and Public Health at the Department of Health and Human Services, in her closing keynote discussed the Obama Administration's commitment to cancer research and providing health coverage for all Americans. She mentioned the provisions within last year's federal economic stimulus package funding to maintain health coverage for unemployed persons as an example of the administration's efforts. She illustrated the administration's commitment to cancer research by mentioning that as of October 28th, 2009, \$877 million from ARRA has been allocated specifically for cancer research and \$105 million of that to breast cancer-related research.



*Clockwise from top left:
Susan Dentzer, Lee Helman, Dora Hughes,
Anna Barker, Lou Weiner*

In closing, all the panelists agreed that access to health care is vital in order to reduce disparities. They spoke of the need for better communication between the public and medical community, increased federal funding for research and incentives to encourage young scientists to enter the field as other measures to combat the disease.

During audience question and answer with the panel, Dr. Rebecca Riggins, an assistant professor at Georgetown, thanked Dr. Hughes and the Obama Administration for an ARRA grant she received which has allowed her team to study how genetic and environmental factors including BisPhenol-A (BPA) exposure affect susceptibility to breast cancer.

For more information on this Town Hall or Friends of Cancer Research, please visit www.focr.org.

AACI, AACR, ASCO, and Friends host Hill Day and Honor Senator Arlen Specter

More than 50 cancer center representatives from 20 states descended upon Washington, DC, on Wednesday, May 6th, to educate the nation's policymakers about the importance of a strong federal commitment to cancer research. Friends of Cancer Research, along with the Association of American Cancer Institutes (AACI), the American Association for Cancer Research (AACR), and the American Society of Clinical Oncology (ASCO) hosted the day-long event.

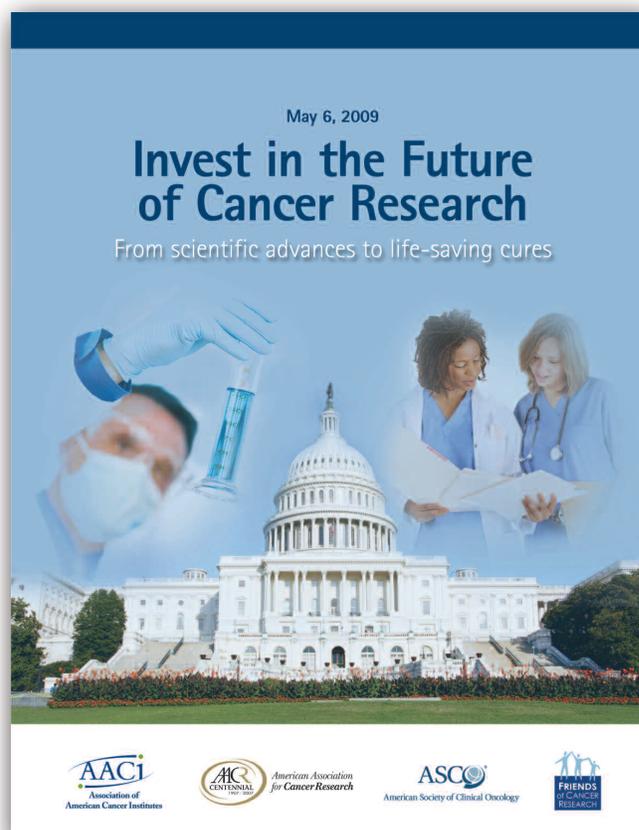
Edward J. Benz Jr., MD, President of the Dana-Farber Cancer Institute and AACI President, welcomed everyone during breakfast and urged all participants to help their elected representatives to better understand the impact of the federal budget on the capacity of the National Institutes of Health (NIH) and the National Cancer Institute (NCI) to fund biomedical research across the country.

Following Dr. Benz' remarks, the cancer center representatives spread out across the Capitol and advocated for increased federal funding for cancer research during the 140 meetings with members of Congress and their aides.

During lunch, Dr. Richard Schilsky, president of ASCO, welcomed everyone and introduced Senator Kay Bailey Hutchison (R-TX). The Senator, joined by Caya Lewis and Cameron Cryer, two top health aides on the Senate's Health, Education, Labor and Pensions (HELP) Committee, discussed the 21st Century Cancer Alert Act.

