Jeff Allen, PhD

CONTACT INFORMATION

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[redacted]

EMPLOYMENT HISTORY

President & CEO – Friends of Cancer Research – Present

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. Responsibilities include creating and implementing research and policy initiatives, engaging with congressional leaders, federal officials and scientific experts, organizational governance and coordinating staff for scientific programs, fundraising, communication and media, policy activities and public education symposia.

Executive Director – Friends of Cancer Research – 2008-2016

Manage a leading non-profit cancer research policy and advocacy organization that focuses on innovative research partnerships and healthcare policy particularly related to the Food and Drug Administration (FDA).

Director of Science Policy – Friends of Cancer Research – 2006-2008

Created and led science policy activities with major focus on drug safety legislation, FDA oncology programs, and advancement of personalized medicine.

Research Fellow – National Institutes of Health – 2005-2006

National Center for Complementary and Alternative Medicine, Laboratory of Clinical Investigation – 2005-2006

EDUCATION & TRAINING

Post-Doctoral Fellow

Department of Cell Biology, College of Medicine, Georgetown University
2004-2005

Georgetown University, Washington, DC

PhD, Cell and Molecular Biology, 2004

Bowling Green State University, Bowling Green, OH

Bachelor of Science, 1999
Major: Biology Minor: Chemistry University Honors, Cum Laude

POLICY & LEGISLATIVE EXPERIENCE

Testimony before the Committee on Energy & Commerce, U.S. House of Representatives:

- *Examining FDA's Prescription Drug User Fee Program.* March 22, 2017

Testimony before the Senate Committee on Health, Education, Labor & Pensions:

- *Laboratory Testing in the Era of Precision Medicine.* September 20, 2016

21st Century Cures Act

- Developed legislative language based on prior Friends' scientific programs that led to new programs and provisions in the Act:
    - Sec. 3001. Patient experience data
    - Sec. 3002. Patient focused drug development guidance
    - Sec. 3011. Qualification of drug development tools
    - Sec. 3031. Summary level review
    - Sec. 3072. Hiring authority for scientific, technical, and professional personnel
    - Sec. 3073. Establishment of Food and Drug Administration Intercenter Institutes.

Testimony before the Committee on Energy & Commerce, U.S. House of Representatives:

- *21st Century Cures: The President's Council of Advisors on Science and Technology (PCAST) Report on Drug Innovation* May 20, 2014

Breakthrough Therapy Designation / Food and Drug Administration Innovation and Safety Act (FDASIA)

- Developed legislative language to create Breakthrough Therapies designation (Sec. 902)
- Established coalition support for legislation (40 organizations)
- Frequent press engagement and public speaking to develop support for the program

Testimony before the Committee on Energy & Commerce, U.S. House of Representatives:

- *FDA User Fees 2012: Hearing on Issues Related to Accelerated Approval, Medical Gas, Antibiotic Development and Downstream Pharmaceutical Supply Chain.* March 8, 2012

Patient Protection and Affordable Care Act:

- Drafted legislative language suggestions incorporated in Senate Finance version (Subtitle D – Patient Centered Outcomes Research)
- Developed coalition support for legislation (68 advocacy organizations)
- Developed coalition support for comparative effectives research provisions (34 organizations)
- Worked extensively with both Senate and House Democrats and Republicans
- Amicus brief participant and signatory supporting minimum coverage requirement

Testimony before the Committee on Energy & Commerce, U.S. House of Representatives:

- *NCI Research: Today's Progress, Tomorrow's Challenge.* March 23, 2010

Food and Drug Administration Amendments Act of 2007:

- Drafted legislative language incorporated in final bill (Title VI – Reagan-Udall Foundation, Title IX – Enhanced Authorities Regarding Post-Market Safety of Drugs)
- Developed coalition support for bill provisions (65 advocacy organizations)
- Worked extensively with both Senate and House Democrats and Republicans
- Wrote editorials for publication supporting drug safety provisions
- Press interviews describing importance of legislative provisions
- Prepared written and oral testimony for House Energy & Commerce Drug Safety hearing

RESEARCH & REGULATORY PROJECTS

Research Partnerships

ctMoniTR

The use of ctDNA to monitor treatment response has been particularly challenging to properly investigate its role as a monitoring tool for treatment response due to variability in the way ctDNA assessment has been designed into clinical trials, the various collection methods used and the way ctDNA changes are reported by different ctDNA assays. The first step of this alignment pilot project is a collaboration with 5 pharmaceutical companies, 4 diagnostic

companies, and Johns Hopkins University with the objective to harmonize the use of ctDNA to monitor treatment response (ctMoniTR), to assess if changes in ctDNA levels accurately reflect the therapeutic effect of cancer therapies. Demonstrating the utility of ctDNA monitoring will enable an earlier determination of treatment response for patients and more rapid evaluation of the effect of new therapies.

