FRIENDS OF CANCER RESEARCH

CLEARING THE WAY FOR BIOMEDICAL INNOVATION

2007 ANNUAL REPORT

from the chair & president

Dear Friends,


Ellen V. Sigal

At this very moment, in hospitals, clinics, and laboratories across the country, physicians and scientists are burning the midnight oil to develop new treatments to save the lives of cancer patients. The efforts of these researchers and their predecessors have undoubtedly yielded countless advances in cancer research over the past several decades, but the truth is that we have only scratched the surface. As biomedical researchers strive for further advances in their fields, their efforts are often faced with numerous hurdles on the way, challenging the development of innovative treatments.


Marlene A. Malek

In 2007, Friends devoted a considerable amount of time and effort to a significant hurdle -- and *opportunity* -- drug safety. As efforts in Washington heightened to increase the effectiveness and efficiency of the U.S. Food and Drug Administration, the primary agency charged with reviewing and approving new treatments, the cancer community collaborated with policy-makers to enhance the scientific foundation of the agency and ensure the essential balance of benefit and risk that is central to medical decision-making.

Friends is fortunate to have developed important partnerships throughout the cancer community over the past 11 years, and has worked closely with those partners to facilitate an important discourse about the future of innovation in cancer research. In conjunction with research institutions, policy-makers, patients, health care providers, and other research advocates, Friends hosted town hall forums across the country, presented educational briefings in the capital, testified before Congress, and convened a panel to publish a white paper report. It was a busy year, indeed, but in the end our community was successful in protecting patients and the research pipeline.

Friends will continue to identify and tackle other issues that influence the progress of cancer research and work closely with our community to fight for innovation in the best interest of patients.

We look forward to working with you in 2008 and the years to come.

Sincerely,

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

Marlene A. Malek, R.N.
President

drug safety

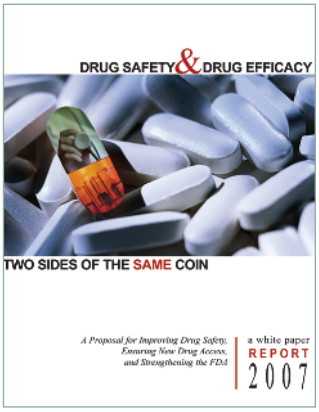
In Washington reauthorization of PDUFA was widely expected to be one of the most important pieces of legislation to receive consideration by the 110th United States Congress.

Central to the debate regarding the reauthorization was the new level of user fees, as well as numerous related issues that would be included in the legislation, such as the expansion of drug safety programs, post-market surveillance, direct-to-consumer advertising, and clinical trials information management.

For Friends, drug safety and efficacy was an especially important component of the legislation and, consequently, a top priority for 2007.

What is PDUFA?

The Prescription Drug and User Fees Act (PDUFA) was created in 1992 amid pressure from the HIV/AIDS community about the Food and Drug Administration's (FDA) lengthy drug review process. PDUFA permits product applicants to pay additional fees to the FDA so the agency can become equipped to process applications more quickly without having any influence on the outcome of the review. PDUFA has greatly reduced the backlog of new product applications, thereby reducing overall product review times and allowing patients earlier access to approved products. It also takes important steps to bring additional scientific expansion to the regulatory arena.



Friends established a working group comprised of advocacy organizations, researchers, and other experts to explore the scientific, medical, and policy issues relevant to assessing the benefits and risks of prescription drugs and the potential effects of drug safety legislation on patients.

The group, led by Dr. Robert C. Young, the chancellor of the Fox Chase Cancer Center, produced specific recommendations and published a white paper report entitled, "Drug Safety & Drug Efficacy: Two Sides of The Same Coin," which was released in March. The group recommended strengthening the FDA through increased resources, personnel, training, product surveillance, and data collection, and advancement of the agency's scientific foundation.

In May Dr. Ellen Sigal offered congressional testimony at the House Energy & Commerce Health Subcommittee hearing on drug safety.