"Our nation declared the War on Cancer nearly forty years ago, yet cancer is still expected to become the leading killer of Americans in the coming years. We must bring renewed focus and vigor to this fight," Sen. Hutchison said. "That is why earlier this year I introduced legislation with Senator Kennedy to improve cancer awareness, research, and treatments."

"Cancer is a relentless disease that doesn't discriminate between men and women, wealthy or poor, the elderly or the young," Sen. Hutchison said. "Every American has been touched in some way by this debilitating illness. I'll continue to work, as I have for over 25 years, to raise cancer awareness and increase funding for cancer research."



The two Senate staff members then urged participants to encourage their representatives to actively support this critically important public policy.

During a reception, hosted the evening prior to Hill day, AACI, AACR, ASCO and Friends, along with cancer center directors from around the country, honored Senator Arlen Specter (D-PA) for his tireless work to ensure that biomedical research receives desperately needed funding and support. Dr. Schilsky welcomed everyone to the reception, and Dr. Ellen Sigal, Chair of Friends, presented the award to Sen. Specter on behalf of all four organizations.



Clockwise from top: Advocates meet with Rep. Dingell, Ellen Sigal, Marlene Malek, Richard Schilsky, Sen. Specter, Ed Benz, Barbara Duffy Stewart, Cameron Cryer and Caya Lewis, Sen. Hutchison addresses advocates at lunch.

Hill Briefing on Chemoprevention with C-Change

"Realizing the Promise of Cancer-Preventing Drugs and Vaccines"

On July 20th 2009, Friends of Cancer Research sponsored a Hill briefing with C-Change titled: "Realizing the Potential of Cancer-Preventing Drugs and Vaccines." The briefing was held in the Dirksen Senate Office Building.

Senator Dianne Feinstein (D-CA) welcomed the audience, and spoke about the urgent need to focus on cancer prevention and cures.

