Committee on Energy and Commerce
U.S. House of Representatives
Witness Disclosure Requirement - "Truth in Testimony"
Required by House Rule XI, Clause 2(g)

1. Your Name: CATHERINE WILLETT		
2. Are you testifying on behalf of the Federal, or a State or local government entity?	**Yes**	**No** X
3. Are you testifying on behalf of an entity that is not a government entity?	**Yes** X	**No**
4. Other than yourself, please list which entity or entities you are representing: THE HUMANE SOCIETY OF THE UNITED STATES		
5. Please list any Federal grants or contracts (including subgrants or subcontracts) that <u>you or the entity you represent have received</u> on or after October 1, 2011:		
6. If your answer to the question in item 3 in this form is "yes," please describe your position or representational capacity with the entity or entities you are representing: DIRECTOR OF REGULATORY TOXICOLOGY, RISK ASSESSMENT AND ALTERNATIVES		
7. If your answer to the question in item 3 is "yes," do any of the entities disclosed in item 4 have parent organizations, subsidiaries, or partnerships that you are not representing in your testimony?	**Yes**	**No** X
8. If the answer to the question in item 3 is "yes," please list any Federal grants or contracts (including subgrants or subcontracts) that were received by the entities listed under the question in item 4 on or after October 1, 2011, that exceed 10 percent of the revenue of the entities in the year received, including the source and amount of each grant or contract to be listed:		
9. Please attach your curriculum vitae to your completed disclosure form.		

Signature: [redacted] **Date:** 1 FEB 2014

CATHERINE E. WILLETT, Ph.D.

The Humane Society of the United States
700 Professional Drive
Gaithersburg, MD 20879
240.599.6785
kwillett@humanesociety.org

18 Burr Street
Jamaica Plain, MA 02130
Tel: 617.271.3194
kptnkate@comcast.net

PROFESSIONAL EXPERIENCE

THE HUMANE SOCIETY OF THE UNITED STATES
Director, Regulatory Toxicology, Risk Assessment and Alternatives
Coordinator, Human Toxicology Project Consortium, November 2011 – present

- Provide expertise on national and international programs focusing on replacing the use of animals in chemical assessment with mechanism-based, human-relevant (or target organism relevant) predictive tools, with particular emphasis on pathway-based approaches.
- Coordinate and carry out all functions of the Human Toxicology Project Consortium (HumanToxicologyProject.org). The HTPC has three primary focus areas: education and outreach regarding scientific advances in systems biology and non-animal assessment tools; direct support for the development and use of new scientific tools; and lobbying for policies and funding that support the development and use of these new tools.
- Manage the AltTox.org website dedicated to advancing non-animal methods of toxicity testing through online discussion and information exchange.

PEOPLE FOR THE ETHICAL TREATMENT OF ANIMALS, Norfolk, VA
Associate Director, Regulatory and Testing Division, March 2011 – November 2012
Science Policy Advisor, Regulatory Testing Division, Aug 2006 – 2011

- Dialogue with regulatory agencies, companies, NGOs and academics on chemical safety regulatory policy in the US and internationally, including the US EPA's EDSP, TSCA, FIFRA, REACH and the Cosmetics Directives. Lobby government officials to reduce animal use and promote use of non-animal methods in testing programs. Represent US animal protection interests at the Organization for Economic Cooperation and Development (OECD). Liaise with companies and organizations on PETA-funded validation studies.
- Provide expertise on non-animal alternatives to chemical and pharmaceutical testing
- Oversee staff and review scientific content of department's products

PHYLONIX PHARMACEUTICALS, INC., Cambridge, MA
Senior Scientist, 2000 – 2006
Phylonix Pharmaceuticals is a contract research organization that uses zebrafish as a vertebrate model to screen compounds for the treatment of human cancers, diseases and toxicity.

- Project Director for screening programs for angiogenesis, ocular neovascularization, developmental toxicity, neurotoxicity, and endocrine disruption
- Generation of tissue-specific antibodies for screening and biomarker applications
- Oversight and management of laboratory and aquaculture facilities
- Hiring and managing personnel
- Securing strategic collaborations in the academic, pharmaceutical and biotech communities
- Communicating commercial opportunities for business to financial audiences

MASSACHUSETTS INSTITUTE of TECHNOLOGY, Cambridge, MA
Biology Department & Center for Cancer Research
Postdoctoral Fellow & Research Scientist, 1992 – 1999

- Pioneered research using zebrafish and genetics to study the immune system
- Directed award-winning research by a team of undergraduates and technicians
- Initiated national and international collaborations with several prominent researchers

UNIVERSITY of CALIFORNIA, Davis, CA
Research Assistant & