15 YEARS OF SCIENCE AND INNOVATION

FRIENDS of CANCER RESEARCH

2011 ANNUAL REPORT

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 one of our country's leading voices 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

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

Senator Michael Bennet, Keynote
Commissioner Margaret Hamburg, Keynote

On November 10, 2011, Friends of Cancer Research (*Friends*) and the Engelberg Center for Health Care Reform at Brookings co-hosted the fourth-annual Conference on Clinical Cancer Research, with the support of The American Society of Clinical Oncology (ASCO), and Susan G. Komen for the Cure. Each year, this conference brings together experts in cancer drug development from academic and clinical research, industry, federal health and regulatory agencies, and the patient advocacy community to develop consensus-driven solutions to challenges in the development of the next generation of anti-cancer drugs. As noted in the opening remarks of Dr. Richard L. Schilsky of ASCO, this conference has a proven track record of producing actionable results in the form of FDA Guidances, original research, and scholarly white papers. This year, the panels addressed some of the most challenging topics to date in an effort to improve the speed, efficiency, and impact of oncology drug trials.

Senator Michael Bennet (D-CO), a member of the Senate Health, Education, Labor, and Pensions (HELP) Committee, delivered the morning keynote address. Senator Bennet is a prominent advocate of advancing regulatory science at the FDA and recently sponsored the 2011 Drug Safety and Accountability Act, which aims to strengthen the quality of regulated pharmaceuticals. Senator Bennet discussed some of the key challenges facing our country today and stated that he was proud to see this conference bring together such diverse and impressive stakeholders for open discussion and collaboration. Senator Bennet emphasized how essential these


Senator Michael Bennet


Janet Woodcock

Ellen Sigal


Mark McClellan

Panel discussion at 2011 conference

types of partnerships are for helping patients find the treatments of tomorrow. He expressed his support for the FDA's recently announced initiatives in developing groundbreaking treatments.

Dr. Margaret Hamburg, Commissioner of the U.S. Food and Drug Administration (FDA), delivered the afternoon keynote address highlighting the need for the FDA to be able to translate the cancer drug discoveries of the past 65 years quickly and safely into medicine innovation, regulatory science, and partnerships to address the challenges of drug development. She announced that the FDA had approved 35 novel drugs in FY2011, including 7 oncology drugs, and also discussed the recent paper from *Friends* that showed that oncology drugs approved by both the FDA and the European Medicines Agency are approved first in the United States. Dr. Hamburg acknowledged that although regulatory uncertainty can cause delays, the FDA has provided increased transparency and guidelines to address these issues. The Commissioner focused her talk on the necessity of using innovation, regulatory science, and partnerships to address the challenges of drug development. She stated that developing innovative approaches is a cornerstone of the FDA, which "must continue to find novel ways to expedite development and delivery of new drugs." Dr. Hamburg concluded by stressing the strength of this conference in bringing together the right people around the right topics, and stating that we must work together to revolutionize drug development and regulation in order to eliminate cancer from the headlines.

Panel One: Alternative Trial Designs Based on Tumor Genetics/Pathway Characteristics Instead of Histology

George Demetri, Director, Ludwig Center at Dana-Farber Cancer Institute
Robert Becker, Medical Officer, U.S. Food and Drug Administration
Janet Woodcock, Director, Center for Drug Evaluation and Research, U.S. Food and Drug Administration
James Doroshow, Director, Division of Cancer, National Cancer Institute
Perry Nisen, Senior Vice President, Cancer Research, GlaxoSmithKline
Joshua Sommer, Executive Director, The Chordoma Foundation

Panel One addressed the issue of trial designs for testing new therapies that specifically target certain molecules that are mutated or dysregulated in cancer cells. As these types of targeted therapies have increased, trials have been performed that test a specific therapy in multiple tumors, and have resulted in FDA approval. However, these trials have been rare, and the main goal of this panel was to propose a histology-agnostic trial that can act as a potential blueprint for other investigators to follow, thus making the drug testing and approval process faster and more efficient. The patient advocate Josh Sommer emphasized the importance and urgency of the panel's work, especially for rare cancers, which, in total, make up over 25% of all cancers. Dr. Perry Nisen described the proposed approach in more detail, using a GlaxoSmithKline BRAF inhibitor and MEK inhibitor combination therapy to treat solid tumors or hematologic malignancies with BRAF V600E mutations regardless of tumor histology. This design, which could potentially be generalized for broader use, would utilize a "learn as you go" approach, allowing for adaptation of the trial based on tumor responses to therapy. The other panel members reiterated that multi-histology trials will be more efficient, and discussed the importance of having a well-specified, defined diagnostic that accurately measures the marker of interest and defines the appropriate patient population to be treated.

The discussion following Panel One addressed multiple issues and challenges that this type of trial design may encounter, including patient accrual, refractory tumors, and combination drug trials. Additionally, many attendees and panelists again emphasized the importance of the development of companion diagnostics and the implementation of diagnostic tests in the community setting, especially as novel driver mutations continue to be identified. In keeping with the organizational goals of Friends of Cancer Research, Dr. Ellen Sigal kept the focus on real future progress, asking the panel what the tangible next steps are, and "What can we do with this information/ proposal?" The concept will go to Dana-Farber, and GSK will do a study to assess the implications. The panelists expressed their hope that a successful trial done once and done correctly will show that this type of trial can result in approval.