Dr. Sigal provided a science-based patient perspective, emphasizing, "We all want the safest possible drugs, but we recognize that no drug is 100% safe or 100% effective. We also realize that each patient responds differently to medication." Dr. Sigal spoke about ways to address drug safety issues at the policy level.

Bottom-left photo: Dr. Ellen Sigal. Bottom-right photo (L-R): Rep. Frank Pallone (D-NJ), Dr. Ellen Sigal. [*Photos by Mike Gatty*]

The FDA held a public hearing in February to welcome comments on the upcoming reauthorization of PDUFA. The meeting allowed interested parties and stakeholders to speak and/or submit comments to the record. Dr. Jeff Allen, Friends' director of science policy, provided oral testimony at the meeting. In addition to urging the timely renewal of the legislation that provides vital funding to the FDA, Dr. Allen outlined proposals for enhancing drug safety and appealed for additional congressional support for the FDA and the Critical Path Initiative. He emphasized the need for strong science to benefit patients: "It is of the utmost importance that we work to improve that process to ensure patient safety, provide access to new therapies, and foster the development of innovative new treatments."

Friends gathered a group of distinguished drug safety experts in March for an educational briefing on Capitol Hill entitled, "Drug Safety: Defining Safe." More than 50 congressional staffers and patient group advocates attended.

Rep. Diana DeGette (D-CO) delivered welcoming remarks and provided an overview of current drug safety legislative issues. Panelists included Dr. Robert C. Young; Dr. Mark McClellan, the former administrator of the Centers for Medicare & Medicaid Services and the former commissioner of the FDA; Dr. Janet Woodcock, the deputy commissioner and chief medical officer of the FDA; and Dan Perry, the executive director of the Alliance for Aging Research. The discussion was moderated by Susan Dentzer, the distinguished health correspondent for *The NewsHour with Jim Lehrer* on PBS.

Top-left photo (L-R): Dan Perry, Dr. Janet Woodcock, Dr. Mark McClellan, Dr. Robert Young, Susan Dentzer. Bottom-left photo: Susan Dentzer. Bottom-middle photo (L-R): Dr. Janet Woodcock, Dr. Mark McClellan. Bottom-right photo: Rep. Diana DeGette (D-CO). [*Photos by Mike Gatty*]

hill day

Friends of Cancer Research, in conjunction with the Association of American Cancer Institutes (AACI) and the American Association for Cancer Research (AACR), brought together cancer researchers, oncologists, and cancer center directors for their annual Capitol Hill Day in Washington, DC, in early May. With more than 70 participants representing 50 research institutions from 23 states, the event facilitated more than 140 meetings with members of Congress and their legislative staffers to discuss the importance of a sustained commitment to cancer research.

> "Many researchers from across the country were inspired to travel to Washington, DC, to deliver our message about the vital importance of increasing federal funding for cancer research. We are deeply grateful to Friends for its sage policy advice and strategic support."
>
> - DR. MARGARET FOTI, CEO OF
> AMERICAN ASSOCIATION FOR CANCER RESEARCH

Top-right photo (L-R): Rep. Rosa DeLauro (D-CT), Dr. H. Shelton Earp, III, Dr. Ellen Sigal, Barbara Duffy Stewart.
Center photo (L-R): Barbara Duffy Stewart, Dr. Geoff Wahl, Dr. Margaret Foti, Marlene Malek, Dr. Ellen Sigal, Dr. H. Shelton Earp, III.
Bottom-left photo: Dr. Sudip Parikh. [*Photos by Mike Gatty*]

around town

Fran Drescher, best known for her role in the sitcom "The Nanny," met with Dr. Ellen Sigal in February to discuss issues relating to the prevention and early detection of cancer.

