



FRIENDS
of CANCER
RESEARCH

ACCELERATING
SCIENCE
AND
TECHNOLOGY

2012 ANNUAL REPORT

2012 Highlights

March 8, 2012

FDA User Fees Hearing:
Friends Executive Director Testifies Before House Energy & Commerce Committee

April 25, 2012

Friends of Cancer Research Symposium: Symptoms and Toxicities of Cancer Therapy

July 9, 2012

President Obama signs Breakthrough Therapy designation into law as part of the Food and Drug Administration Safety and Innovation Act

October 17, 2012

White Paper Released "Eliminating Breast Cancer Health Disparities: Communicating to At-Risk Populations"

March 26, 2012

The bipartisan Advancing Breakthrough Therapies for Patients Act Introduced

May 17, 2012

Friends co-hosts annual Congressional Advocacy Day on Capitol Hill with Congressional Honorees: Congresswoman Diana DeGette (D-CO) and Congressman Brian Bilbray (R-CA)

September 14, 2012

Creating a Blueprint for Future Drug/Diagnostic Co-Development

November 14, 2012

Friends of Cancer Research and the Engelberg Center for Health Care Reform at Brookings Conference on Clinical Cancer Research

September 20, 2012

Friends of Cancer Research Leadership Awards Reception Honoring Senator John McCain, Dr Richard Pazdur, Neera Tanden

FRIENDS of CANCER RESEARCH

Because patients deserve better options

Because a father, a sister, a child or friend deserve
the best treatment possible

Because cancer won't wait

Friends of Cancer Research is our country's leading voice in advocating for policies and solutions that will get treatments to patients in the safest and quickest way possible.

Friends of Cancer Research (*Friends*) develops groundbreaking partnerships and creates a more open dialogue among both public and private sectors and tears down the barriers that stand in the way of conquering cancer. By collaborating with premier academic research centers, professional societies and other advocacy organizations, *Friends* is able to accelerate innovation.

We work closely with government agencies (FDA, NCI, NIH, HHS) and Congressional leadership to create educational, policy, and scientific approaches to improve health outcomes and cancer care. As a respected independent think tank and advocacy organization, *Friends* is able to cut through bureaucratic red tape, put aside partisan politics and engage all stakeholders, producing real results.

- We have made great strides in the fight against cancer but challenges still exist
- 79% of cancer research grants go unfunded each year
- It still takes more than 12 years for newly discovered treatments to get from the research bench to the patient's bedside

Imagine what discoveries could be made and the lives that could be saved if more grants were funded, if the barriers between discovering new treatments and getting them to a patient's bedside were overcome.

We are working every day to make new treatments a reality for patients everywhere.

To learn more please visit: www.focr.org or 202.944.6700

Getting Breakthrough Therapies to Patients

Each year Friends of Cancer Research (*Friends*) convenes conferences, forums and working groups to address critical issues accelerating science and technology. These annual venues bring together leaders from federal health and regulatory agencies, academic research centers, patient advocacy organizations and the private sector to propose consensus solutions and develop a clear path forward on critical issues surrounding the development and regulation of drugs and therapies.

Through our unique collaborative model, we have created a path to better drug development and approval through scientific, cultural, regulatory and legislative solutions. Our 2011 Conference included a panel entitled: Development Paths for New Drugs with Large Treatment Effects Seen Early. The panel proposed scientific strategies to ultimately expedite FDA approval for a drug showing dramatic responses in the early stages of development while maintaining drug safety and efficacy standards. The following is a timeline of action and success, taking this concept from scientific white paper presented at our conference, to bipartisan legislative solution, to a tool in use by the Food and Drug Administration to expedite the approval of multiple drugs all in a year's time.

On **March 8, 2012**, *Friends* Executive Director, Dr. Jeff Allen introduced the topic during a hearing of the House Energy and Commerce Committee.

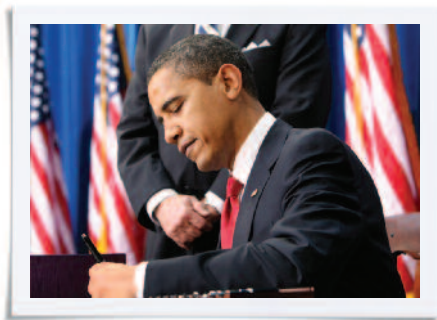
On **March 22, 2012**, *Friends* held a congressional briefing titled "Expediting New Treatments to Patients: FDA Approval Mechanisms" to review and define the use of FDA mechanisms for accelerating drug development. This briefing highlighted the concept of a new "Breakthrough Therapy" designation which received public endorsement from FDA, industry and academia.



In the **spring of 2012**, the bipartisan Advancing Breakthrough Therapies for Patients Act was introduced by Senators Michael Bennet (D-CO), Orrin Hatch (R-UT) and Richard Burr (R-NC) and Representatives Diana DeGette (D-CO) and Brian Bilbray (R-CA).

A Timeline Of Success

On **July 9, 2012**, The Advancing Breakthrough Therapies for Patients Act was passed into law as part of Prescription Drug User Fee Act (PDUFA)



On **February 12, 2013**, the first designation for a cancer drug was given by the U.S. Food and Drug Administration for patients with relapsed or refractory mantle cell lymphoma.

At the **2012 Conference**, Friends developed a white paper and panel discussion in the pursuit of encouraging use of the new pathway and informing FDA guidance.

On **January 7, 2013**, only 6 months after being signed into law, the first two breakthrough designations have been given for the treatment of cystic fibrosis.

A designation was also given on **March 15, 2013** for a therapy to treat a type of non-small cell lung cancer.

Friends Executive Director Testifies before U.S. House of Representatives and Introduces Breakthrough Therapies Designation to Congress

On Thursday, March 8, 2012, *Friends* Executive Director, Dr. Jeff Allen, testified before the House Energy and Commerce Committee, Subcommittee on Health, at a hearing titled, "FDA User Fees 2012: Hearing on Issues Related to Accelerated Approval, Medical Gas, Antibiotic Development and Downstream Pharmaceutical Supply Chain."

The three panel hearing convened members of government, academia, and industry to address pressing issues surrounding the reauthorization of the Prescription Drug User Fee Act (PDUFA) as well as additional proposals to improve mechanisms for drug approval and pending legislation in the House. The second panel featured Dr. Allen, who discussed the need to examine opportunities to expand the accelerated approval process, and introduced a "Breakthrough Therapies" designation for new therapies that show great benefit early in development.