Real-World Evidence Pilot Project Series
There is a need for better characterization of the role real-world endpoints may play in evaluating product effectiveness. This project brings together 10 leading health research organization to assess several frontline treatment regimens in real-world patients with advanced non-small cell lung cancer (aNSCLC). This project evaluates the extent to which real-world endpoints (such as time to treatment discontinuation) relates to traditional clinical measures of response to therapies. This will better enable development of new research methods, consistent result reporting, and further the use of quality real world data to accelerate research.

TMB Harmonization
Tumor mutation burden (TMB) has emerged as a potentially predictive biomarker for identifying patients with increased likelihood to respond to IO therapy. Currently, there is a lack of standardization for TMB calculation and reporting. This collaborative partnership brings together 15 leading laboratories, FDA, NCI, and expert researchers to align different tests used to assess TMB. Ultimately, this project will help ensure consistent identification of patients who are likely to respond to IO therapies.

Lung-MAP: Lung Cancer Master Protocol
Based on the concept paper developed for the Conference on Clinical Cancer research in 2012, a large-scale collaborative effort was established between *Friends*, FDA, NCI, SWOG Oncology, the Foundation for the NIH, several pharmaceutical and biotech companies, Foundation Medicine, and numerous patient advocacy organizations. This led to the 2014 launch of Lung-MAP a multi-drug, biomarker-driven master protocol designed to increase efficiencies in drug development and improve access to cutting-edge new products. Today the trial is available at over 700 research institutions.

Regulatory Initiatives

FDA Oncology Center of Excellence
- Worked with a broad group of stakeholders, including FDA leadership, to promote the concept of oncology-focused, cross-functional process between existing medical product Centers at the FDA.
- Developed coalition support across the oncology community and implemented legislative strategy for the inclusion of the concept in the 21st Century Cures Act and the Obama Administration Cancer Moonshot

Blueprint for Breakthroughs
Building on the establishment of the 2012 Breakthrough Therapy Designation, this scientific conference series developed consensus recommendations for challenging aspects to the efficient development a Breakthrough Designated Drug
  - 2013 - A Risk-based Approach for In Vitro Companion Diagnostic Device FDA Approval Process Associated with Therapies that have a Breakthrough Designation
  - 2014 – A Blueprint for Drug/Diagnostic Co-Development: Next-Generation Sequencing (NGS) in Oncology
  - 2015 - Examining Manufacturing Readiness for Breakthrough Drug Development
  - 2016 – Exploring the Utility of Real-world Evidence
  - 2017 – Charting the Course for Precision Medicine
  - 2018 – Research and Reimbursement in the Age of Precision Medicine
  - 2019 – Validating Real-World Endpoints for an Evolving Regulatory Landscape

Collaborations to Develop and Submit Proposed FDA Guidance Documents

- *Co-development of Two or More Unmarketed Investigational Drugs for Use in Combination* (FDA Draft Released 2011)
- *Broadening Eligibility Criteria to Make Clinical Trials More Representative: American Society of Clinical Oncology and Friends of Cancer Research Joint Research Statement.* Kim E, et al. Journal of Clinical Oncology. Vol 35 No. 33, Nov 2017.
    - Expert working groups developed recommendations for expanding cancer clinical trial eligibility related to minimum age for enrollment, patients with HIV, patients with brain metastases, organ dysfunction and prior and current malignancies.
    - FDA Guidance Series Released 2019

Conference on Clinical Cancer Research

A goal-oriented conference that convenes leaders from NCI, FDA, Academia, Industry, and Advocacy to address specific scientific and regulatory issues impacting drug development. This conference series has evolved to the Friends of Cancer Research Annual Meeting (13th Annual) and provided the foundation for future policy initiatives.