Panel Two: Evidence for Use of Maintenance Therapy

Richard Schilsky, Deputy Director, University of Chicago Comprehensive Cancer Center
Anthony Murgo, Associate Director for Regulatory Science, U.S. Food and Drug Administration
Margaret Mooney, Chief, Clinical Investigations Branch, National Cancer Institute
Tal Zaks, Vice President, Oncology, Sanofi-Aventis
Patty Spears, Patient Advocate, Susan G. Komen for the Cure

Panel Two discussed trial approaches to test the utility of maintenance therapy. Many cancers may respond well to initial treatment but eventually progress or relapse, and maintenance treatment with targeted therapies, which often have fewer side effects than standard chemotherapy, presents an opportunity to prevent or delay cancer progression. As discussed by Dr. Richard Schilsky and patient advocate Patty Spears, while maintenance therapy is attractive in theory, it may not necessarily be superior to allowing patients a "break" from treatment before beginning second-line therapy, and it increases the exposure of patients to the toxicities of that therapy. Therefore, rigorous studies are necessary to demonstrate the clinical benefit of maintenance therapy.

This panel presented two clinical trial scenarios to evaluate how studies should be designed to test the benefits of long-term maintenance with targeted therapies. In the first scenario, patients are placed on a targeted maintenance therapy immediately after obtaining best-response to traditional first-line chemo. In the second scenario, patients are maintained on a targeted therapy that was a component of first-line therapy throughout subsequent lines of therapy. Dr. Tal Zaks noted that the trial designs outlined will require more resources and will face real-world challenges to enrollment and timely completion, especially for drugs that are already available in the marketplace. Further, studies of maintenance therapy must be designed to show an improvement in either overall survival or patient symptoms.

FDA Commissioner Hamburg

Panel Three: Symptom Measurement in Clinical Trials

Ethan Basch, Associate Attending Physician, Memorial Sloan-Kettering Cancer Center
Laurie Burke, Associate Director for Study Endpoints and Labeling, U.S. Food and Drug Administration
Gini Kwitkowski, Lead Clinical Analyst, U.S. Food and Drug Administration
Lori Minasian, Chief, Community Oncology and Prevention Trials Research Group, National Cancer Institute
Brian Seal, Director, Health Economics and Outcomes Research, Bayer HealthCare
Richard Levy, Executive Vice President, Chief Drug Development and Medical Officer, Incyte
Mark Gorman, Director of Survivorship Policy, National Coalition for Cancer Survivorship

Panel Three discussed the barriers to symptom measurement oncology clinical trials and the inclusion of symptom information in oncology drug labels, as well as possible solutions to those barriers. As discussed by Dr. Brian Seal, symptom measurements are often neglected in favor of efficacy measurements because of the many methodological and logistical challenges to measuring symptoms. These challenges can be overly time-consuming and expensive to overcome. Dr. Ethan Basch described the communication barriers that exist between sponsors and the FDA. Many sponsors may feel that it is not worthwhile to address these challenges, and do not believe that the FDA will be receptive to symptom endpoints. Although the FDA is willing to consider symptom endpoints, reviewers do not actively encourage sponsors to pursue symptom measurements, and may lack the necessary expertise to give methodological guidance.

Using a successful case study, Dr. Richard Levy and Gini Kwitkowski described ways in which the methodological/logistical challenges can be overcome, in the hopes that this success story may encourage more sponsors to actively pursue incorporating symptom measurements as a high priority in their development plans. This panel also proposed that new communication mechanisms be developed or existing communication mechanisms be improved to allow for more productive exchange between sponsors and FDA reviewers for the development of symptom measurements that are both acceptable to regulators and feasible for sponsors. A key point discussed by Laurie Burke is that symptom endpoints should be considered early in drug development. Sponsors should screen for signals of symptomatic improvement in early trials, and then work with the FDA towards including symptoms as primary or key secondary endpoints.

Panel Four: Development Paths for New Drugs with Large Treatment Effects Seen Early

Mikkael Sekeres, Associate Professor of Medicine, Cleveland Clinic
Tom Fleming, Professor, Biostatistics, University of Washington
Raji Sridhara, Director, Division of Biostatistics, Center for Drug Evaluation and Research, U.S. Food and Drug Administration
Janet Woodcock, Director, Center for Drug Evaluation and Research, U.S. Food and Drug Administration
Ed Korn, Biometric Research Branch, National Cancer Institute
Wyndham Wilson, Senior Investigator, Chief, Lymphoma Therapeutics Section, National Cancer Institute
Gracie Lieberman, Director, Biostatistics, Genentech
Jane Perlmutter, President and Founder, Gemini Group

Panel Four addressed potential new approaches that would speed up drug development pathways to FDA approval for drugs that show large treatment effects early in development, while still ensuring drug safety and efficacy. The panel reached approximate consensus on one alternative developmental pathway, presented by Dr. Tom Fleming, that would result in full approval. The proposed trial is a randomized "2b" trial that could be used as either a screening trial into a phase 3 trial, if effects were moderate, or a registration trial if effects were extraordinary. Importantly, drugs with poor results would be screened out. The proposed randomized phase 2b trial could optimize development strategies by saving time and reducing the number of patients exposed to potentially ineffective treatments.

Friends and MD Anderson Cancer Center Co-host Clinical Cancer Research Roundtable on Cancer Treatment-Related Toxicities and Symptoms

Building on a previous discussion at the 2010 Conference on Clinical Cancer Research, *Friends* partnered with MD Anderson Cancer Center to host a clinical cancer research roundtable titled "Developing Strategies for Reducing Cancer Treatment-Related Toxicities and Symptoms" on March 25th in Houston, TX. The conference brought together stakeholders in cancer research, drug development, regulation, and advocacy to identify the challenges that have prevented progress in reducing treatment-related symptom burden and to develop strategic steps to meet these challenges.