Panel One: Janet Woodcock, Director of the Center for Drug Evaluation and Research at the Food and Drug Administration

Panel Two: John Maraganore, PhD., Chief Executive Officer, Alnylam Pharmaceuticals; Jeff Allen, PhD., Executive Director, Friends of Cancer Research; Barry Eisenstein, MD, FACP, FIDSA, FAAM, Senior Vice President Scientific Affairs, Cubist Pharmaceuticals; John H. Powers, MD, FACP, FIDSA, Assistant Clinical Professor of Medicine, George Washington University School of Medicine; Michael D. Walsh, President, LifeGas, on behalf of the Compressed Gas Association

Panel Three: Shawn Brown, Vice President, State Government Affairs, Generic Pharmaceutical Association; Elizabeth A. Gallenagh, JD, Vice President, Government Affairs, General Counsel, Healthcare Distribution Management Association; Tim Davis, Pharm.D., Beaver Health Mart Pharmacy, on behalf of the National Community Pharmacists Association; Allan Coukell, Director, Medical Programs, Pew Health Group, The Pew Charitable Trusts

In his opening testimony, Dr. Jeff Allen, explained how accelerated approval, priority review, and fast track mechanisms play an important role in advancing new products and therapies and explored new ways in which to enhance these mechanisms, while

applying them "consistently, efficiently, and effectively" over all therapeutic areas without sacrificing safety and efficacy. Dr. Allen emphasized that the FDA needs updated mechanisms to respond to the rapid advancement of science.

Dr. Allen went on to describe the need for clear guidelines and a new approach for treatments that show remarkable benefit early in development. He called on Congress to enact legislation that would designate a new compound that shows substantial clinical activity in early phase trials as a "Breakthrough Product". This, he explained, would potentially minimize the number of patients who would need to be assigned to a less effective or ineffective control arm of a study.

Rep. Frank Pallone, Jr., a member of the committee, stated that the breakthrough therapy and expanded accelerated approval proposals warrant serious consideration, and asked Dr. Allen to expand on safety and efficacy in these processes. Dr. Allen first reiterated that safety and efficacy standards currently in place must be upheld. He went on to explain that breakthrough therapies would likely be highly targeted drugs for specific populations. Because of their high magnitude of early activity, the traditional approach to drug development may not be optimal, and that ways to expedite the process should be explored as early as possible.

Panel two also featured a variety of witnesses who spoke to topics ranging from the regulation of medical gases to antibiotic development. Dr. John Powers of the George Washington University School of Medicine discussed needing to treat patients and their symptoms rather than organisms, and stated that the number of drugs approved by the FDA is not a measure of public health. When asked by Chairman Joe Pitts why accelerated approval has not led to gains in treatments for rare disorders, Dr. John Maraganore, CEO of Alnylam Pharmaceuticals, said it speaks to the need for clarity Dr. Woodcock talked about in panel one. Repeating a question from earlier in the hearing, Rep. Pitts also asked if the FDA is seeking to limit the use of accelerated approval. Dr. Maraganore echoed his previous statement about the need to clarify accelerated approval, and time and cost are also significant barriers to getting innovative medicines to market.



Friends Executive Director Jeff Allen Testifies Before Congress



House Energy and Commerce Subcommittee on Health Chairman Pitts and Ranking Member Pallone Question Panel

Friends of Cancer Research Holds Congressional Briefing on Expediting New Treatments to Patients: FDA Approval Mechanisms

On Thursday, March 22, 2012, Friends of Cancer Research (*Friends*) held a congressional briefing titled "Expediting New Treatments to Patients: FDA Approval Mechanisms" to discuss and define the use of current Food and Drug Administration (FDA) mechanisms for accelerating drug development and explore the prospect of new and/or enhanced tools to bolster FDA's ability to get drugs to market sooner and safer. The four-person panel featured: **Dr. Janet Woodcock**, Director, Center for Drug Evaluation and Research, FDA; **Mr. Jonathan Leff**, Managing Director, Warburg Pincus; **Dr. Howard Scher**, Chief, Genitourinary Oncology Service, Memorial Sloan-Kettering Cancer Center; **Dr. Ellen Sigal**, Chair, Friends of Cancer Research and was moderated by **Dr. Mark McClellan**, former commissioner of the FDA and Director of the Engelberg Center for Health Care Reform at the Brookings Institution.

Dr. Sigal introduced **Senator Michael Bennet (D-CO)** as a "champion for FDA and cancer research." Senator Bennet, in delivering opening remarks, underscored the importance of discussing new approval pathways to get treatments to patients in a faster and safer way, particularly with the upcoming reauthorization of the Prescription Drug User Fee Act legislation in Congress. He praised the bipartisan nature of the discussion and highlighted the need for patients, as well as the scientific community, to have confidence in the future of drug approvals in a rapidly changing scientific environment.

Dr. Jeff Allen, *Friends* Executive Director, gave a brief overview of a proposal for a "Breakthrough Therapies" designation for the FDA. The designation, which originated from a panel at the annual Friends-Brookings Conference on Clinical Cancer Research, would trigger close communication between FDA and the drug sponsor, to develop trial designs to shorten or combine traditional phases of development, expedite the pathway to approval and avoid giving larger numbers of patients a potentially harmful or ineffective drug as part of a control arm.

Dr. Woodcock then began the panel discussion by summarizing some of the FDA's current mechanisms for expediting drug development and review. They include accelerated approval, fast-track designation, and priority review status. Dr. Woodcock pointed out that 80 drugs have been approved under accelerated approval since 1992, 29 of them cancer drugs.

Dr. McClellan asked the panel where drug development is headed as a result of new scientific discoveries and progress. Dr. Scher stated that genetics and biomarkers have changed the way many have looked at and classified certain diseases, using prostate cancer, once thought of as a site specific disease but now known to comprise up to 30 different diseases, as an example.

The panel discussed current proposals to enhance the FDA, including enhanced accelerated approval and the breakthrough therapy designation. Dr. McClellan asked Dr. Woodcock what she thought of the proposal and whether a mechanism like "breakthrough" would be beneficial. Dr. Woodcock stated that it would be helpful and that there should be an "all hands on deck" by the FDA when significant benefit is seen early so that a potential breakthrough can be tested and developed as rapidly as possible. She stressed the need for FDA and developers to design trials that are ethical and able to yield information as rapidly as possible. Dr. Scher agreed and said that anytime you can get everyone together and on the same page, things get done faster.



(L-R) Howard Scher, Janet Woodcock, Ellen Sigal, Mark McClellan



(At Podium) Sen. Bennet (D-CO) Delivers Opening Remarks

Dr. Sigal also reiterated this point and went further to say that "since people, especially in Washington, tend to work in silos, collaboration, communication and clarity are of the utmost importance to alleviating the confusion in all communities about what the agency will or will not do."

Mr. Leff went on to discuss the opportunities and challenges to investors in light of these new discoveries. While the scientific developments present opportunities themselves, Mr. Leff said, the high costs and time delays getting drugs through the regulatory cycle are significant barriers to new investment. He described a growing trend toward new areas of investment including health information technology and social media.

Asked later what investors are looking for to reverse this trajectory, Mr. Leff replied that looking at new approaches and ways to speed up the process is the right conversation to be having, but also cautioned that it is important not to forget about the many drugs that may not be designated breakthrough therapies moving through the pipeline or lose focus on other treatments because they are not considered to be breakthroughs.

Dr. Sigal emphasized the importance of continued development of targeted therapies and getting safe and effective treatments to patients, who "at the end of the day want treatment options that will work for them."

The Bipartisan Advancing Breakthrough Therapies for Patients Act Introduced

On March 26, 2012, U.S. Senators Michael Bennet (D-CO), Orrin Hatch (R-UT) and Richard Burr (R-NC) introduced **The Advancing Breakthrough Therapies for Patients Act** to help bring breakthrough drugs and treatments to patients who need them more quickly.

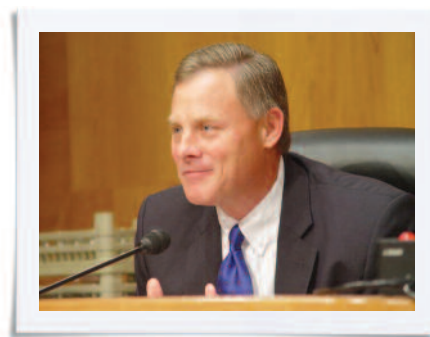
The bipartisan bill would expedite U.S. Food and Drug Administration (FDA) approval and provide more flexibility when a drug or treatment shows dramatic responses early in development, while still ensuring drug safety and efficacy. For patients, this proposal would allow FDA the ability to move towards more innovative clinical trials, such as minimizing the number of patients enrolled in trials and shortening the duration of trials, when scientifically appropriate.

"Through the bipartisan 'Breakthrough' legislation, Senators Bennet, Hatch and Burr are showing great leadership to address the real needs of patients suffering from diseases like cancer," said Dr. Ellen Sigal, Chair and Founder of Friends of Cancer Research.

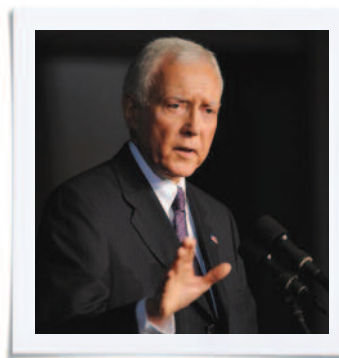
The 'Breakthrough' proposal originated from a discussion at the 2011 annual cancer conference co-hosted by *Friends* and the Engelberg Center for Health Care Reform at Brookings at Brookings Conference on Clinical Cancer Research. A panel from this conference addressed potential new approaches that would speed up the process for FDA approval of drugs that show large treatment effects early in development, while still ensuring drug safety and efficacy.

On Thursday, March 8, 2012, *Friends* Executive Director Dr. Jeff Allen testified before the House Energy and Commerce, Subcommittee on Health, where he discussed the need to examine opportunities to expand the accelerated approval process, and introduced a "Breakthrough Therapies" designation for new therapies that show great benefit early in development.

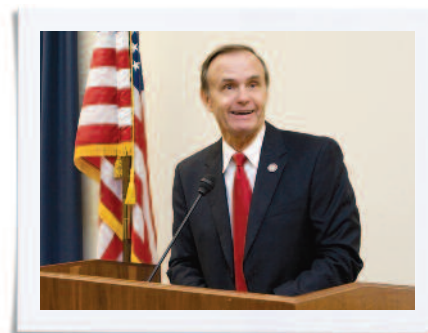
Breakthrough therapy legislation was also introduced in the House of Representatives by Reps. Brian Bilbray and Diana DeGette. Both bills were folded into the Prescription Drug User Fee Act bill the Food and Drug Administration Safety and Innovation Act and signed into law by President Obama on July 9, 2012.



Sen. Burr (R-NC)



Sen. Hatch (R-UT)



Rep. Bilbray (R-CA)



Sen. Bennet (D-CO)



Rep. DeGette (D-CO)

President Obama signs Breakthrough Therapy designation into law as part of the Food and Drug Administration Safety and Innovation Act



"While people like to talk about polarization and gridlock in Washington, this bill is a victory for both bipartisanship and for the millions of Americans who rely on medicines and medical devices."

– Senator Tom Harkin (D-IA) and Senator Michael Enzi (R-WY)

"FDASIA is the culmination of the work of the administration and Congress, in partnership with patients, the pharmaceutical and medical device industries, the clinical community and other stakeholders, to provide the FDA with the tools needed to continue to bring drugs and devices to market safely and quickly and promote innovation in the biomedical industry, and to help secure the jobs supported by drug development."

– Secretary Kathleen Sebelius, US Department of Health and Human Services

Friends of Cancer Research and the Engelberg Center for Health Care Reform at Brookings Conference on Clinical Cancer Research

Each year, Friends of Cancer Research (*Friends*) and the Engelberg Center for Health Care Reform at Brookings convene the Conference on Clinical Cancer Research to address critical issues in the development of new drugs. This annual conference brings together leaders from federal health and regulatory agencies, academic research centers, patient advocacy organizations and the private sector to propose consensus solutions and develop a clear path forward on critical issues surrounding the development and regulation of drugs and therapies.

Through our unique collaborative model, we have created a path to improve drug development and approval through scientific, cultural, regulatory and legislative solutions. Our reports have been published in 10 peer-reviewed scientific journals and featured in major news and trade publications.

On November 14, 2012, the fifth-annual Conference on Clinical Cancer Research was convened in Washington DC with the support of Susan G. Komen for the Cure, the American Society of Clinical Oncology (ASCO), and the American Association for Cancer Research (AACR). The 2012 conference focused on new policies and research strategies to improve and expedite drug development. Through a series of Issue Briefs released at the meeting, members of the expert panels proposed ways to implement the newly created Breakthrough Therapies designation and how to optimize the Accelerated Approval pathway. In addition, a proposal for a biomarker-driven, multi-drug registration trial for potential agents to treat lung cancer was also presented as an innovative approach to accelerate drug development.