SELECTED POLICY & RESEARCH PUBLICATIONS

Stewart M, Keane A, Butterfield L, Levine B, Thompson B, Xu Y, Ramsborg C, Lee A, Kalos M, Koerner C, Moore T, Markovic I, Lasiter L, Ibrahim R, Bluestone J, Sigal E, **Allen J**. ***Accelerating the Development of Innovative Cellular Therapy Products for the Treatment of Cancer***. Cytotherapy. (2019) Meeting Report. Accepted.

Merino D, McShane L, Fabrizio D, Funari V, Chen S, White J, Wenz P, Baden J, Barrett J, Chaudhary R, Chen L, Chen W, Chen J, Cyanam D, Dickey J, Gupta V, Hellmann M, Helman E, Li Y, Maas J, Papin A, Patidar R, Quinn K, Rizvi N, Tae H, Ward C, Xie M, Zehir A, Zhao C, Dietel M, Stenzinger A, Stewart M, **Allen J**. ***Establishing Guidelines to Harmonize Tumor Mutational Burdern (TMB): In Silico Assessment of Variation in TMB Quantification Across Diagnostic Platforms- Phase 1 of the Friends of Cancer Research TMB Harmonization Project.*** Journal for ImmunoTherapy of Cancer. (2019) Original Research Article. Under Review.

Stewart M, Norden A, Dreyer N, Henk H, Abernethy A, Chrischilles E, Kushi L, Mansfield A, Khozin S, Sharon E, Arunajadai S, Carnahan R, Christian J, Miksad R, Sakoda L, Torres A, Valice E, **Allen J**. ***An Exploratory Analysis of Real-World End Points for Assessing Outcomes Among Immunotherapy-Treated Patients with Advanced Non-Small-Cell Lung Cancer****. JCO Clinical Cancer Informatics*. (July 2019) Special Article. 1-15. Doi: 10.1200/cci.18.00155.

Stenzinger A, **Allen J,** Maas J, Stewart M, Merino D, Wempe M, Dietel M. ***Tumor Mutational Burden Standardization Initiatives: Recommendations for Consistent Tumor Mutational Burden Assessment in Clinical Samples to Guide Immunotherapy Treatment Decisions.*** Genes Chromosomes and Cancer. 58: 8. (Jan 2019) 578-88. Research Article. Doi: 10.1002/gcc.22733.

Shea M, Stewart M, Van Dyke H, Ostermann L, Allen J, Sigal E, ***Outdated Prescription Drug Labeling: How FDA-Approved Prescribing Information Lags Behind Real-World Clinical Practice.*** Ther Innov Regul Sci. 52: 6. (Nov 2018) 771-7. Research Article. Doi: 10.1177/2168479018759662

Allen J, Stewart M, Roberts S, Sigal E. ***The Value of Addressing Patient Preferences****.* Value in Health. 20: 2. (Feb 2017) 283-5.

Audibert CM, Shea MB, Glass DJ, Kozak ML, Caze AP, Hohman RM, **Allen JD**, Sigal EV, Leff JS. ***Use of FDA-Approved and Laboratory-Developed Tests in Advanced Non-Small Cell Lung Cancer: Results of a Retrospective Market Analysis****.* Personalized Medicine in Oncology. 5: 7. (Sept 2016) 278-84.

Shea M, **Allen J**, Sigal E. ***A Century of Medical Product Regulation: The Historic Framework for Personalized Medicine in Oncology***. Personalized Medicine in Oncology. (Mar 2016) 1-16.

Shea M, Ostermann L, Hohman R, Roberts S, Kozak M, Dull R, **Allen J**, Sigal E. ***Regulatory Watch: Impact of breakthrough therapy designation on cancer drug development***. Nat Rev Drug Discov. 15: 3. (Mar 2016) 152.

Hohman R, Shea M, Kozak M, Roberts S, **Allen J**, Sigal E. ***Regulatory decision-making meets the real world***. Sci Transl Med. 11: 7 (Nov 2015) 313.

Rubin E, **Allen J**, Nowak J, Bates S. ***Developing Precision Medicine in a Global World***. Clin Cancer Res. 15;20(6) (Mar 2014) 1419-27.

Hayes D, **Allen J**, Compton, C, et al. ***Breaking a Vicious Cycle***. Sci Tans Med 5:196 (July 2013) 1-7.

