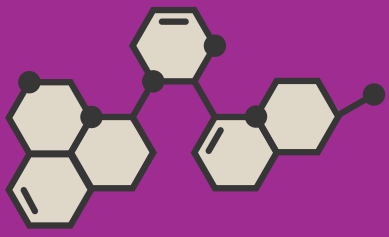


ADVANCING INNOVATION FOR PATIENTS

2017

FRIENDS of CANCER RESEARCH

FRIENDS OF CANCER RESEARCH TAKES ACTION

ON BEHALF OF PATIENTS

FRIENDS OF CANCER RESEARCH (*Friends*) drives collaboration among partners from every healthcare sector to power advances in science, policy, and regulation that speed life-saving treatments to patients. During the last two decades, *Friends* has been instrumental in the creation and implementation of policies ensuring patients receive the best treatments in the most efficient and safest way possible. We've been successful due to our ability to convene the right people at the right time and put forth revolutionary, yet realistic ideas. We are more energized now than ever to continue this critical work with our trusted partners, creating innovative solutions to overcome barriers standing in the way of conquering cancer.

INNOVATE

COLLABORATE

LEGISLATE

ADVOCATE & ACCELERATE

ANTICIPATE

BRINGING TOGETHER KEY LEADERS FROM DIFFERENT SECTORS

INNOVATE

FRIENDS' SCIENTIFIC CONFERENCES CATALYZE INNOVATION BY BRINGING TOGETHER KEY LEADERS FROM DIFFERENT SECTORS.

Friends of Cancer Research Annual Meeting 2017

The Friends of Cancer Research (*Friends*) Annual Meeting convenes leading experts to discuss solutions to pressing challenges in the development of new medicines. Each year, working groups are formed to generate white papers to be presented at the meeting and propose new approaches that build on cutting-edge science. This venue has led to the development of innovative policies, transformative projects, and unique partnerships.

In 2017, recognizing the rapid advancements in oncology and the potential impact on cancer care, the working groups sought to address ways to effectively identify additional uses of new medicines, advance the development of multi-drug combinations, and ultimately enhance the ability to update product labeling.

FDA Commissioner, Dr. Scott Gottlieb, NCI Director, Dr. Norman Sharpless, and Director of the FDA Oncology Center of Excellence, Dr. Richard Pazdur participated in the Annual Meeting to share their ideas on these topics, additional priorities for the future, and ways that different sectors can collaborate toward advancements in cancer treatments.

The outcomes of the Annual Meeting have been championed by leadership at the FDA, including Commissioner Gottlieb who has pointed to these proposals as initiatives FDA is now bringing forward.

Disrupting BioPharma

"We have to be resilient. We have to be innovative. We have to be collaborative. And we have to be engaged to succeed." – Senator Daschle

Friends of Cancer Research (*Friends*) and Prevision Policy's Bio-Pharma Congress has become a unique venue for leaders to address top priorities in health policy. Thought leaders participating in this year's BioPharma Congress began to lay out policy strategies to promote innovation, enhance patient access, and examine programs for high quality, cost-effective healthcare for years to come.

A key panel included Director of the FDA's Center for Biologics Evaluation and Research, Dr. Peter Marks, Director of the FDA's Center for Drug Evaluation and Research, Dr. Janet Woodcock, and Director of the FDA Oncology Center of Excellence, Dr. Richard Pazdur discussing the evolution FDA will undergo in order to best respond to emerging science and technologies as they look to the future. The concluding keynote was led by *Friends*' Vice President of Public Affairs, Ryan Hohman, discussing unprecedented cost and coverage issues facing the U.S. healthcare market in 2017 with Former FDA Commissioner Dr. Mark McClellan and Former Senate Majority Leader Tom Daschle.

BioPharma Congress addresses issues spanning regulatory policy and pressing topics in healthcare delivery and coverage, which are vital to getting therapies to patients.

Friends Convenes Forum to Accelerate Pediatric Drug Development

Developing cancer treatments for small subsets, such as children with cancer, presents unique challenges. Building on our experience in creating innovative research partnerships, Friends of Cancer Research (*Friends*) convened leaders in pediatric drug development to explore new frameworks to facilitate research of new cancer medicines in pediatric populations.

Due to the need for new approvals to capitalize on current science and enhance future policies, *Friends* hosted the Accelerating Pediatric Drug Development forum, which was supported by the St. Baldrick's Foundation.

This *Friends* forum led the way to changes being made in pediatric drug development by providing a framework for innovative clinical trial designs.

Updating Outdated Product Labels

FDA-approved labels are an important source of information that guide the safe and effective use of prescription drugs. In many instances, however, labels may fail to be updated as new information about drug efficacy emerges in the post-market setting. This is illustrated by wide discrepancies between FDA-approved labels and other sources of prescribing information, such as federally-designated drug compendia. In at least some cases, labels may be outdated and not reflective of high-quality post-market evidence of drug efficacy.

Therefore, Friends of Cancer Research held a workshop in March 2017 that brought together multiple stakeholders to examine circumstances that cause product labels to become outdated and discuss opportunities for incorporating high-quality post-market evidence into FDA-approved labels. Updating outdated product labels with information regarding new indications and uses would support public health by ensuring that labels for widely-used drugs are accurate and up-to-date. This is particularly true for generic drug cases where a reference product's new drug application (NDA) has been withdrawn for reasons other than safety or effectiveness.

***Friends'* work proposes new ways to resolve the critical issue of outdated product labels, which is an issue *Friends* will continue to take action on in 2018.**

EXECUTE ON VITAL ACTION FOR PATIENTS

COLLABORATE

THROUGH THE POWER OF COLLABORATION, *FRIENDS* EXECUTES ON VITAL ACTION FOR PATIENTS.

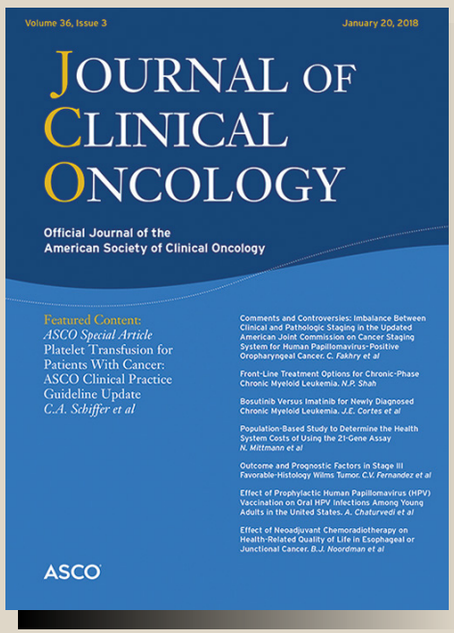
ALEXANDRIA.
Building the Future of Life-Changing Innovation™

Friends and Alexandria Chart "A Blueprint for Breakthrough"

In recent years there has been an increase in research and use of precision medicine, an emerging and exciting field in drug development. To address issues in the field, Friends of Cancer Research (*Friends*) and Alexandria Real Estate Equities Inc. have developed a collaborative partnership, "A Blueprint for Breakthrough" to help chart a course for advancements in cancer research.

Each year, the Blueprint for Breakthrough event convenes leaders in the field to address pressing issues in precision medicine. This year the event addressed companion diagnostics and the lack of consistency in regulation, which leaves room for improvement in diagnostic test standards and development processes. The conference resulted in the release of a *Friends*-Alexandria white paper with recommendations on adopting analytical standards and streamlining approval pathways for post-market modifications for next-generation sequencing tests in oncology.

