Committee on Energy and Commerce
U.S. House of Representatives

Witness Disclosure Requirement - "Truth in Testimony"
Required by House Rule XI, Clause 2(g)(5)

1. Your Name: Jeff Allen		
2. Your Title: President & CEO		
3. The Entity(ies) You are Representing: Friends of Cancer Research		
4. Are you testifying on behalf of the Federal, or a State or local government entity?	**Yes**	**No** X
5. Please list any Federal grants or contracts, or contracts or payments originating with a foreign government, that you or the entity(ies) you represent have received on or after January 1, 2015. Only grants, contracts, or payments related to the subject matter of the hearing must be listed.		
6. Please attach your curriculum vitae to your completed disclosure form.		

Signature [redacted] **ate: 3/20/17**

Jeff Allen, PhD

EMPLOYMENT HISTORY

President & CEO – Friends of Cancer Research - Present

Manage a leading non-profit cancer research policy and advocacy organization that focuses predominantly on the Food and Drug Administration (FDA). 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.

Executive Director – Friends of Cancer Research – 2008-2016

Led the growth of *Friends*' programs and development to transition the organization from a $900K annual operating budget to the current $3.4M annual operations. Responsibilities include creating and implementing policy agenda, engaging with congressional leaders, federal officials and scientific experts, and coordinating staff for scientific programs, fundraising, communication and media, policy activities and public education symposia.

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

National Center for Complimentary 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 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

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

REGULATORY EXPERIENCE

FDA Oncology Center of Excellence

- Worked with a broad group of stakeholders, including the FDA, to develop and 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 Breakthrough: 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 – Blueprint for Breakthrough: Exploring the Utility of Real-world Evidence

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.

Developed and Submitted draft Guidance Document: *Co-development of Two or More Unmarketed Investigational Drugs for Use in Combination* (FDA Draft Released 2011)

Created and led 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 provided the foundation for future policy initiatives. Past topics include:

5th Annual Conference on Clinical Cancer Research (2012)

Coordinated writing and publication of issue briefs providing recommendations on:

- Developing Standards for Breakthrough Therapy Designation
- Re-Evaluating Criteria for Accelerated Approval
- Design of a Disease-Specific Master Protocol

4th Annual Conference on Clinical Cancer Research (2011)

Coordinated writing and publication of issue briefs providing recommendations on:

- Alternative Trial Designs Based on Tumor Genetics/Pathway Characteristics Instead of Histology
- Evidence for Use of Maintenance Therapy
- Symptom Measurement in Clinical Trials
- Development Paths for New Drugs with Large Effects Seen Early

3rd Annual Conference on Clinical Cancer Research (2010)

Coordinated writing and publication of issue briefs providing recommendations on:

- Use of Adaptive Clinical Trial Designs in Oncology
- Methods for Improved Pre-clinical Safety Testing
- Incorporation of Pain Metrics into Clinical Trials

2nd Annual Conference on Clinical Cancer Research (2009)

Coordinated writing and publication of issue briefs providing recommendations on:

- Blinded Independent Central Review to Reduce Bias for PFS
- Development of 2 New Molecular Entities for Use in Combination

1st Annual Conference on Clinical Cancer Research (2008)

Coordinated writing and publication of issue briefs providing recommendations on:

- Use of Progression-Free Survival (PFS) as an Endpoint
- Co-development of Diagnostics and Therapeutics

POLICY PUBLICATIONS

Allen J, Stewart M, Roberts S, Sigal E. *The Value of Addressing Patient Preferences.* Value in Health. Accepted/In-Press

Audibert CM, Shea MB, Glass DJ, Kozak ML, Caze AP, Hohman RM, **Allen JD**, 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.

Cleeland CS, **Allen JD**, Roberts SA, Brell JM, Giralt SA, Khakoo AY, Kirch RA, Kwitkowski VE, Liao Z, Skillings J. *Reducing the toxicity of cancer therapy: recognizing needs, taking action*. *Nat Rev Clin Oncol*: e-pub ahead of print (July 2012)

Roberts S, Karnes E, **Allen J**, Benner J, Sigal E, McClellan M. *Achieving the Goals of Effective, Safe, and Individualized Cancer Care*. Clinical Cancer Research 17:21 (Nov 2011) 6632-3.

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.

Schilsky R, **Allen J**, Benner J, Sigal E, McClellan M. *Tackling the Challenges for Developing Targeted Therapies for Cancer*. The Oncologist (2010) 15:484-7.

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 ce*lls. 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)

Lung-MAP: Policy Leadership Committee Member

Chemotherapy Infusion Quality Measures Technical Expert Panel: Optimal Solutions, Center for Medicare and Medicaid Services

Food and Drug Administration: *Entrepreneurs in Residence Program*, Strategic Team Member

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

National Patient Advocate Foundation: Global Access Project Committee Member

Multi-Payer Claims Database (MPCD) Governance Board Member: Chair, Data Partner and Community Engagement Subcommittee

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

Regulatory Education and Action for Patients (REAP): Co-chair

SELECTED PRESENTATIONS

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

Design of a Disease specific Master Protocol. Partnering for Cures. November 4, 2013

Lung Cancer Trials in the Genomic Era. National Lung Cancer Partnership Annual Meeting, May 25, 2013

FDA Safety and Innovation Act. BIO Annual Meeting, April 22, 2013

Breakthrough Therapies. BioCentury This Week, December 2, 2012

Regulatory Compliance in Drug/Diagnostic Co-Development. Cambridge Health Institute, August 21, 2012

The Food and Drug Administration Safety & Innovation Act: Breakthrough Therapies and Accelerated Approval. Policy, Advocacy, Engagement and Action Network Forum, May 23, 2012

Prescription Drug User Fee Act (PDUFA). FDA Public Meeting, October 24, 2011

Off Label Drug Use. National Organization for Rare Disorders, October 11, 2011

Translating Data into Improved Patient Care. 19th Annual Association of Community Cancer Centers President's Retreat, February 18, 2011.

The Patient Protection and Affordable Care Act: The Future of Comparative Effectiveness Research. Food and Drug Administration (FDA) Scientific Rounds, December 8, 2010

Comparative Effectiveness Research and the Development of a Linked Data Network. CDISC 2010 Interchange North America. November, 2, 2010

Translational Medicine and Therapeutics: Engaging in a Dialogue with the Public. National Institutes of Health Scientific Management Review Board, September 15, 2010

Harnessing Innovations in Molecular and Regulatory Sciences to Accelerate Cancer Cures. Massachusetts Institute of Technology NEW Drug Development ParadIGmS Initiative (NEWDIGS), September 1, 2010

Opportunities for the Advancement of Regulatory Science. Institutes of Medicine Drug Forum, April 29, 2010

Expanding Multidisciplinary Collaborations to Advance Cancer Research. National Cancer Institute Physical Sciences in Oncology Meeting, April 6, 2010

Impact of Health Reform on Cancer Research and Care. Eastern Cooperative Oncology Group Annual Meeting. June 16, 2010

The Role of Comparative Effectiveness Research in Improving Cancer Care. Association of Community Cancer Centers 36th Annual National Meeting, March 18, 2010