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 effect medical decision making, and potentially prevent further treatment for patients.

The working group concluded with a discussion moderated by *Friends'* Executive Director Dr. Jeff Allen about defining a proactive strategy, including advocacy opportunities to promote research about treatment-related toxicities. The discussion centered on the need for more research into the molecular mechanisms that result in toxic side effects, how to capitalize on existing data sources to better understand acute and long term effects of treatment, and how to develop additional information about emerging treatments in the context of changes to the U.S. health care system.

The Ohio State University, Cancer Drug Development Roundtable

Roundtable explored challenges to the co-development of two or more investigational compounds and discussed implementation of a recent FDA guidance document on the same topic.

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 develop a clear path forward on key issues surrounding the development and regulation of cancer drugs and therapies. The 2009 conference included a panel titled "Development of Rational Drug Combinations with Investigational Targeted Agents". On December 14, 2010, the FDA released a draft guidance document that mirrors the 2009 panel, subsequent white paper, and submitted draft guidance.

Building on this momentum, *Friends* and the James Comprehensive Cancer Center at The Ohio State University (OSUCCC) co-hosted the ***Cancer Drug Development Roundtable at Ohio State*** on May 4, 2011. The conference brought together high-level stakeholders to discuss obstacles to the co-development of two or more experimental cancer drugs owned by different companies for potential use in combination therapies.

The consensus among the roundtable participants was clear: By focusing more on patients than practicalities, even a dilemma as daunting as drug co-development can be resolved.

"I left it feeling we'd achieved what we set out to accomplish," OSUCCC Director and James CEO Michael A. Caligiuri, MD, says of the Roundtable. "Participants were enthusiastic about solving these problems and agreed that, while scientists' discoveries and companies' investments are critical considerations, it is most important to focus on patients."

The Roundtable marked the first time key players in drug development – including representatives of academia, government, the pharmaceutical industry, legal services and advocacy groups – had come together to address business and legal barriers to co-developing cancer drugs owned by competing interests. The ultimate goal is to smooth the process and more quickly bring new cancer treatments to patients.

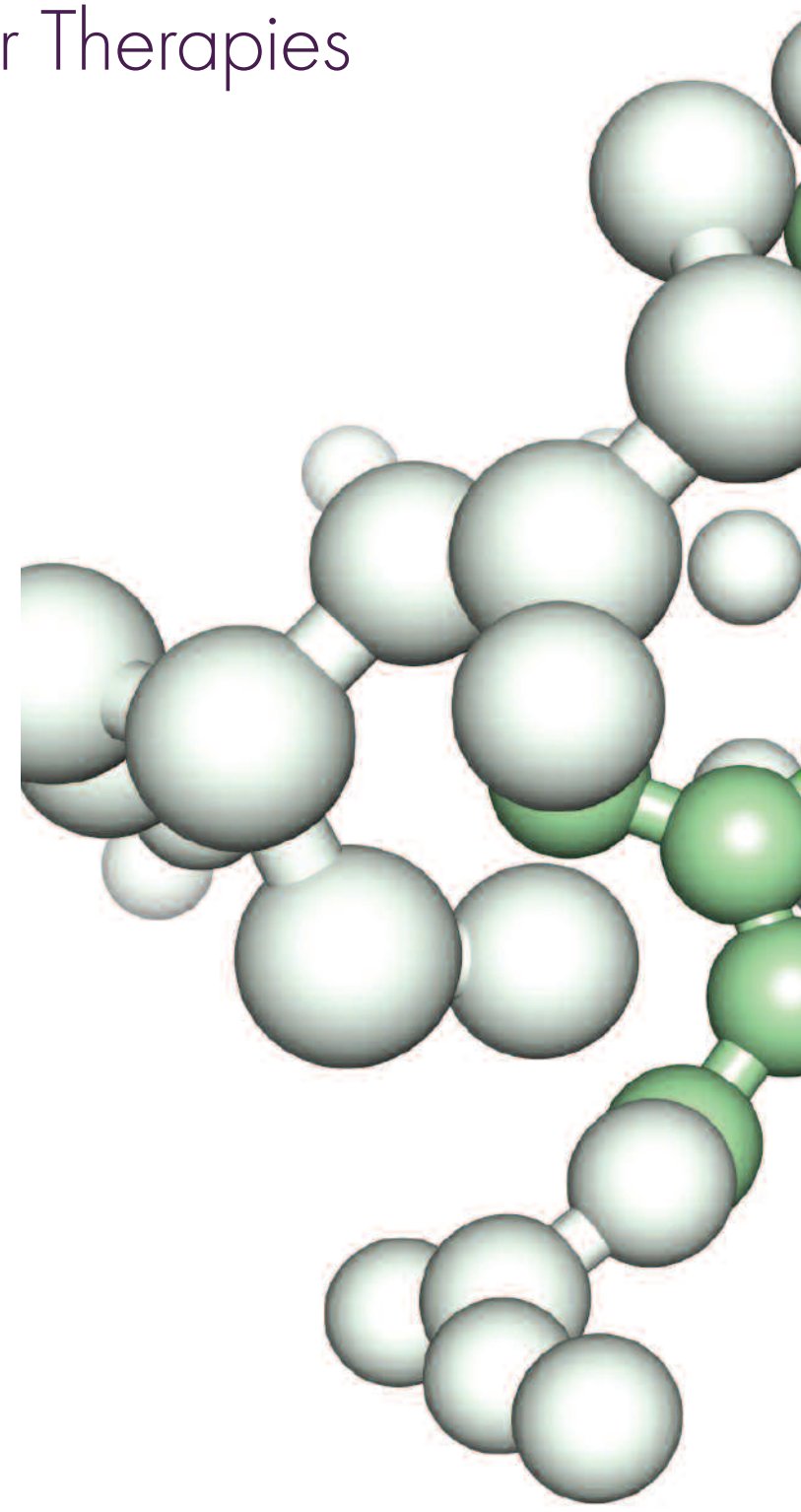
Officials from Ohio State, Friends of Cancer Research, the National Cancer Institute, the U.S. Food and Drug Administration, Merck Research Laboratories, Battelle, Sanofi-Aventis, Pfizer Inc., FoxKiser, Eli Lilly and Company, BioOhio and Signal Hill Advisors attended the event.