Drescher, a survivor of uterine cancer, is quickly becoming well-known for her advocacy efforts in Washington on behalf of gynecological cancer issues. After receiving treatment and then a clean bill of health, Drescher wrote a book about her experiences entitled "Cancer Schmancer," and started a non-profit organization to raise public and congressional awareness about gynecological cancer issues. ■

The Institute of Medicine hosted a symposium in March that gathered a broad panel of experts and stakeholders to examine the role of the FDA in ensuring the safety and efficacy of drugs and the issues that impact the FDA's ability to fufill its mission.

Dr. Ellen Sigal participated in a panel discussion alongside former U.S. Health and Human Services Secretary Tommy Thompson, and spoke about the need to balance drug safety and efficacy effectively and in the best interest of patients. ■

The department of Science and Regulatory Affairs at Pharmaceutical Research and Manufacturers of America (PhRMA) held its annual meeting in October with a focus on post-market drug safety and patient outcomes. Dr. Ellen Sigal gave a keynote address regarding the challenges and opportunities that the biomedical community will face as steps are taken to enhance the FDA drug safety system. ■

At the AACI annual meeting in October, nearly 300 clinical and administrative leaders from the nation's top cancer research institutes gathered to discuss the challenges and opportunities facing their centers and the national effort to advance cancer research.

During a discussion about the role of Congress in shaping cancer policy, Dr. Ellen Sigal shared her perspective as a cancer research advocate. Dr. Sigal charged those in the audience to engage actively their members of Congress in the exciting work being done at their centers: "We all must be better at informing our nation's leaders of the immediate opportunities and innovative discoveries that come from their investment in biomedical research. These discoveries improve the lives of the millions of people facing this terrible disease each year." ■

Top-left photo (L-R): Fran Drescher, Dr. Ellen Sigal. Bottom-left photo [*by Mike Gatty*] (L-R): Susan Dentzer, Carolyn Gluck, Dr. Sudip Parikh, Dr. Ellen Sigal. Bottom-right photo [*by Mike Gatty*]: Dr. Ellen Sigal.

town hall forums

Friends' flagship program is an ongoing town hall forum series. These events generate greater awareness about current opportunities in, and barriers to, cancer research, as well as recommendations for addressing those issues.

Friends partners with distinguished cancer centers across the nation to host these public forums and bring together diverse and accomplished panelists, including scientists, physicians, industry respresentatives, public officials, patients, and other research advocates.

In 2007, Friends worked with three world-class cancer centers to produce town hall forums in Michigan, Ohio, and Connecticut.

University of Michigan
Comprehensive Cancer Center

The first town hall forum of the year was held in April with the University of Michigan Comprehensive Cancer Center (UMCCC). With approximately 150 people in attendance, and a "virtual" audience of nearly 200 people viewing the event via live online broadcast, the event reached a broad group of scientists, researchers, media, and the general public.

Panelists included Dr. Max Wicha, the director of UMCCC; Rep. John Dingell (D-MI); Dr. John Niederhuber, the director of the National Cancer Institute; Dr. Andrew von Eschenbach, the commissioner of the FDA; Drs. Stephen Gruber and Dean Brenner, professors at the University of Michigan; Dr. Joseph D. Purvis, of AstraZeneca Pharmaceuticals; and Ruth Freedman, a cancer survivor.

Panelists emphasized the importance of personalized medicine, funding basic science, further developing the biomedical industry, and supporting future generations of researchers.

> "Just as collaboration in the lab is key to furthering cancer research, collaboration between organizations such as Friends and the University of Michigan is equally important in advancing public knowledge and sentiment about critical issues."
>
> - DR. MAX WICHA, DIRECTOR OF UNIVERSITY OF MICHIGAN CCC

Top-right photo (L-R): Rep. John Dingell (D-MI), Dr. Andrew von Eschenbach. Center-left photo (L-R): Susan Dentzer, Rep. John Dingell (D-MI), Dr. Andrew von Eschenbach, Dr. John Niederhuber, Dr. Max Wicha, Dr. Stephen Gruber, Dr. Dean Brenner, Dr. Joseph Purvis, Ruth Freedman.