In her opening remarks, Dr. Ellen Sigal, Chair of *Friends* (pictured right), described some of the major accomplishments that have been achieved through this unique collaborative model, including the release of an FDA guidance in 2010 on the co-development of two new molecular entities (2NMEs) for use in combination, and the passage by Congress of The Advancing Breakthrough Therapies for Patients Act earlier this year. Echoing these remarks, Dr. Mark McClellan, Director of the Engelberg Center praised the actionable and practical recommendations that this conference has produced each year.

During the breakfast keynote, Dr. Harold Varmus, Director of the National Cancer Institute (NCI), described four approaches that

the NCI is taking to bring precision medicine to oncology: The Cancer Genome Atlas; The development of an informatics infrastructure for joint mining of genomics data and clinical outcomes to inform systems biology and predictive modeling; The Provocative Questions Initiative, which seeks to stimulate new ways of thinking about cancer care; and the development of new ways to test novel therapeutics in suitable settings. This encompasses the reorganization of the cooperative groups as well as the Exceptional Cases Initiative, which calls for genomic analysis in all clinical trials and is aimed at understanding the rare responders in otherwise unsuccessful trials, or conversely, those that do not respond to otherwise effective therapies.



Ellen Sigal Delivers Opening Remarks

Senator Michael Bennet (D-CO), a member of the Senate Health, Education, Labor and Pensions (HELP) Committee, delivered the afternoon keynote address. Senator Bennet is a prominent advocate of advancing the scientific rigor of new medical product development and FDA review processes, and was a co-sponsor of the Advancing Breakthrough Therapies for Patients Act. Senator Bennet discussed some of the challenges facing our country today, and emphasized the need for continued investment in biomedical research in the current fiscal climate. He stated that partnership between the public and private sectors will be needed to maintain the United States' position as a leader in medical innovation. He praised this conference for bringing together such diverse stakeholders for open discussion and collaboration, and

emphasized how essential these types of partnerships are for helping patients by finding the treatments of tomorrow.

Dr. Janet Woodcock, the Director of the Center for Drug Evaluation and Research (CDER) at the Food and Drug Administration, also addressed the conference in the afternoon keynote session. She highlighted the importance of drug development being patient-focused, utilizing the benefit-risk framework, and incorporating natural disease history, patient experience, patients' willingness to trade-off side effects for drug benefits into the evaluation and development pathway.

Dr. Woodcock announced that the Breakthrough Therapy Designation has already been given to one drug. She stressed the importance now of focusing on how the designation affects the development process. The FDA is aware that with a faster regulatory pathway, drug manufacturing may be the rate-limiting step in the development process. Dr. Woodcock stressed the importance of having separate, early meetings on manufacturing that discuss the scale up plan for the drug.

PANEL ONE - Developing Standards for Breakthrough Therapy Designation

Charles L. Sawyers, Chair, Human Oncology and Pathogenesis Program, Memorial Sloan-Kettering Cancer Center; Investigator, Howard Hughes Medical Institute

Daniel A. Haber, Director, Cancer Center, Massachusetts General Hospital; Investigator, Howard Hughes Medical Institute

Sandra J. Horning, Senior Vice President, Global Head, Clinical Development Hematology/Oncology, Genentech

S. Percy Ivy, Associate Branch Chief, Investigational Drug Branch, CTEP, NCI

Wendy K.D. Selig, President and CEO, Melanoma Research Alliance

Robert Temple, Deputy Director for Clinical Science, CDER, FDA

Panel One discussed the implementation of the newly designed FDA Breakthrough Therapy Designation. This designation was created by The Advancing Breakthrough Therapies for Patients Act, which was introduced into legislation following the 2011 Conference on Clinical Cancer Research panel, Development Paths for New Drugs with Large Effects Seen Early. With this pathway, a new drug may be designated as a Breakthrough Therapy if it is intended to treat a serious or life-threatening



Janet Woodcock Delivers Lunch Keynote

disease and preliminary clinical evidence suggests that it provides a substantial improvement over existing therapies. Upon designation, the FDA and sponsor would collaborate in a dynamic and cross-disciplinary process to determine how to condense or abbreviate development of the investigational agent without compromising the FDA's rigorous standards for safety and efficacy. As described by Wendy Selig and Dr. Dan Haber, the Breakthrough Therapies designation could enable highly effective therapies to quickly reach the patients who need them most.

Dr. Percy Ivy described the panel's proposed qualitative criteria for Breakthrough Therapy designation: 1) the potential Breakthrough Therapy should seek to treat a serious disease with no established standard of care or a standard that yields poor outcomes; 2) Breakthrough designation should be based on compelling early evidence suggesting major clinically meaningful improvement over existing therapies in a defined disease setting; 3) the potential Breakthrough Therapy under consideration will typically have a compelling scientific rationale and promising mechanism of action, such as targeting a molecular driver of a biologically characterized disease. Dr. Sandra Horning called for flexibility in current manufacturing and companion diagnostics requirements for Breakthrough Therapies, and proposed a new category of meetings between a single point of contact at FDA and the sponsor to enable a close working relationship and allow real-time sharing of study findings. Dr. Robert Temple concluded that the Breakthrough Therapy Designation will bring collective

wisdom to efforts to expedite truly exceptional new drugs, and encourage the use of innovative trial designs and analyses.

PANEL TWO - Design of a Disease-Specific Master Protocol

Roy Herbst, Chief of Medical Oncology, Yale Cancer Center

Eric Rubin, Vice President, Clinical Research Oncology, Merck

Lisa LaVange, Director, Office of Biostatistics, CDER, FDA

Jeffrey Abrams, Associate Director, Cancer Therapy Evaluation Program, NCI

David Wholley, Director, The Biomarkers Consortium, FNIH

Karen Arcsott, Patient Advocate, Lung Cancer Alliance

Shakuntala Malik, Medical Officer, FDA

The second panel detailed a potential biomarker-driven, multi-arm, multi-drug registration trial in non-small cell lung cancer (NSCLC) that was designed to address some of the current drug development challenges that result in inefficient, expensive trials. As mentioned by Dr. Shakun Malik, this type of project had been suggested by Dr. Rick Pazdur at the February 2012 thoracic malignancies steering committee and workshop. Other groups are also designing and implementing alternative trial designs that include biomarker screening, such as I-SPY 2 and ALCHEMIST, described by Dr. David Wholley and Dr. Jeff Abrams, respectively. The benefits of this type of trial, described by Dr. Roy Herbst, include reducing the overall screen failure rate of trials for targeted therapies, providing consistency by establishing a trial infrastructure, and resulting in bringing safe, effective drugs to patients faster. NSCLC was chosen as the prototype disease for a master protocol trial as it is a common cancer with multiple mutations and potential therapeutic targets. Dr. Eric Rubin described the master protocol trial design: upon enrollment, patients will receive a fresh core needle biopsy, and the tissue analyzed with appropriate assay(s); patients are then directed to a trial arm based on tumor subtype and randomized between the experimental drug and SoC. The primary endpoint is overall survival, with an interim analysis of either PFS or OS. In order for drugs to be included in the trial, they must already have clinical data demonstrating activity. Over time, new drugs will be able to be added to or removed from the study. Importantly, this trial would be run by a neutral third party, allowing data to be