THE OHIO STATE UNIVERSITY The James
Ohio State is a Comprehensive Cancer Center designated by the National Cancer Institute

Friends and the Reagan-Udall Foundation Convene Symposium on Systems Toxicology Analysis of Targeted Anti-Cancer Therapies

On July 22, 2011, Friends of Cancer Research and the Reagan-Udall Foundation for the FDA, supported by Susan G. Komen for the Cure, convened a Cardiotoxicity Protocol Development Workshop on *"Systems Toxicology Analysis of Targeted Anti-Cancer Therapies"* at FDA's White Oak Campus. The topic was the outgrowth of the 2010 Conference on Clinical Cancer Research hosted by *Friends* and the Brookings Institution. At the workshop, oncologists and cardiologists, academic experts in systems biology and toxicology, as well as experts from industry, the NIH, the FDA, and non-profit organizations came together to help shape the design of a pilot project using a systems toxicology approach to evaluate the mechanisms of cardiotoxicity of tyrosine-kinase inhibitors (TKIs). This ongoing systems toxicology project is being managed by the Reagan-Udall Foundation with expert input from FDA, Battelle Memorial Institute, and several academic research institutions.

This project will involve the development of a predictive systems model for TKI-induced nonQT cardiotoxicity. Data to populate the systems model will be obtained from the published literature and from studies using several preclinical models to test specific TKIs for cardiotoxicity endpoints. Microarray and proteomic analyses will be performed to expand and support data already available, and to further identify the principal toxicological pathways associated with TKI-induced cardiotoxicity. The ultimate goals of this pilot project will be to utilize a systems pharmacology approach to determine how well different preclinical models correlate to clinical adverse events, and to identify biomarkers of cardiotoxicity that can be screened for early in development. This study represents a "use case" and learnings from this work will guide future similar studies of other toxicities.



Friends Releases Promotional Video Narrated by Michael Douglas

In October of 2011, Friends of Cancer Research released a new promotional video to bring awareness to the organization's accomplishments and our mission of getting new and innovative treatments to patients in the safest and quickest way possible. This video, available at http://youtu.be/1doUdNj9wjQ, is narrated by Academy Award-winning actor and cancer survivor, Michael Douglas. *Friends* is greatly appreciative of Mr. Douglas's time and his continued advocacy for cancer research, treatment and awareness.

Ryan Hohman, JD, MPA, *Friends* Director of Communications & Policy, with Michael Douglas during taping of promotional video

Expanding Comparative Effectiveness and Patient-Centered Outcomes Research in the United States: Opportunities in Oncology

Friends of Cancer Research (*Friends*) with the generous support of Oracle Health Sciences, Avalere, and the National Pharmaceutical Council, held a forum entitled "Expanding Comparative Effectiveness and Patient-Centered Outcomes Research in the United States: Opportunities in Oncology" at the Capitol Hill Hyatt in Washington, D.C. on June 8, 2011. The event brought together key members of government, industry, and advocacy to discuss current efforts and future projects relating to comparative effectiveness research (CER). Ellen Sigal, Chair of *Friends* and Brett Davis, of Oracle, made brief introductory statements emphasizing the role of the patient in CER, which was a common theme throughout the panel discussions.

Discussion with Federal Leaders on the Future of CER

Panel 1 consisted of a discussion with Dr. Francis Collins (Director, NIH), Dr. Janet Woodcock (Director, CDER, FDA) and Dr. Carolyn Clancy (Director, AHRQ) moderated by Ramsey Baghdadi of The RPM Report. The panelists began by addressing CER and its expanding role at their agencies. Dr. Collins and Dr. Clancy discussed how CER has been present in their agencies for many years, but enactment of the federal Patient Protection and Affordable Care Act formalized a relationship between AHRQ and the NIH that could allow CER to have a much greater impact. Looking to the patient perspective, Dr. Woodcock described how CER cannot be too broad and and requires a sophisticated approach to answer the key concern of every patient: 'Is this going to work for me?' All panelists agreed there must be significant coordination and cooperation between all stakeholders to see successful CER results.

The panelists also talked about the "Comparison of Age-related macular degeneration Treatment Trial" (CATT). Providing each agency's reaction, the panelists showed encouragement for the findings and critiques, with Collins praising the study and Clancy noting that an observational arm would have further aided the work.

Additionally, panelists discussed the Patient-Centered Outcomes Research Institute (PCORI) and its role in disseminating CER information to the public. Panelists

NIH Director Collins


Brett Davis of Oracle Health Sciences


Jeff Allen

ELLEN SIGAL

Friends Chair & Founder delivers opening remarks at 2011 CER Conference with (L-R) Ramsey Baghdadi, Carolyn Clancy (AHRQ), Francis Collins (NIH), Janet Woodcock (FDA) on stage before panel discussion.

agreed greater communication directly from the agencies through medical journal, social media, and other communication mediums will be beneficial to helping the public understand the nuance of research data, and will better inform patients.

Audience members asked questions throughout the panel, including how FDA data can be used to aid CER and how to get more patient involvement in CER.

Roundtable Discussion with Oncology Leaders

Building off Panel 1, a main focus of Panel 2 was how to disseminate information to patients and doctors and the integration of research into the clinical setting. Patients often feel as though they are labeled under one heading, and it can be difficult for doctors to convince patients they are not a patient in a clinical trial and that what works for some may not work for them. Patient advocates on the panel discussed the need to engage patients and work with them "on their level" so they can fully understand information that is being disseminated.

Providers, on the other hand, are facing additional challenges with influxes of data and the need to integrate that information to the clinical environment. Dr. Amy Abernethy, Director of the Duke Cancer Care Research Program, noted that newly released studies offer new information for doctors as well, and they are not always aware of the best way to communicate those results to the patient during a visit. "It can be difficult when a patient has certain expectations and you don't have an answer for that particular patient," agreed Dr. Sandra Wong, Assistant Professor, Division of Surgical Oncology, University of Michigan.

The panel then conducted an overview of some of the projects and goals submitted prior to the forum and distributed to all in attendance. These include going after some projects that have yet to be addressed on a large scale, such as complex illnesses and the care of those with special needs; international clinical trial data collection; and developing guidelines for high quality care. All panelists agreed there needs to be more research about how patients and clinicians make medical decisions and equal stakeholder investment.

Dr. Jeff Allen of *Friends* concluded the forum by highlighting the need for continued communication between government agencies, the medical community, industry, and advocacy organizations to maximize the benefit of CER.

Science and Progress at the Food and Drug Administration: Exploring the Future of Innovation and Global Competitiveness

On June 16, 2011, Friends of Cancer Research (*Friends*) held a Capitol Hill briefing titled "Science and Progress at the Food and Drug Administration (FDA): Exploring the Future of Innovation and Global Competitiveness." The briefing was held in conjunction with the release of a study conducted by *Friends* and published in the peer-reviewed medical journal *Health Affairs* that compares approval rates for cancer drugs by the FDA versus the European regulatory arm, the European Medicines Agency (EMA).

The study found that between 2002 and 2010, the FDA approved 32 new anti-cancer drugs while the EMA approved only 26. FDA not only approved more new cancer drugs than did the EMA; it approved these drugs more quickly. Of 23 drugs approved by both agencies, the median time from marketing submission to FDA approval was 182 days vs. EMA approval of 350 days. A Reuters exclusive broke the story about the study, and was later covered by over 30 major news outlets including; *The New York Times, The Wall Street Journal, CNBC, Fox News, The Chicago Tribune, The Boston Globe,* and a featured op-ed in *Roll Call*.

Moderated by Kate Rawson of The RPM Report, the briefing featured a panel including Dr. Janet Woodcock, Director, CDER, FDA; Dr. John Marshall, Clinical Director of Oncology, Georgetown-Lombardi Comprehensive Cancer Center; Jonathan Leff, Managing Director, Warburg Pincus; and Dr. Ellen Sigal, Chair, Friends of Cancer Research.

The study found that FDA was approving new anti-cancer drugs in an average of 182 days while EMA was taking an average of 350 days

Friends Chair Ellen Sigal introduced Congresswoman Diana DeGette of Colorado who delivered the keynote address praising the study and discussing the ways in which the FDA is a crucial instrument in getting drugs to consumers. Representative DeGette specifically discussed the recent wave of drug shortages in the oncology community and told the audience about the development of a new system that would warn about an impending drug shortage. The Congresswoman

Ellen Sigal

Panel and audience at House briefing

Janet Woodcock

CONGRESSWOMAN DIANA DEGETTE

Rep. DeGette (D-CO), Chief Deputy Whip, delivers opening remarks at Friends 2011 FDA Hill Briefing.

concluded by saying that if the FDA can act as a "communication hub" for disseminating information about market responses to drug shortages, they can have a significant impact on the drug approval track record.

Dr. Woodcock made the point that while this is important news, "We are not in a contest or a race with the European Union or any of our regulatory partners around the world." Dr. Sigal agreed and said that while the study was great news for patients here in the United States, there must be further public and federal support for the agency to ensure this trend continues.

The briefing reached beyond the study to dig deeper into the drug approval process. Panelists were unanimously pleased with the study results but acknowledged that the road to drug approval can be arduous and talked about areas of improvement, particularly in clinical trials. They discussed patient participation in clinical trials as a crucial factor in the continuing development of the drug approval process as well as expanding the use of molecular profiling within groups of patients across the country.

The panel also fielded questions about public and private investment in drug approvals, a shift from development of blockbuster drugs to more personalized medicine, and whether speed or safety should be the top priority.

While some challenges still face the FDA, Dr. Woodcock expressed that she was pleased with the study and hopes the information will begin to dispel the "urban myth" that patients diagnosed with cancer in the U.S. are at a disadvantage over their European counterparts. "FDA review of cancer drugs is efficient. It's rapid," Woodcock said. "The real problems are in the scientific development programs and scientific uncertainty."

Friends of Cancer Research Holds Special Screening of Major Motion Picture "50/50" in Washington DC

On Wednesday July, 13, 2011 Friends of Cancer Research hosted an exclusive pre-screening of the major motion picture "50/50" at the E Street Cinema Landmark Theatre in Washington, DC. The Golden Globe-nominated film was released in theaters across the country in September.