> We appreciate the opportunity to work together with Friends to emphasize the critical need for increased federal funding for vital cancer research.
>
> - DR. MICHAEL CALIGIURI, DIRECTOR OF OHIO STATE CCC

More than 300 researchers, health care professionals, patients, and other cancer research advocates piled into the state-of-the-art Biomedical Research Tower at Ohio State University in early October to hear discussion on the future of cancer research. The forum, which was co-sponsored by the Ohio State University Comprehensive Cancer Center (OSUCCC) and Friends, was moderated by Susan Dentzer. The panel included: Sen. Sherrod Brown (D-OH); Rep. Deborah Pryce (R-OH); Dr. Michael Caligiuri, the director of OSUCCC; Dr. John Niederhuber; Dr. Janet Woodcock, the deputy director and chief medical officer of the FDA; Dr. Rainer Boehm, of Novartis Oncology; and Carl Stewart, a cancer survivor.

In late October, Friends, Yale Cancer Center (YCC), and Yale-New Haven Hospital co-sponsored a public forum in New Haven with a focus on translational research.

Dr. Richard Edelson, the director of YCC, and Dr. Sigal provided introductory remarks, and Susan Dentzer moderated the panel of experts. The panel included: Rep. Rosa DeLauro (D-CT); Dr. Andrew von Eschenbach; Dr. Gary Kelloff, a special advisor at the National Cancer Institute; Dr. Louis Denis, of Pfizer Oncology; Drs. Edward Chu, Daniel DiMaio, and Susan Mayne, of YCC; and Barbara Oliver, a cancer survivor and the executive director of Y-ME Connecticut.

> We are extremely grateful to Friends for its ambitious efforts to highlight cancer research and care on the national platform.
>
> - DR. RICHARD EDELSON, DIRECTOR OF YALE CANCER CENTER

Top-left photo (L-R): Carl Stewart, Dr. David Schuller, Rep. Deborah Pryce (R-OH), Dr. John Niederhuber, Sen. Sherrod Brown (D-OH), Dr. Michael Caligiuri, Marlene Malek, Dr. Ellen Sigal, Dr. Rainer Boehm, Dr. Janet Woodcock, Susan Dentzer. Bottom-left photo (L-R): Dr. Richard Edelson, Rep. Rosa DeLauro (D-CT), Dr. Andrew von Eschenbach, Dr. Edward Chu, Dr. Gary Kelloff, Dr. Louis Denis, Dr. Daniel DiMaio, Dr. Susan Mayne, Ms. Barbara Oliver. Bottom-right photo [*by Terry Degradi*] (L-R): Dr. Andrew von Eschenbach, Rep. Rosa DeLauro (D-CT).

appearances

The 2007 AACR-Industry Roundtable took place in April and was entitled, "Sustaining and Developing Partnership to Advance the Prevention and Cure of Cancer."

The conference successfully brought together leaders from the world's largest scientific organization, representatives of leading health care corporations, and other research advocates to enforce the need for greater collaboration across all sectors.

Dr. Jeff Allen delivered a presentation at the conference outlining the drug safety legislative environment and imminent issues facing the research community. ■

AACR held its annual meeting in April in Los Angeles, CA, where more than 17,000 people gathered to discuss groundbreaking cancer research.

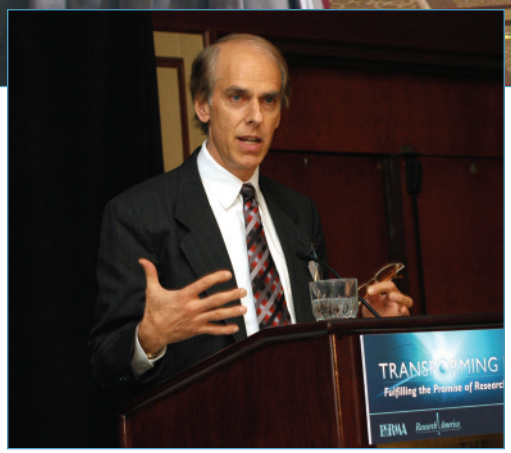
Dr. Ellen Sigal was a special guest at the AACR Centennial Ceremony where she and others were recognized for their outstanding contributions and commitment to eradicating cancer.