centralized and firewalls to be established, so that active drugs will not be compared to each other. Dr. Lisa LaVange explained that if firewalls were used, control patients could be leveraged between experimental arms, further shortening timelines and reducing costs. Dr. Shakun Malik offered the FDA perspective, and agreed that the master protocol could provide consistency to drug development and improve trial efficiency an, but stressed that FDA approval is dependent on trial integrity, clear clinical results and risk:benefit ratio.



NCI Director Varmus Delivers Morning Keynote

The discussion following Panel Two addressed some of the practical concerns that may arise during this trial. One focus was on the necessity of standardization and streamlining of trial protocols, in order to encourage both patient and doctor participation. Dr. Jeff Abrams mentioned that NCI has created a single database across the US that may be appropriate for this type of screening trial. There was also further discussion on some of the particulars of the trial design, including the best organization to run the trial, how the inclusion of drugs and biomarker would be determined, and how to encourage sponsors to include their drugs in this trial.



Panel Two Participants Discuss Master Protocol

PANEL THREE - Re-evaluating Criteria for Accelerated Approval

Richard L. Schilsky, Chief, Section of Hematology-Oncology, University of Chicago Medical Center

David P. Schenkein, CEO, Agios Pharmaceuticals

Wyndham H. Wilson, Senior Investigator, Chief, Lymphoma Therapeutics Section, NCI

Cheryl L. Jernigan, Research/Patient Advocate, Susan G. Komen for the Cure

Janet Woodcock, Director, CDER, FDA

The final panel proposed ways to optimize the accelerated approval pathway and promote the use of accelerated approval in earlier disease settings. Currently, the increasing number of available therapies, coupled with the lack of qualified surrogate endpoints and the lack of clarity early in development regarding circumstances in which a new product will qualify for accelerated approval, is pushing developers to pursue accelerated approval in heavily pre-treated patients in order to fulfill an "unmet need". The panel proposed broadening the definition of "unmet medical need" and narrowing the definition of "available therapy". Dr. Richard Schilsky stated that despite the availability of new therapies, unmet medical need still exists because the majority of existing therapies are not curative, have major toxicities, and also because there is a need for mechanistic diversity. The panel proposed that any cancer lacking a curative therapy should be regarded as having "unmet medical need", that a new therapy could be considered eligible for accelerated approval if it demonstrates clear activity on a surrogate endpoint, and that "Available Therapy" should be defined in a biological context for targeted agents- i.e., if an investigational agent targets a specific

pathway and will be labeled for use in a selected patient population, the only drugs that should be considered "available therapy" are those that target the same pathway.

The panel also discussed the need for new qualified surrogate endpoints. Dr. Wyndham Wilson described four criteria needed for qualification of a surrogate endpoint: 1) a standardized definition; 2) a statistically robust correlation between surrogate endpoint and clinically meaningful outcome; 3) large trials designed prospectively to validate the correlation between surrogate endpoint and clinical outcome; and 4) prospective studies to determine the context-dependent utility of surrogate endpoint. Dr. David Schenkein proposed a structured process for designating a product for development through the accelerated approval pathway. In this process, sponsors and FDA would meet early and agree that a drug will be developed by either an "Adaptive Clinical Development Plan" with possibility for accelerated approval if certain results are generated, or through the full approval process.

A decision to pursue accelerated approval should include agreement on the patient population being studied, the surrogate endpoint to be assessed, the trial design and magnitude of benefit needed for accelerated approval, and on post-marketing commitments. In the discussion that followed, Dr. Richard Pazdur, Director of the Office of Hematology and Oncology Products at FDA, stressed the need for sponsors to complete their confirmatory trials in a timely fashion and said that the FDA could benefit from an easier way to remove drugs from the market that fail to confirm clinical benefit.

Forum and Blueprint for Future Drug/Diagnostic Co-Development

On September 14, 2012, Friends of Cancer Research (*Friends*) and Alexandria Real Estate Equities, Inc, held a half-day forum that brought together researchers, sponsors, advocates and regulators to discuss the opportunities and challenges associated with co-development of drugs and the diagnostic tests used to determine which patients should receive a new treatment.

Co-development of a targeted therapy and its companion diagnostic test present unique challenges to sponsors and regulatory agencies. To begin to address these challenges, FDA issued a guidance in July 2011, entitled "In Vitro Companion Diagnostic Devices," to provide information about preferred approaches to effective co-development of a drug and diagnostic. Also in 2011, two anti-cancer drugs and their simultaneously developed diagnostics were approved, confirming that the approach can effectively and efficiently be used. However, many questions remained about the best way to co-develop companion diagnostics. Therefore, this forum was organized to identify and address some of the most important questions sponsors and regulators face during the companion diagnostic development process, as well as discuss overarching questions that may affect companion diagnostics in the future.

Prior to the forum, panelists wrote a detailed consensus document, "A Blueprint for Future Drug/Diagnostic Co-development," that was distributed to attendees in advance. The Blueprint proposed potential approaches for sponsors in dealing with those identified challenges in the companion diagnostic co-development process and provides strategies to help guide future co-development. It focused on three specific areas:

- 1) A developmental strategy for diagnostically selected populations.
- 2) Approaches to defining a diagnostically selected population.
- 3) Strategies for multi-marker diagnostic development.

PANEL ONE: A Blueprint for Future Drug/Diagnostic Co-development

Howard Scher, Chief, Genitourinary Oncology Service, Memorial Sloan-Kettering Cancer Center

Richard Buller, Vice President, Translational Oncology, Pfizer Inc

Jane Fridlyand, Senior Statistical Scientist, Genentech, Inc.