***Friends'* work with Alexandria charts the path ahead for innovation in precision medicine.**



Changing the Face of Clinical Trials

Advancements in molecular technologies are leading to new opportunities for the future of precision medicine. As such, Friends of Cancer Research (*Friends*) and the American Society of Clinical Oncology (ASCO) launched a joint effort aimed at modernizing eligibility criteria in clinical trials when scientifically appropriate. The project resulted in a comprehensive examination of eligibility criteria for cancer clinical trials with recommendations to address eligibility criteria in five specific areas:

- Minimum age requirements for trial enrollment
- HIV/AIDS status
- Brain metastases
- Organ dysfunction
- Prior and concurrent malignancies

These five areas were identified as most likely to restrict a patient's participation in a trial, and the least likely to affect the safety of participants.

Friends and ASCO worked closely with the U.S. FDA and the NCI throughout the project to address these issues. Work with clinical trial sponsors and regulators is ongoing to turn these recommendations into action and identify additional opportunities for the safe expansion of eligibility criteria in oncology trials.

This *Friends*-ASCO project proposes ways to expand access to clinical trials for more patients.

PARKER INSTITUTE
for CANCER IMMUNOTHERAPY

Standardizing PD-(L)1 Toxicity Management

Friends of Cancer Research and the Parker Institute for Cancer Immunotherapy convened a group of leading experts in immunotherapy to review existing immune checkpoint inhibitor toxicity management guidelines and develop consensus recommendations to reconcile differences between existing guidelines. The final document was distributed to professional societies, including the American Society of Clinical Oncology, National Comprehensive Cancer Network, and the Society for Immunotherapy of Cancer, to inform future clinical guideline development and education initiatives to promote proper management of immune-related adverse events.

This collaborative effort lays the foundation for improved side effect monitoring and treatment for patients receiving immunotherapy.

THE UNIVERSITY OF TEXAS
MD Anderson Cancer Center
Making Cancer History®

Obtaining Consensus on Symptom Attribution

Friends of Cancer Research and the University of Texas MD Anderson Cancer Center co-hosted a workshop in September 2017 to identify the challenges and opportunities associated with attribution of adverse events in oncology clinical trials.

The meeting resulted in the development of actionable recommendations to change current practice and promote the collection of high-quality patient experience data.

TRANSLATE SCIENTIFIC OPPORTUNITY INTO FORWARD THINKING POLICY

LEGISLATE

FRIENDS TRANSLATES SCIENTIFIC OPPORTUNITIES INTO FORWARD THINKING POLICIES THAT ENACT REAL CHANGE FOR PATIENTS.

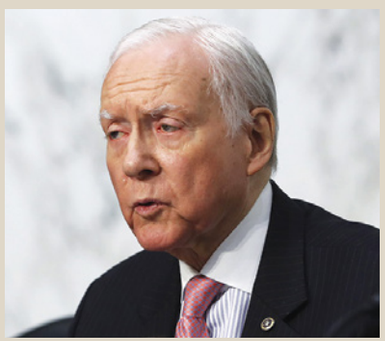
Friends' President & CEO Testifies at First House Energy & Commerce PDUFA Reauthorization Hearing

"For the people who currently depend on safe and effective medicines, for those who are holding strong for the breakthroughs to come, and for every future patient, there isn't time to waste." – Dr. Jeff Allen

The Prescription Drug User Fee Act (PDUFA) allows FDA to collect user fees from drug manufacturers to fund the drug approval process. Up for reauthorization in 2017, Friends of Cancer Research (*Friends*) worked to ensure the following initiatives were included: exploring the development of innovative clinical trial design and use of new data sources for research, transforming the way new treatments are evaluated through the development and use of patient experience data, boosting FDA hiring and retention processes, and enhancing drug development through the qualification of surrogate endpoints and other drug development tools.

In March 2017, *Friends*' President & CEO, Jeff Allen, testified at the first House Energy & Commerce PDUFA VI hearing. During his testimony, Allen stressed the importance of user fees in providing new resources to build upon the success of the breakthrough therapy designation, which *Friends* spearheaded during the last user fee reauthorization. Allen urged Congress to swiftly pass the sixth reauthorization of PDUFA for those who depend on safe and effective medicines.