Dr. Sigal also spoke at the Science Policy and Legislative Affairs Symposium during the meeting. During her presentation, "Legislative Impact on Drug Safety, Access and Innovation," Dr. Sigal discussed important legislative proposals under consideration in Congress designed to strengthen the FDA. ■

Top-left photo (L-R): Nancy Brinker, Dr. Ellen Sigal.

On November 16 Dr. Sigal spoke about the role advocates play in fostering innovation at a conference entitled, “Transforming Health: Fulfilling the Promise of Research.” The conference was co-sponsored by Research!America and PhRMA.

Dr. Sigal discussed the current opportunities in science and described a future of collaborative research involving diverse stakeholders: “No one sector can do this on its own. We must all be relentless in our pursuit of innovation because at the end of the day it is personal to each of us.”



A conference was held at the FDA in early November in order to start discussions about new methods of modeling and quantifying benefits and risks associated with therapeutic regimens.

Dr. Ellen Sigal spoke at the conference about the potential benefits that could come from the use of mathematical modeling to influence patients’ and doctors’ treatment decisions as well as the need to balance formulaic assessments with other evidence and indications.

Top-right photo: Dr. Elias Zerhouni. Center photo (panelists L-R): Billy Tauzin, Mary Woolley, Dr. Elias Zerhouni. Bottom-left photo: Dr. Tony Altar. [*Photos by Mike Gatty*]

contributors

Friends relies heavily on the generosity of its compassionate contributors. Friends extends sincere gratitude to the many individuals, corporate partners, cancer centers, non-profit organizations and foundations that generously provided support in 2007. Friends would also like to thank all donors whose names do not appear below; every level of support is critical to Friends' continued success.

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leaders

Friends hosted its Annual Cancer Leadership Awards Reception in November. Awards were presented to Sens. Edward Kennedy (D-MA) and Michael Enzi (R-WY), and Dr. Robert C. Young in recognition of their extraordinary efforts to advance the field of cancer research.

Among the many friends and supporters in attendance were Speaker of the House Nancy Pelosi (D-CA), Sen. Ted Stevens (R-AK), Dr. Elias Zerhouni, the director of the NIH, Dr. Andrew von Eschenbach, Dr. John Neiderhuber, Dr. Steven K. Galson, the acting surgeon general, and Sherry Lansing, the chief executive officer of The Sherry Lansing Foundation.

Dr. Stephen Baylin, the deputy director of the Johns Hopkins Sidney Kimmel Comprehensive Cancer Center, provided touching remarks in remembrance of Dr. Martin D. Abeloff, who was the director of the center for 15 years and a member of Friends' board of directors, and who died of leukemia in September. Friends also honored Dr. Abeloff with a $10,000 contribution to the Martin D. Abeloff Scholars Program in Cancer Prevention and Control.

Top-left photo (L-R): Marlene Malek, Dr. Ellen Sigal, Sen. Edward Kennedy (D-MA), Sherry Lansing. Bottom-left photo (L-R): Speaker Nancy Pelosi (D-CA), Marlene Malek, Sherry Lansing, Dr. Ellen Sigal. Bottom-center photo: Dr. Robert Young. Bottom-right photo: Sen. Michael Enzi (R-WY). [*Photos by Mike Gatty*]

Mission and Background

Friends of Cancer Research is a 501(c)(3) non-profit organization that creates effective collaboration between medical professionals, scientists, public officials, patients, and other research advocates in order to accelerate innovation in cancer prevention, detection, and treatment.

For more than ten years Friends has convened leading cancer advocates and researchers to create strategic consensus; educated policymakers and the general public about new research opportunities and existing obstacles; pioneered valuable public-private partnerships to maximize resources; and created an effective dialogue between researchers and regulators to minimize institutional barriers

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