Rich Simon, Chief, Biometric Research Branch, National Cancer Institute (NCI)

Nancy Roach, Chair & Founder, Fight Colorectal Cancer

Rick Pazdur, Director, Office of Hematology and Oncology Products, Center for Drug Evaluation and Research (CDER), U.S. Food and Drug Administration

Liz Mansfield, Director, Personalized Medicine, Center for Devices and Radiological Health, U.S. Food and Drug Administration



(L-R) Liz Mansfield and Howard Scher question panel from audience

The first panel presented the Blueprint and addressed some of the specific issues, mentioned above, that sponsors and regulators felt were not dealt with sufficiently in the FDA guidance. While the forum focused on the common factors that sponsors may need to address throughout the co-Dx development pathway, Dr. Howard Scher stressed in his introduction that sponsors will face different challenges dependent on drug, biomarker and type of assay, and stressed the importance of interacting with the FDA early and often throughout the process. Dr. Richard Buller described the factors, which include understanding of the patient population and biomarker behavior and the nature of the assay, involved in determining when studies should be restricted to diagnostically selected patients. Dr. Buller also suggested how to make these decisions in order to provide the greatest benefit to all patients while minimizing negative reactions, but stressed the importance of not ignoring the marker-negative population. Dr. Jane Fridlyand then discussed issues that arise when using non-binary biomarkers without clear thresholds. She proposed potential approaches towards re-adjusting pre-specified thresholds using pre-specified algorithms, as well as the importance of planning prospective-



Panel Two fields questions from Audience

retrospective analyses for unknown biomarkers. Dr. Rich Simon addressed multi-marker assays, explaining that while single biomarkers are the ideal, the complicated nature of tumors will sometimes require the summary measurement of several biomarkers in determining appropriate treatment. Dr. Simon described how to define, clinically validate, and reassess thresholds for summary measures in multi-marker assays. Nancy Roach highlighted the impact that companion diagnostics can have on patients, but stressed the importance of testing in marker-negative populations so as not to miss unexpected therapeutic response, and emphasized the willingness of even marker-negative patients to receive new and potentially exciting drugs.

Dr. Rick Pazdur from the Center for Drug Evaluation and Research (CDER) and Dr. Liz Mansfield from the Center for Devices and Radiological Health (CDRH) then gave the FDA response to the suggested proposals. Dr. Pazdur emphasized that the diagnostic test must be well-defined and essential to be considered a companion diagnostic, and also stressed that drug efficacy trumps all other considerations. Dr. Mansfield spoke of the importance of appropriate trial design in co-development of companion diagnostics, but also stressed that trial design is only important if the biomarker assay is accurate and valid.

PANEL TWO: Creating an Environment for Personalized Medicine

- Keith Flaherty**, Director of Developmental Therapeutics, Cancer Center, Massachusetts General Hospital
- Pat Mahaffy**, President, CEO and Co-Founder, Clovis Oncology, Inc.
- Vince Miller**, Senior Vice President, Clinical Development, Foundation Medicine

- Debra Rasmussen**, Senior Director, Global Regulatory Affairs, Janssen Diagnostics, Inc.
- Jeff Roche**, Medical Officer, Centers for Medicare and Medicaid Services (CMS)
- Jeff Shuren**, Director, Center for Devices and Radiological Health, U.S. Food and Drug Administration
- Janet Woodcock**, Director, Center for Drug Evaluation and Research, U.S. Food and Drug Administration

The second panel, moderated by Dr. Keith Flaherty, discussed their responses to the companion diagnostic blueprint, with a focus on those issues that will affect targeted therapies and the use of companion diagnostics in the future, including Laboratory Developed Tests (LDTs), insurance reimbursement for diagnostic tests, new technologies including next generation sequencing, and the use of platform technologies.

Specifically, Dr. Janet Woodcock mentioned that companion diagnostics are used in many disease areas, and also expressed her hope that ideally the paradigm of clinical trials will change, due in part to targeted therapies and diagnostic tests. Dr. Jeff Shuren discussed that as technological changes result in testing changes, bridging will be necessary for analytical and clinical validation. He also discussed current FDA policy on LDTs, and how the agency is still determining what their future approach will be. Dr. Jeff Roche described the collaborative efforts of FDA and CMS in determining reimbursement for diagnostic tests. In the discussion, Dr. Mansfield mentioned that CDRH considers regulatory approval of a multi-marker test “imminently doable,” but they need a sponsor to bring such a test forward.

Friends of Cancer Research Symposium: Symptoms and Toxicities of Cancer Therapy

As part of a productive ongoing collaboration, *Friends* and MD Anderson Cancer Center hosted a symposium, "Symptoms and Toxicities of Cancer Therapy", on April 26th in Houston, TX. This conference followed the 2011 panel "Developing Strategies for Reducing Cancer Treatment-Related Toxicities and Symptoms", which developed a series of recommendations for increasing research into treatment-related toxicities that have been published in *Nature Reviews Clinical Oncology*. At the 2012 symposium, stakeholders in basic and clinical cancer research from industry, academia, the federal government, and the advocacy community came together to develop toxicity-specific recommendations for reducing the side effects of cancer therapies.

Although cancer treatment-related toxicities are prevalent and often severe, there is little systemic research on the mechanisms of these toxicities or on the development of new agents to reduce or eliminate them. The result of treatment-related toxicities can be life altering, greatly affect medical decision making, and potentially prevent further treatment for patients. As more people are now living with cancer or are cured of it, the unique medical problems created or worsened by successful cancer treatment regimens, including targeted therapies, will continue to grow in frequency.

The symposium examined specific side effects of cancer therapies, including cardiotoxicity, pulmonary damage from radiation or chemotherapy, metabolic toxicities, immune toxicity, and peripheral and central neurotoxicities. Speakers discussed what is currently understood about the mechanisms of these toxicities, ongoing efforts to reduce their occurrence, and how to move forward in each of these areas. From these talks, six common areas of need emerged: 1) the ability to predict patients at risk for specific toxicities; 2) mechanism-of-action studies; 3) early phase trials directed at measuring toxicities; 4) improved patient-reported outcomes and quantitative metrics; 5) the ability to learn from other therapeutic areas; and 6) improved strategies for determining dose and scheduling to achieve optimal response and tolerability.



MD Anderson Cancer Center



The core of my passion as an advocate began with the terrible loss of my beloved sister at age 40 leaving a 4-year old child, followed by losing both parents to this disease. The determination to end the devastation of cancer and find a tangible way to make a difference is why I founded this organization 17 years ago. There isn't a day where I'm not overwhelmed by how many people are dealing with this disease, and that's what drives all of our work at Friends of Cancer Research. We are leading the battle through collaboration with all stakeholders, making sure we are doing what's right for the patient. Never forgetting about the burden of this disease and our imperative to make a difference in their lives.

Ellen Sigal PhD
Chairperson & Founder
Friends of Cancer Research

Friends of Cancer Research Celebrates 16th Cancer Leadership Awards Reception

Honoring Senator John McCain, FDA's Dr. Richard Pazdur and
Center for American Progress President Neera Tanden

On September 20, 2012, leaders from government, advocacy, business and science came together to celebrate Friends of Cancer Research (*Friends*) and the accomplishments of great leaders in our field.

Each year *Friends* takes the opportunity at this event to acknowledge great contributions to the cancer research community. Past honorees include: Secretary Kathleen Sebelius, Senator Orrin Hatch, Senator Edward Kennedy, Secretary Michael Levitt, Senator Daniel Inouye, Senator Judd Gregg, Dr. Francis Collins, Ambassador Nancy Brinker, Senator Arlen Specter and Congressman John Dingell.

This year, *Friends* honored Senator John McCain, FDA's Dr. Richard Pazdur and Center for American Progress President Neera Tanden for their steadfast support of biomedical research, advocacy for patients and their families, and commitment to the health and well being of the American people.

Dr. Margaret Hamburg, Commissioner of the Food and Drug Administration (FDA), provided a perspective on the close and productive relationship between the agencies and Friends of Cancer Research over the last 16 years.



Richard Pazdur

All of us at Friends of Cancer Research would like to thank our Board of Directors, our supporters, colleagues and collaborators from academia, industry and advocacy for another incredible year of progress. We are deeply appreciative of all you have done to help grow *Friends* to the incredible organization it is today.



Neera Tanden



FDA Commissioner Hamburg



The view from the Hay-Adams during 2012 Awards Reception



(L-R) Ellen Sigal and Marlene Malek present Sen. McCain with Lifetime Leadership Award

Friends of Cancer Research Released a New Report During National Breast Cancer Awareness Month

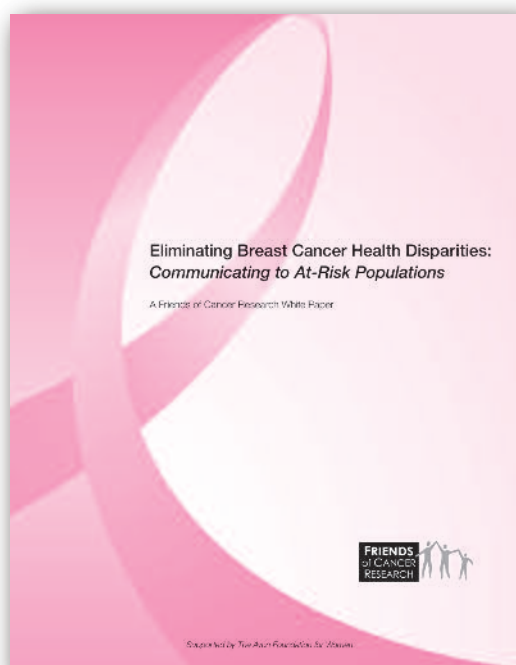
Eliminating Breast Cancer Health Disparities: Communicating to At-Risk Populations

In an effort to explore and address the critical public health issue of health disparities, Friends of Cancer Research, with the support of the Avon Foundation for Women, and the George Washington University, assembled a panel of experts to participate in a symposium and develop recommendations on how to help eliminate breast cancer health disparities through better communication to at-risk populations.

The resulting white paper, released on October 17, outlines recommendations that focus on the best ways to communicate with members of at-risk populations through existing and new outlets; how to address common misconceptions that result in inferior cancer care; how to build relationships of trust and create expectations between the medical and underserved communities; and how to diversify the fields of cancer research and the health sciences as another way to improve outreach to the most vulnerable groups of patients.

Key Recommendations:

- Investigate disparities between women with cancer and healthy women
- Build relationships with groups that work directly with at-risk populations
- Create expectations for minority participation in the scientific field
- Use current and emerging technologies to engage a larger number of patients





My interest in health care, especially cancer, developed early in my life when my father died of the disease at age 49. Since that time, unfortunately, like most of us, I have lost many good friends to cancer and only a few years ago my mother-in-law succumbed to this dreaded disease.

Years ago, as a young oncology nurse, I saw patients battling cancer first hand. Over time as I saw more devastation from cancer, I felt more and more helpless in the face of so much suffering. In fact, I felt that cancer was becoming epidemic. And that led me to join Ellen Sigal when she launched Friends of Cancer Research 17 years ago, where I remain a devoted advocate today.

Marlene A. Malek, R.N.
President
Friends of Cancer Research

Celebration of Science - Washington DC The FDA: Past, Present and Future



(L-R) Ellen Sigal, Mark McClellan, Margaret Hamburg, and Margaret Anderson of *FasterCures*

Dr. Ellen Sigal participated in the first *Celebration of Science* in Washington DC the weekend of September 7-9, 2012. This marked the beginning of a new initiative spearheaded by *FasterCures* and the Milken Institute. More than 1,000 leaders from across the scientific and policy communities convened in Washington to reaffirm America's commitment, especially in bioscience. Dr. Sigal served as a key panelist for a session titled: *The FDA: Past, Present and Future*. The panel, which also included current FDA Commissioner Margaret Hamburg and former FDA Commissioner Mark McClellan, addressed many key issues,

including: The Food and Drug Administration is the regulatory body that has the most direct and daily impact on average American consumers, whether they know it or not; It has a complex mission of ensuring that the products under its purview are safe and effective, while at the same time advancing innovation that will benefit the American people; And answered questions as to how the FDA's responsibilities and challenges have changed over time, what the state of the agency's capacity and resources are today and where do the greatest opportunities to benefit patients in the future lie.



Some of my earliest childhood memories involve the fear and uncertainty of cancer, as it related to my grandfather's battle with the disease. Since that time, at nearly every stage of my life, there were always friends and loved ones dealing with the difficulties of cancer. Some survived and are thankfully able to continue to enrich the lives of the people around them. Some did not, and are now part of those memories. As a student and researcher, the biologic complexity of cancer intrigued me. But what drives me today is the chance to stop cancer from being a common thread through the memories of children in future generations.

Jeff Allen, Ph.D.
Executive Director
Friends of Cancer Research

Friends Co-hosts Annual Congressional Advocacy Day on Capitol Hill

On May 17, 2012 Friends of Cancer Research (*Friends*) joined the American Association for Cancer Research, the Association of American Cancer Institutes, the Oncology Nursing Society and the American Society of Clinical Oncology, to boost congressional support for cancer research and biomedical science.