"50/50" stars Joseph Gordon-Levitt and Seth Rogen as best friends whose lives are changed by a cancer diagnosis. Inspired by personal experiences, 50/50 is an original story about friendship, love, survival and finding humor in unlikely places. The movie also featured Anna Kendrick and Anjelica Huston.

New Study Shows that FDA Approves Cancer Drugs Faster Than its European Counterpart

Study compared approval rates for cancer drugs by the FDA versus the European regulatory arm, the European Medical Association (EMA).

Friends of Cancer Research (*Friends*), in June of 2011, announced the release of a study, published in *Health Affairs*, showing that approval rates of oncology drug products are higher in the United States than in Europe. The study examined the approval rates of new oncology drugs that were submitted to the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA) between 2003 and 2010.

The study found that:

- In this time period, FDA approved 32 new anti-cancer drugs while EMA approved only 26.
- FDA not only approved more new cancer drugs than did the EMA, it approved these drugs more quickly: of 23 drugs approved by both agencies, the median time from marketing submission to FDA approval was 182 days vs. EMA approval of 350 days.
- Furthermore, drug companies typically submitted their clinical findings to the FDA prior to submitting these findings to the EMA.
- All 23 of the drugs approved by both agencies in this time period were available to patients in the United States before becoming available to patients in Europe.

The FDA has been portrayed by many critics as slow and inefficient compared to the EMA. While this criticism is particularly strong in the field of cancer, where severely ill patients have few therapeutic options, the new study reveals that the FDA is approving novel anti-cancer drugs in a timely fashion and, in fact, is actually exceeding the EMA.

By Samantha A. Roberts, Jeff D. Allen, and Ellen V. Sigal

Despite Criticism Of The FDA Review Process, New Cancer Drugs Reach Patients Sooner In The United States Than In Europe

ABSTRACT The US Food and Drug Administration is often criticized as inefficient compared to its European counterpart, the European Medicines Agency. This criticism is especially common in the field of oncology, where severely ill patients have few therapeutic options. We conducted a direct drug-to-drug comparison of the two regulatory agencies' approvals of new oncology drugs. We found that contrary to public assertions, the median time for approval for new cancer medicines in the United States was just six months—and that these new anticancer medicines are typically available in the United States before they are in Europe. Our findings reinforce the need for strong financial and public support of the Food and Drug Administration, so that such medicines can continue to be made available speedily to patients in need.

While the FDA should be praised for this, it is important to note that strong public support and additional Congressional appropriations are needed for the FDA to continue this trend and to improve its scientific foundation, so that all therapeutic classes of drugs can benefit from efficient and high-quality FDA review. Furthermore, these findings reinforce the need for strong post-marketing surveillance, so that these medicines can continue to be made available to patients in need without compromising their safety.

A Reuters exclusive broke the story about the study, and was later covered by over 30 major news outlets including; *The New York Times, The Wall Street Journal, CNBC, Fox News, The Chicago Tribune, The Boston Globe,* and a featured op-ed in *Roll Call*

Friends of Cancer Research Chair
Dr. Ellen Sigal
Testifies Before Congress

On July 7, 2011, the House Energy and Commerce Committee Subcommittee on Health held a hearing titled "Prescription Drug User Fee Act V: Medical Innovation, Jobs, and Patients" (PDUFA). The hearing convened two expert panels from government, academia, and advocacy to discuss the upcoming reauthorization of PDUFA legislation and talk about pertinent issues surrounding the Food and Drug Administration (FDA). Panel I featured Dr. Janet Woodcock, Director, Center for Drug Evaluation and Research, FDA. Panel II consisted of Friends of Cancer Research (*Friends*) Chair and Founder Dr. Ellen Sigal, as well as Paul J. Hastings, President and CEO of OncoMed Pharmaceuticals Inc.; Jonathan Leff, Managing Director, Warburg Pincus; Marc Boutin, Executive Vice President, National Health Council; and Allan Coukell, Director of Medical Programs, Pew Health Group.

After opening remarks by the Chair and Ranking Member, the first panel commenced with the statement of Dr. Janet Woodcock. In her testimony, Dr. Woodcock outlined the beneficial impact of PDUFA in the years since its enactment in 1992, current challenges to the program, and drug safety at the FDA. She called for the upcoming reauthorization of PDUFA to be held with a high degree of transparency and increased patient and stakeholder involvement.

During an extensive question and answer period, Dr. Woodcock was asked about a range of topics including innovation, outsourcing of jobs, the predictability of the drug approval process, drug safety, and budgetary issues. Although she expressed optimism in light of an increase of drug approvals in 2011, Woodcock remains concerned about a lag in applications coming through the door, stating, "It is no exaggeration to say that the industry is in crisis."

Panel II began with statements by the panel praising the reforms brought about by the original PDUFA, but also recognizing the need to strengthen the FDA and use the reauthorization of PDUFA to reexamine areas of FDA policy. Mr. Hastings and Mr. Leff both reiterated the need to revise and strengthen the FDA mission statement, with Mr. Boutin underscoring the need for stakeholders to come "back to the table" in order to see continuing benefits from PDUFA.