Roberts S, **Allen J**, Sigal E. ***Despite Criticism of the FDA Review Process, New Cancer Drugs Reach Patients Sooner in the United States than in Europe.*** Health Affairs 30:7 (July 2011) 1375-81.

SCIENTIFIC PUBLICATIONS

Allen J, Khwaja F, Byers S, and Djakiew D. ***The p75^{NTR} Mediates a Bifurcated Signal Transduction Cascade through the NFkB and JNK Pathways to Inhibit Cell Survival*****.** Exp Cell Res (2005) 304(1): 69-80.

Allen J, Khwaja F, and Djakiew D. ***Gene Therapy of Prostate Xenograft Tumors with a p75^{NTR} Lipoplex*****.** Anticancer Res. (2004) 24, 5A: 2997-3004.

Khwaja F, **Allen J**, Andrews P, and Djakiew D. ***Ibuprofen Inhibits Growth of Bladder Cancer Cells by Induced Expression of the p75^{NTR} Tumor Suppressor Protein*****.** Cancer Res (2004) 64: 6207-6213.

Liu X, **Allen JD**, Arnold JT, Blackman MR. ***Lycopene inhibits IGF-I signal transduction and growth in normal prostate epithelial cells by decreasing DHT-modulated IGF-I production in cocultured reactive stromal cells*****.** Carcinogenesis (2008) 29(4):816-23.

Arnold JT, Liu X, **Allen JD**, Le H, McFann KK, Blackman MR. ***Androgen receptor or estrogen receptor-beta blockade alters DHEA-, DHT-, and E(2)-induced proliferation and PSA production in human prostate cancer cells*****. Prostate.** (2007) 67(11):1152-62.

Khwaja F, Tabassum A, **Allen J**, and Djakiew D. **The *p75^{NTR} Tumor Suppressor Induces Ligand Independent Cell Cycle Arrest and Caspase Mediated Apoptosis in Prostate Tumor Cells*****.** Biochemical and Biophysical Research Communications (2006) 341(4):1184-92.

PROFESSIONAL BOARDS & COMMITTEES

Alliance for a Stronger FDA: Board of Directors member, Past President (2015)

American Association for Cancer Research

American Society of Clinical Oncology

Lung-MAP: Policy Leadership Committee Member

National Cancer Institute: *Director's Consumer Liaison Group*, Federal Advisory Committee Member (2010-2013)

President's Council of Advisors on Science and Technology (PCAST): Provisional Working Group Member, Advancing Innovation in Drug Development and Evaluation

SELECTED PRESENTATIONS

Tumor Mutational Burden (TMB): Harmonization and Future Application. Society for Immunotherapy in Cancer Annual Meeting. November 9, 2019

The Use of Real-World Endpoints in Cancer Drug Development. 2019 AMCP Foundation 9th Annual Research Symposium. October 29, 2019

Recent policy initiatives that have helped facilitate drug development for rare cancer population. World Orphan Drug Congress. April 11, 2019

Physician-Built and Evidence-Based: How Electronically Accessible Pathways standardize world-class Cancer Care. 2019 Health Datapalooza. March 27, 2019

Future Directions in Regulatory Policy: The Role of Real World Evidence. 19th Annual AcademyHealth National Health Policy Conference (NHPC) February 4, 2019

Companion Diagnostics: Trends and Perspectives. AdvaMed Med Tech Conference. September 24, 2018

Correlation of real-world endpoints to overall survival among immune checkpoint inhibitor-treated aNSCLC patients. Establishing a Framework to Operationalize and Validate Real-World Data Sets. July 10, 2018

Safeguarding the Public Health: Enhancing Information About Prescription Drugs. Congressional Briefing. March 20, 2018

Patient-Focused Drug Development: Developing and Submitting Proposed Draft Guidance Relating to Patient Experience Data. FDA Public Workshop on Patient-Focused Drug Development. March 19, 2018

Optimizing Early Clinical Strategies to Support Breakthrough Therapy Designation. DIA Annual Meeting. June 21, 2017

Real-World Evidence in Oncology and its Implication. American Association of Cancer Research Annual Meeting. April 1, 2017

FDA Oncology Center of Excellence: Implications for Intercenter Coordination. DIA Combination Products Annual Meeting. October 25, 2016

The Future of Precision Medicine & Patient Care: Policy Solutions to Address the Current Genomic Testing Landscape. Senate Briefing. October 13, 2016