The five organizations brought more than 100 researchers, oncology nurses, clinicians and advocates to Capitol Hill to meet with 150 House and Senate aides and lawmakers, including House and Senate leadership, from 30 states. Advocates called on lawmakers to approve a fiscal year 2013 budget that will fund the NIH and FDA at a level that stakeholders say is necessary to sustain scientific momentum.

While in Washington, the organizations also took time to recognize U.S. Reps. Diana DeGette (D-CO) and Brian Bilbray (R-CA) for their great passion and commitment to cancer research. The lawmakers were honored with cancer leadership awards during an evening reception.

Bilbray has been an outspoken advocate for continued investment in NIH and has worked tirelessly to rally bipartisan support for cancer research and biomedical science. As co-chair of the Congressional Biomedical Research Caucus, Bilbray has been a strong advocate for moving clinical research from the bench to the bedside.

DeGette, in addition to being a stalwart champion of the NIH and FDA in her own right, has demonstrated tremendous leadership in working to combat drug shortages, a growing crisis that is jeopardizing the care of cancer patients across the country. DeGette's "Preserving Access to Life-Saving Medications Act" would, among other things, require manufacturers to notify the FDA of any discontinuance or interruption in the production of a drug at least six months in advance.



Rep. Bilbray (R-CA)



Rep. DeGette (D-CO)

*Friends collaborates with AACR, AACI, and ASCO
to build support for cancer research*



Rep. Heger (R-CA) and Ellen Sigal discuss congressional support of biomedical research



Friends Continues as a Leader in Shaping Comparative Effectiveness Research

The Patient-Centered Outcomes Research Institute (PCORI)

Dr. Ellen Sigal continues to serve on 21-member Board of Governors of the Patient-Centered Outcomes Research Institute (PCORI). The Board represents a broad range of perspectives and collective expertise in clinical health services research. PCORI was authorized by Congress through the Affordable Care Act to conduct research to provide information about the best available evidence to help patients and their health care providers make more informed decisions. PCORI's research is intended to give patients a better understanding of the prevention, treatment and care options available, and the science that supports those options. So far, PCORI has approved 25 awards, totaling \$40.7 million, to fund patient-centered comparative clinical effectiveness research projects under the first four areas of its National Priorities for Research and Research Agenda. For more information we encourage you to visit www.pcori.org

Friends Co-Sponsors Conference with the National Pharmaceutical Council (NPC)- *The Myth of Average: Why Patient Differences Matter*

On November 30, 2012, policy and health care experts broke down the "myth" of the average patient and explored how health policy decisions can impact patient care. National Pharmaceutical Council (NPC) President Dan Leonard kicked off the conference by thanking sponsors and outlined the main goals of the conference, which included: Understanding how biology, genetics, demographics and/or individual preferences may lead to clinically important differences among patients; Exploring the extent to which these variations exist and should be considered in developing treatment decisions, practice guidelines, and/or coverage and reimbursement policies; Understanding the benefits and limitations of subgroup analyses to predict which treatments are best for individual patients; Assessing how failure to individualize care may contribute to poor clinical outcomes and health disparities; and Considering how to engage, educate and train your constituents in support of individualized patient care.

In addition to being an organizational co-sponsor of the conference, *Friends* Chair, Dr. Ellen Sigal participated in a panel: *Issues and Opportunities on the Journey to Individualized Care*. The panelists agreed and discussed that patients are hungry for more information about how they will likely respond to a given

treatment and what potential side effects they might experience, according to a panel of patient advocacy experts. Although researchers are making progress in mapping some biomarkers, more evidence is still needed to help patients and health care professionals navigate the decision-making process. To address these needs, panelists agreed patients must remain at the forefront of the comparative effectiveness research conversation. Dr. Sigal explained the importance of individual treatment effects, especially for cancer patients. "Ultimately, they need treatments that work for them the first time around," she noted.



(L-R) Robert Zwolak, Ellen Sigal



PCORI National Patient and Stakeholder Dialogue Forum in Washington DC



Panel at National Pharmaceutical Council Conference (L-R) Sharon Allison-Ottoy, Daniel Mullins, Robert Dubois, Myrl Weinberg, Ellen Sigal



Early in life I remember family members battling cancer. I remember their resilience, determination and hope to beat the disease that would eventually overcome them. Their strength during that time has lived with me, and inspired me. Later on, the loss of a close friend, while we were only in our early 20's, erased any sense of invincibility I had to this disease and made me a determined advocate. The work we do at Friends of Cancer Research each and every day brings all of us, and future generations, one step closer to never having to tell a story of a loved one lost, a life cut all too short.

Ryan M. Hohman, JD, MPA
Managing Director, Policy & Public Affairs
Friends of Cancer Research

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FRIENDS of CANCER RESEARCH

About Us

Friends of Cancer Research (*Friends*) is a cancer research think tank and advocacy organization based in Washington, DC. *Friends* is a leader in developing partnerships and advocating for policies that will get treatments and therapies to patients in the safest and quickest way possible. Working with federal health agencies, congressional leadership, academic research centers and private sector industry, *Friends* continues to create innovative educational, policy, and scientific approaches to improve health outcomes and cancer care.

Founded to mark the 25th Anniversary of the National Cancer Act, *Friends* set out to organize highly effective public policy forums that bring together researchers, leaders of the FDA, NCI, and NIH, industry, elected officials, and patients to discuss critical issues and develop collaborative strategies to assist in the translation of research to treatments and therapies.

When she founded the organization in 1996, Dr. Ellen Sigal saw a compelling need to increase public awareness and support for cancer research and for increased scientific capacity across all federal health agencies. At that time Ellen was a Presidential Appointee to the National Cancer Advisory Board along with Marlene Malek, who joined Ellen in 1996 as President of *Friends*.

Friends of Cancer Research began tackling its mission by holding educational “town halls” across the nation, bringing leaders from science, industry, and academia to the district or home state of key members of Congress. By doing so, Ellen and Marlene were able to not only educate lawmakers but also create new champions for biomedical research.

Now, 17 years later, Friends of Cancer Research continues to expand upon its expertise in developing unique partnerships and creating a more open dialogue among both public and private sectors.

As a respected independent think tank, *Friends* is able to cut through bureaucratic red tape, put aside partisan politics and engage all stakeholders, producing real results.

Join us as we strive to bring new research, treatment, and hope to patients and families battling cancer.

Friends of Cancer Research is a 501(c)(3) non-profit organization



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