In her statement, Dr. Sigal stressed the need to get safe and effective treatments to patients quickly and highlighted the findings of a recent study conducted by *Friends* and published in *Health Affairs* that showed on average, the FDA approves new oncology drugs faster than its European counterpart, the European Medicines Agency (EMA). Later in the hearing, Dr. Sigal was asked by Rep. Brian Bilbray (R-CA) about what appeared to be a shrinking gap between U.S. and European approvals in the later years examined in the study. Dr. Sigal noted that since the study was completed, the U.S. has approved three additional oncology drugs not yet approved by the EMA. She emphasized the science of these drugs is complex and it is not a matter of which agency approves drugs the fastest, but the safety and effectiveness of those drugs for patients. She also explained how the study compared reviewed times at the end of a long and increasingly expensive development process. "In order to begin to solve this larger problem, all of the sectors represented at this hearing today, and several of those that are not, must at times, set aside our individual interests and work toward the common goal of improving the health of the country, both economic and personal, through innovation", she said.

Throughout the second panel, witnesses fielded questions about venture capital investment in biomedical research and development, job creation in the scientific sector, and challenges facing companies going through the drug approval process. The hearing concluded with a short discussion regarding conflict of interest rules and the need for a review of the current rule structure to maintain transparency and ensure availability of expertise.

Ellen Sigal testifies before House committee

"In order to begin to solve this larger problem, all of the sectors represented at this hearing today, and several of those that are not, must at times, set aside our individual interests and work toward the common goal of improving the health of the country, both economic and personal, through innovation."

– Dr. Ellen Sigal

Friends of Cancer Research Celebrates 15th Anniversary with Reception Honoring Secretary Sebelius, Senator Hatch and Pulitzer Prize-Winning Author

NIH Director Collins, FDA Commissioner Hamburg, and Members of Congress Help Celebrate 15 Years of 'Progress in Science and Innovation'

On October 12, 2011, leaders from government, advocacy, business and science came together to celebrate the 15th Anniversary of Friends of Cancer Research (*Friends*). 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, Dr. Sigal was a Presidential Appointee to the National Cancer Advisory Board along with Marlene Malek, who joined Ellen in 1996 as President of *Friends*.

Now, Friends of Cancer Research is a respected independent think tank and advocacy organization that continues to develop unique partnerships and create a more open dialogue among both public and private sectors. In acknowledgement of 15 years of "progress in science and innovation", *Friends* held an anniversary celebration at the St. Regis Hotel in Washington, DC.

The evening kicked off with the premiere of *Friends'* new video narrated by Oscar-winning actor and cancer survivor, Michael Douglas.

Each year *Friends* takes the opportunity at this event to acknowledge great contributions to the cancer research community. Past honorees include: Senator Edward Kennedy, Secretary Michael Levitt, Senator Daniel Inouye, Senator Judd

Siddhartha Muhkerjee


L-R, Ellen Sigal, Secretary Sebelius, Marlene Malek

L-R, Francis Collins, Sec. Sebelius, Ellen Sigal, Marlene Malek, Margaret Hamburg

Gregg, Dr. Francis Collins, Ambassador Nancy Brinker, Senator Arlen Specter and Congressman John Dingell.

This year, to mark the organization's 15th anniversary, and the 40th anniversary of the declaration of the war on cancer, *Friends* honored HHS Secretary Kathleen Sebelius and Senator Orrin Hatch 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. Francis Collins, Director of the National Institutes of Health (NIH) and 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 15 years. The two heads of agencies went on to present Secretary Sebelius with the Government Leadership Award.

"The work that Secretary Sebelius began as Governor of Kansas , and continues now as Secretary, on behalf of patients and in support of biomedical research, is truly astounding," said Dr. Ellen Sigal, in acknowledgement of the Secretary being chosen for this honor.

In acknowledgement of his Pulitzer Prize-winning book, "The Emperor of All Maladies", and his great contributions to the world's understanding of cancer research and treatment, Dr. Sigal presented the Cancer Leadership award to the author, and accomplished cancer physician, Dr. Siddhartha Muhkerjee.

Friends President Marlene Malek acknowledged Senator Orrin Hatch's contributions to cancer research and patients everywhere, presenting him with the Congressional Leadership Award later in the evening. "Senator Hatch has been a steadfast supporter of science, innovation and biomedical research during his six terms in the United States Senate," said Malek. "He has reached across the aisle on so many occasions to do what is right for patients everywhere."

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 15 incredible years of progress. We are deeply appreciative of all you have done to help grow *Friends* to the incredible organization it is today.

Jeff Allen

Friends Symposium with Congresswoman Debbie Wasserman Schultz Aims to "Eliminate Breast Cancer Health Disparities"

On March 10, 2011, Friends of Cancer Research (*Friends*) hosted a symposium titled "Eliminating Breast Cancer Health Disparities: Communicating to At-Risk Populations." Panelists included: Dr. Rachel Brem, The George Washington University Medical Center; Tesha Coleman, the Capitol Breast Care Center; Dr. Marc Hurlbert, Avon Foundation Breast Cancer Crusade; Dr. Christopher Masi, The University of Chicago; and Dr. Stephen Taplin, the National Cancer Institute.

The event, supported by the Avon Foundation for Women and the George Washington University Medical Faculty Associates, was held at the George Washington University Jack Morton Auditorium in Washington, D.C. The event drew members from across the cancer and health care communities to discuss how cancer centers, community health centers, advocacy organizations and government agencies can best disseminate information to at-risk populations.

L-R, Jeff Allen, Marlene Malek, Rep. Wasserman Schultz, Ellen Sigal

After a welcome by GWU President Dr. Steven Knapp and *Friends* Chair Dr. Ellen Sigal, a keynote address was delivered by Congresswoman Debbie Wasserman Schultz, a breast cancer survivor and outspoken advocate for prevention and early detection measures. "There have been so many advances in screening and treatment of cancer," she stated, "but all of that is moot if women are not learning about their bodies, taking steps to reduce risk factors and getting regular and appropriate screening." She used her own experience to highlight the need for education and awareness for those who may be at higher risk of developing breast cancer.

Friends President Marlene Malek gave brief remarks and introduced the panel. Dr. Brem opened the discussion by summarizing actions that have already been taken to reduce disparities among at-risk populations and challenges still facing the community. Topics addressed during the panel discussion included how organizations are reaching out to at-risk populations, what government entities are doing to ensure all women have access to screenings and information, understanding the unique biological differences in breast cancer, how to engage diverse groups in clinical trials, and the impact the United States Prevention Services Task Force

Rep. Wasserman Schultz delivers keynote address

L-R, Stephen Taplin, Christopher Masi, Marc Hurlbert, Tesha Coleman, Rachel Brem

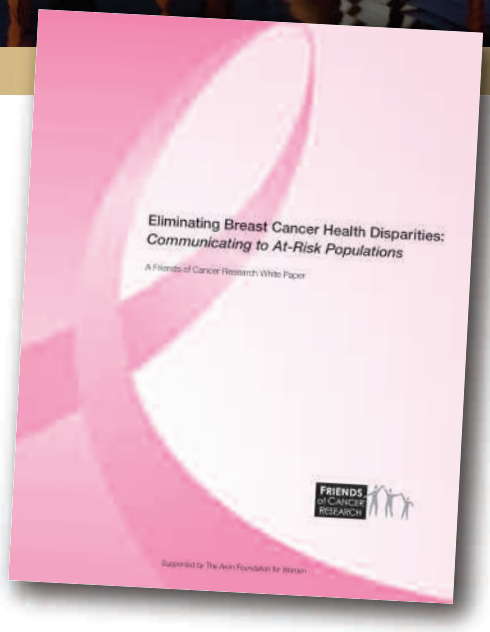
recommendation to delay regular mammography screenings has had on the at-risk community.

Panelists agreed that a comprehensive approach, including studying women without cancer, is necessary in order to have the greatest impact on the broader cancer community. "If you don't do research on all women...you're not going to solve the problem in all women," said Dr. Masi. The Avon Foundation's Army of Women, a large volunteer group of women who have expressed interest in receiving information or participating in research studies, was cited as an example of engaging healthy women in clinical research.

Another prevalent topic of the symposium was the need for collaboration between all stakeholders in order to best reach those in the community. "I think it really is going to take all the parties to really come together to solve this disparity issue," stated Dr. Taplin.

During the question and answer period, the panelists fielded a number of questions regarding linguistic barriers to minority participation in clinical trials, increasing the diversity of the medical workforce, and utilizing social media and technology to communicate with at-risk populations.

The recommendations developed throughout the symposium were explored and expanded upon in a Friends of Cancer Research white paper released in early 2012.



Marlene Malek

Advocates meet with Congress

L-R, Ellen Sigal, Sen. Brown, Eric Winer

Friends of Cancer Research Co-hosts Annual Hill Day

More than 80 cancer center directors, researchers and oncologists from 24 states descended upon Washington, DC, on May 11, 2011 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.

On behalf of Chairman Tom Harkin (D-IA), a majority clerk for the Senate Appropriations Subcommittee on Labor, Health and Human Services, Education, and Related Agencies addressed challenges facing the cancer research enterprise in the current political climate and urged advocates to educate Congress on the economic and lifesaving value of cancer research. The cancer center representatives then spread out across the Capitol and advocated for increased federal funding for cancer research during more than 150 meetings with members of Congress and their aides.

During a reception that evening, AACI, AACR, ASCO and *Friends*, along with cancer center directors from around the country, honored Senator Harkin for his tireless support of cancer research.

Ellen Sigal is presented with the 2011 Advocacy Distinction Award

Dr. Ellen Sigal Honored at the Kennedy Center by Susan G. Komen for the Cure

On October 28, 2011, Susan G. Komen for the Cure honored "the real life heroes powering the best science, boldest community and biggest impact in the fight against breast cancer" at the Kennedy Center in Washington, DC. At this year's *Honoring the Promise* gala, Dr. Ellen Sigal, Chair & Founder of Friends of Cancer Research, received the 2011 Advocacy Distinction Award. Michigan Congressman John Dingell won the same honor last year.

"Ellen is a real force of nature. She's always everywhere we need her to be — often blazing new trails that advance our knowledge, and understanding, of disease. Her service to the National Institutes of Health has been invaluable. Ellen energizes and enhances any group fortunate enough to call her a member," said Dr. Francis Collins, Director of the National Institutes of Health."For these reasons — and many more — I cannot think of a more deserving recipient of this award."

"Ellen Sigal is the advocate's advocate — a woman who works tirelessly on behalf of women who often cannot speak for themselves on the issues that matter for women facing breast cancer," said Ambassador Nancy G. Brinker, founder and CEO of Susan G. Komen for the Cure.

Komen presented Awards of Distinction in four additional categories.

For Scientific and Medical achievement, to Charles M. Perou, Ph.D., head of the University of North Carolina, Chapel Hill, Lineberger Cancer Center; for Community, to Sandra M. Swain, M.D., medical director of the Washington Cancer Institute, and project director of the Breaking Down Barriers program to reach medically underserved women in the National Capitol Area; for Global Leadership, to Sarah Brown, wife of former British Prime Minister Gordon Brown, for her work for women and children; and a Lifetime Achievement Award to former First Lady Betty Ford, presented to Mrs. Ford's daughter, Susan Bales.

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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 their 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 Senators and Congressmen and women, but create new champions for biomedical research.

Now, 15 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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