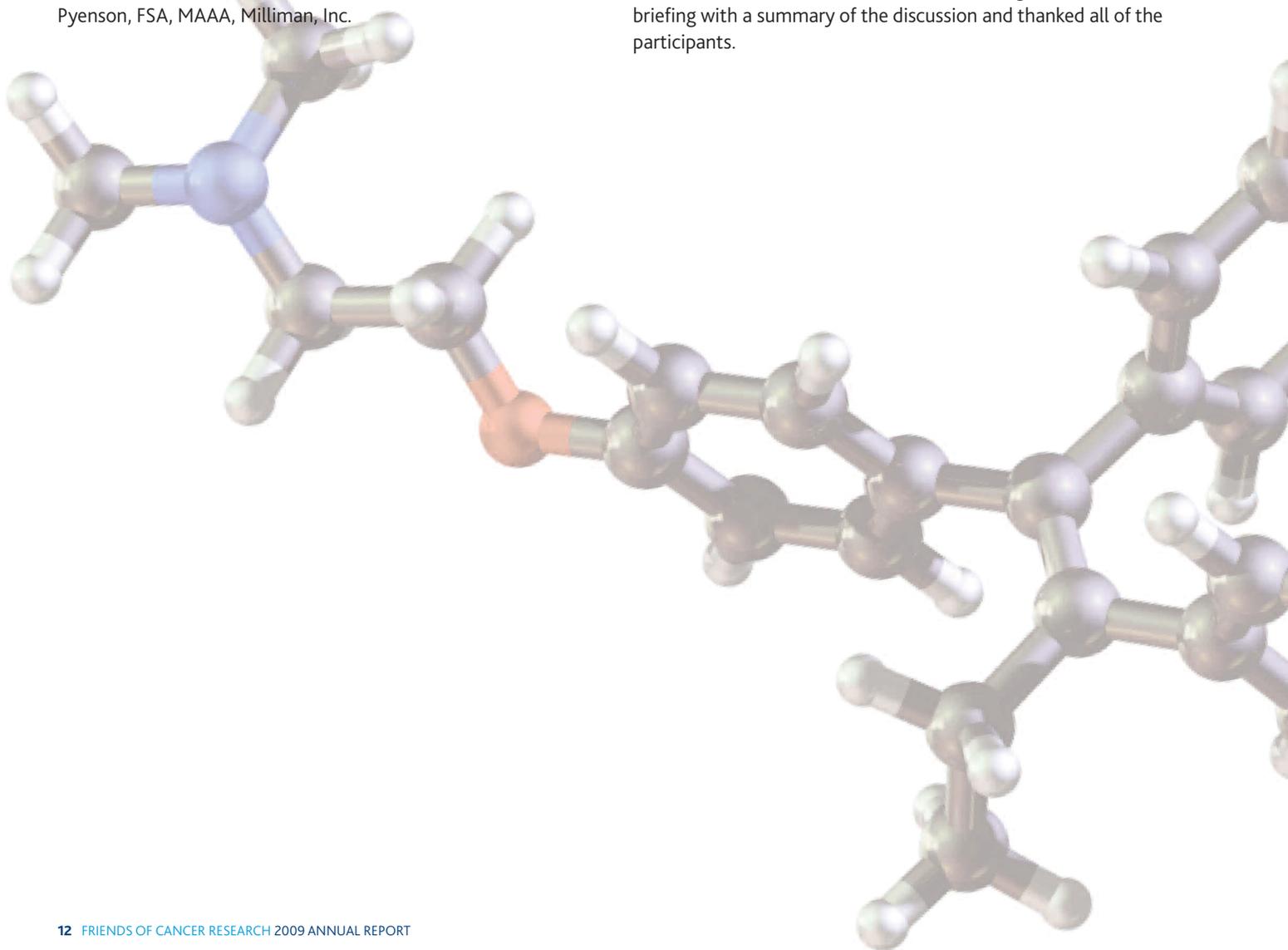
Dr. Victor Vogel, Chief Medical Officer of the American Cancer Society, gave an introduction and acted as moderator for a panel discussion that included: Ronald B. Herberman, MD, University of Pittsburgh Cancer Institute; Frank Meyskens, MD, Chao Family Comprehensive Cancer Center, University of California - Irvine; Samir N. Khleif, MD, National Cancer Institute / Food and Drug Administration; Catherine P. Bennett, MA, JD, cancer survivor, Prevent Cancer Foundation Board; and Bruce Pyenson, FSA, MAAA, Milliman, Inc.

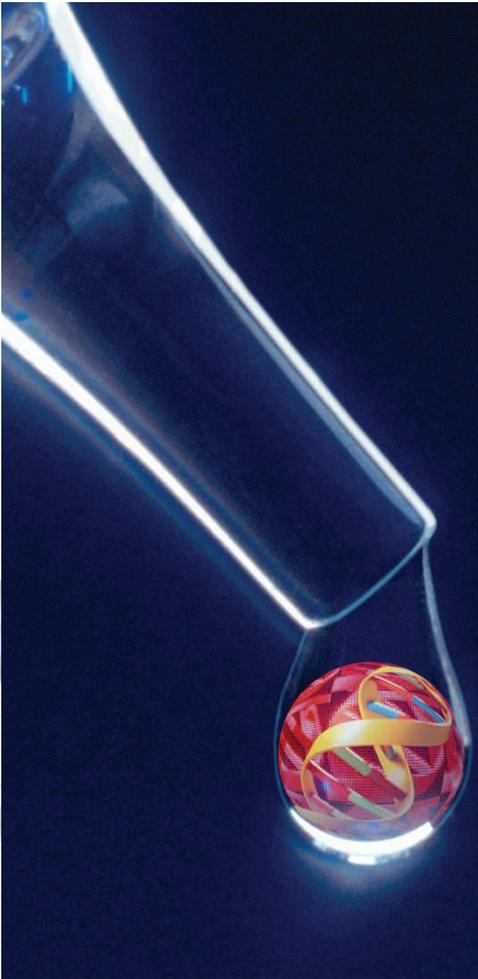
The panel discussed how, as a nation, we are missing important opportunities to reduce the burden of cancer, further accelerate the national priority of disease prevention, and maintain and advance our position as a global leader in science.

Panelists also discussed several major barriers that deter the research community and businesses from investing time, attention, and funding in chemoprevention research.