Since the PDUFA VI Reauthorization, *Friends* has worked closely with the FDA to execute on priorities that help patients.



Friends Collaborates with Senate to Enact Bipartisan Policy

Senators Orrin Hatch (R-UT), Michael Bennet (D-CO), Richard Burr (R-NC), and Bob Casey (D-PA) highlighted their tireless commitment to patients and took important steps in reducing barriers to clinical trial participation by offering an amendment to the PDUFA VI Reauthorization bill. The amendment capitalizes on and implements the work Friends of Cancer Research has championed in this area. The amendment will spur development of methods and study designs to broaden eligibility criteria in appropriate trials, which will allow more patients to participate in clinical studies. By allowing more patients to participate, the results of clinical trials may be more reflective of the patients that will ultimately use the drug once it is on the market.

This bipartisan action reflects *Friends*' work and is helping to increase patient access to clinical trials.

Friends' Chair & Founder to Congress: "More Needs to be Done for Patients"

In October 2017, Friends of Cancer Research (*Friends*) Chair & Founder, Ellen Sigal, testified before Congress in the first House Energy & Commerce hearing on proposed Right-to-Try legislation. The proposed legislation would let terminally ill patients try experimental therapies that have completed Phase 1 testing but have not been approved by the FDA. Dr. Scott Gottlieb, the FDA Commissioner, was also a witness in the hearing and stated that FDA encourages companies to utilize new clinical trial designs to increase patient access to promising therapies before they are approved by the agency.

During her testimony, Sigal acknowledged that more needs to be done to save patient lives, and asked the committee to make serious changes to the current legislation in order for it to be safe for patients. Her testimony also covered her experience with experimental therapies when her sister, Gale, was being treated for metastatic breast cancer. It was this experience, and Gale's tragic death, that inspired Sigal to start *Friends* more than 20 years ago.

***Friends* works to ensure patients receive treatments in a safe manner and fights to make sure this is a top priority for new public policy.**

ACCELERATE PATIENT ACCESS TO REVOLUTIONARY THERAPIES

ADVOCATE & ACCELERATE

FRIENDS' WORK ACCELERATES PATIENT ACCESS TO REVOLUTIONARY THERAPIES BY ADVOCATING FOR THE SAFEST AND MOST EFFICIENT PATH FORWARD.

Five Years of Breakthrough Therapy Designation Success Recognized at Cancer Leadership Awards Reception

"To Friends of Cancer Research, the only thing I have to say is not only did you have an impact on the U.S. patient, but your effects are seen globally." – Dr. Richard Pazdur

With the advent of more targeted therapies, oftentimes a drug shows significant improvement over existing therapies early in its development. In 2011, Friends of Cancer Research (*Friends*) created a review process for these drugs—the breakthrough therapy designation. *Friends* worked with partners in all sectors, and took breakthrough from concept, to scientific white paper, to bipartisan legislative solution, to a tool in full use by FDA in just 13 months.

Friends marked the five-year anniversary since breakthrough was signed into law by recognizing leaders from the different sectors that played key roles in conceptualizing and implementing the program at the 2017 Cancer Leadership Awards. Four FDA Commissioners joined in the celebration, and those honored included: Sen. Michael Bennet (D-CO); Sen. Richard Burr (R-NC); Sen. Orrin Hatch (R-UT); Rep. Diana DeGette (D-CO); Rep. Fred Upton (R-MI); Dr. Rick Pazdur, U.S. FDA; Dr. Janet Woodcock, U.S. FDA; Katherine Couvillon, patient advocate; and Angela Stancil, patient advocate.

The breakthrough therapy designation continues to be one of the most revolutionary initiatives in medicine in recent history with more than 80 therapies already approved.

Implementing the FDA Oncology Center of Excellence

Friends of Cancer Research (*Friends*) spent several months analyzing the current regulatory environment and examining opportunities for potential improvement in the review of new cancer treatments. At the end of this review, *Friends* made a recommendation to institute an Oncology Center of Excellence (OCE) at FDA as a pilot project for streamlining the review process with the hope that the structure could be replicated in other disease settings. The OCE was formally established, and subsequent funding was included in the Cancer Moonshot, when President Barack Obama signed the 21st Century Cures Act into law in December 2016. The OCE is led by Director Dr. Richard Pazdur.

In 2017, FDA Commissioner, Dr. Scott Gottlieb testified that the OCE was vital to the approval of CAR-T cell therapies, which provided a prime example of how the OCE is intended to function by streamlining the review process.

***Friends* continues to support the streamlined process of the Oncology Center of Excellence, which is bringing revolutionary treatments to patients in a more efficient manner.**

FRIENDS of CANCER RESEARCH

ProgressForPatients.org
ADVOCACY ALLIANCE & EDUCATION

Seeking Solutions to Advance Science Through Engagement and Education

In recent years, the role of patient advocates has been elevated and their input has helped shape major public policy initiatives. As such, Friends of Cancer Research (*Friends*) developed a new initiative, ProgressForPatients.org, that launched in 2017. The program brings together those who seek solutions to advance science through engaging, educating, and empowering patients.

ProgressForPatients.org houses *Friends*' Advocacy Education program, an online education platform with a focus on the FDA, drug development, and regulatory policy to enable advocates to better engage with policymakers. Through ProgressForPatients.org, *Friends* has helped identify and train new patient advocates that participate in our project working groups, as well as provide valuable input to other healthcare initiatives.

ProgressForPatients.org has already allowed for hundreds of patient advocates to be more engaged with drug development and regulatory policy than ever before.

LOOKING TO THE FUTURE TO ENSURE BETTER TREATMENTS FOR PATIENTS

ANTICIPATE

FRIENDS IS ALWAYS LOOKING TO THE FUTURE AND ANTICIPATING NEW WAYS TO ENSURE BETTER TREATMENTS FOR PATIENTS.

Letter from the President & CEO

On behalf of Friends of Cancer Research, I would like to thank **you**: our continued supporters and collaborators without whom our work would not be possible. In the past year alone, we have made great advances in achieving our mission to help patients and that is only possible because of you.

As we look ahead in 2018, we look to address new ways we can advance science, policy, and regulations to speed life-saving treatments to patients in a safe and effective manner. This includes projects to identify new methods to accelerate research, streamline the use of new biomarkers for innovative therapies, and pursue policy modifications to ensure that patients have timely access to new medicines and the best information about their treatments.

Collaboration is a powerful force, and our success over the past 21 years has been built on it. As we strive to continue advancing innovation for patients we are deeply appreciative of your support.

With great appreciation,

Jeff Allen, PhD

Priorities for 2018

Throughout 2018, Friends of Cancer Research's programs and events will continue to enhance innovation to speed life-saving treatments to patients in the most efficient and safest way possible.

- **ANALYZE** the best way to use and include real world evidence in regulatory review and clinical trials.
- **DEFINE** tumor mutational burden and establish analytical approaches for its measurement.
- **DEVELOP** clinical trial strategies for tissue agnostic drug development.
- **ADDRESS** the challenges and needs of patient-focused drug development.

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COURTNEY WISE
Executive Assistant

LINDA OSTERMANN
Science Policy Research Assistant

Publications

As part of Friends of Cancer Research's work, white papers, studies, and research are published throughout the year to inform decision makers on new strategies for developing treatments for patients.

The following are the published documents from 2017.

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FRIENDS OF CANCER RESEARCH

1800 M Street NW, Suite 1050 South
Washington, DC 20036

Tel: 202.944.6700 *Email:* info@focr.org

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