Solutions to these issues were presented by all panelists regarding how cancer-preventing drug and vaccine research should be prioritized and well funded, how the drug approval process should be updated to support the science and accelerate discovery and reimbursement for cancer-preventing agents should be provided to assure patient access.

Tom Kean, MPH, Executive Director of C-Change, closed the briefing with a summary of the discussion and thanked all of the participants.





Top to bottom: Hill staff and advocates at briefing, Sen. Feinstein, Catherine Bennett

Conference on Clinical Cancer Research

Friends co-hosted conference with the Engelberg Center for Health Care Reform at Brookings, supported by ASCO, AACR, Lance Armstrong Foundation and Susan G. Komen for the Cure.

Building on the success of the conference on clinical cancer research held in 2008, a follow up conference was held to develop a clear path forward on key issues surrounding the development and regulation of cancer drugs and therapies. The conference, held at the Hyatt Regency Hotel in Washington DC on September 14th 2009, was attended by more than 175 attendees representing a cross-section of academia, industry, advocacy and government.

NCI Director Dr. John Neiderhuber in his opening remarks reiterated that cancer is a special case and that "drugs that work in 10 percent of the patient population are not a failure in cancer". He stressed the need for integrating emerging genomic knowledge about tumors into drug development and using that information to better predict prognosis during treatment.

Dr. Margaret Hamburg, Commissioner of the Food and Drug Administration, delivered the afternoon keynote address where she highlighted the importance of taking a rigorous scientific approach to the regulation of drugs and devices. She emphasized that various federal health agencies, particularly the NIH and FDA, should capitalize on the scientific expertise of each agency through enhanced collaborations. Such an effort would help advance the missions of each individual agency and ultimately benefit the American people.

There were four panels that discussed specific topics in clinical cancer research:

PANEL ONE: Data Submission Standards and Evidence Requirements

Issue focus: Developing optimized standards for data collection for well-studied cancer therapies to improve the efficiency of safety evaluations without sacrificing the scientific integrity and validity of study results.

Panelists: Robert Temple, Food and Drug Administration; Robert Erwin, Marti Nelson Cancer Foundation; Jeffrey Abrams, National Cancer Institute; Gwen Fyfe, Consultant; Richard L. Schilsky, University of Chicago and ASCO.

Taking into account the recommendations that resulted from last year's discussion on data submission standards and an in-depth analysis performed by the ASCO Data Optimization Work Group, the panel provided concrete proposals that would lead to collection of necessary and sufficient toxicity data in the case of supplemental applications. In order to provide additional information about what is acceptable to the agency, FDA will begin to develop a guidance document on this topic.

PANEL TWO: Blinded Independent Central Review (BICR) of PFS as an Endpoint

Issue focus: Progression-Free Survival or PFS has been accepted as an endpoint in certain clinical trials. However, there still remain concerns about the reliable measurement of PFS as an endpoint. A unique source of bias related to PFS is reader evaluation bias in unblinded trials, which was the focus of this panel, because of the potential for subjective elements to influence the disease progression evaluation.

Panelists: Richard Pazdur, Food and Drug Administration; Nancy Roach, C3: Colorectal Cancer Coalition; Lori Dodd, National Institute of Allergy and Infectious Diseases; Ohad Amit, GlaxoSmithKline; Will Bushnell, GlaxoSmithKline; Daniel Sargent, Mayo Clinic.

The panel put forward two proposals to quantify bias and suggested ways of handling discrepancies between local and central reviewers.

The need for quantifiable metrics to evaluate PFS as an endpoint and the need to objectively evaluate whether BICR is needed are issues that FDA would very much like to reach consensus on. They have indicated that these topics will be the subject of discussion at an Oncologic Drugs Advisory Committee (ODAC) meeting soon.

PANEL THREE: Accelerating Development and Approval of Targeted Cancer Therapies

Issue Focus: Proposing specific opportunities for more efficient development, regulatory review, and post-approval evaluation of targeted cancer therapies with companion diagnostics and suggesting a means to overcome these deficiencies.

Panelists: Patricia Keegan, Food and Drug Administration; Cindy Geoghegan, Patient and Partners; Anna Barker, National Cancer Institute; David Sidransky, Johns Hopkins University; Stephen Friend, Sage Bionetworks; Ray Woosley, Critical Path Institute; David Epstein, Novartis; David Kessler, UCSF School of Medicine.

Opportunities for more efficient development of targeted cancer therapies include identifying unique molecular targets for specific types and sub-types of cancer, development of an analytically valid and reliable diagnostic test to identify the presence of a molecular target or background mutation and co-development of a diagnostic and therapeutic agent.



*Clockwise from top:
Dr. Hamburg delivers lunch keynote,
Mark McClellan, Commissioner Hamburg and
Ellen Sigal, David Kessler, Richard Pazdur*



The panel explored the potential for a targeted approval paradigm to outline a pathway for the evaluation of targeted cancer therapies and to provide the basis for new levels of coordination and interaction between device and drug developers, as well as between FDA centers.

PANEL FOUR: Development of Rational Drug Combinations with Investigational Targeted Agents

Issue Focus: Advances in basic research have led to improved understanding of the biological mechanisms of cancer. The complexity of disease biology involving multiple redundancies and pathway crosstalk obligates targeting at least two disparate pathways or molecules to achieve significant therapeutic success. The panel explored specific examples and criteria in which an alternative regulatory process to the existing combination rule would be appropriate and feasible and thus could be adopted by developers.

Panelists: Janet Woodcock, Food and Drug Administration; James Zwiebel, National Cancer Institute; Stuart Lutzker, Genentech; Matthew Ellis, Washington University, St. Louis; Adam Clark, Lance Armstrong Foundation; and Charles Erlichman, Mayo Clinic.



The panel examined three specific cases (synthetic lethality, co-enhancement and uni-enhancement) wherein a four-arm factorial clinical trail may perhaps be amended to an adaptive trial involving the combination compared to the standard of care.

Rational drug combinations have the potential for greater efficacy in oncology areas as well as other disease settings. Recognizing this, the FDA will begin to develop a guidance document that specifically addresses the unique challenges surrounding development of therapies involving two (or more) new molecular entities (2NMEs).

Annual Cancer Leadership Awards Reception

On March 4, 2009 Friends of Cancer Research hosted its Annual Cancer Leadership Awards Reception at the Hotel Monaco in Washington, DC. The reception was attended by supporters of Friends and by key leadership within advocacy, government, and industry.

Awards were presented to United States House Majority Leader Steny H. Hoyer (D-MD), United States Senator Judd Gregg, (R-NH), Entertainment Industry Foundation President and CEO Lisa Paulsen, and Director of the Center for Drug Evaluation and Research at the Food and Drug Administration, Dr. Janet Woodcock. The honorees were awarded in recognition of their extraordinary efforts to advance the fields of cancer research,

awareness, treatment, and detection. Representative John Dingell (D-MI) presented the award to his long-time colleague Leader Hoyer, who delivered a heartfelt acceptance telling the story of his own mother's battle with breast cancer. Friends President Marlene Malek presented Senator Gregg with his award for his career in the Senate working to advance the cause, and for his tireless work on issues relating to cancer and the FDA. Dr. Robert Young, Chancellor of Fox Chase Cancer Center, and Friends Board Member, presented Dr. Woodcock her award in recognition for her exceptional career at the FDA. Friends Chair and Founder Dr. Ellen Sigal closed out the program with the award for Ms. Paulsen, who shared a video montage from her work on "Stand Up To Cancer."



*Clockwise from top:
Majority Leader Hoyer, Marlene Malek,
Rep. Dingell, Sen. Gregg, Lisa Paulsen,
Ellen Sigal and Sen. Gregg*

In Appreciation

Thank you!

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A Note from Friends Executive Director



All of us at Friends of Cancer Research are proud of what we have accomplished with our partners and colleagues in 2009, and are eager to maintain this momentum in the coming year.

In 2010, we will continue to lead the way in creating innovative public-private partnerships, policy forums, and educational programs focused on overcoming the hurdles that stand between patients and new promising cancer treatments and therapies.

We look forward to another exciting year.

Dr. Jeff Allen
Executive Director



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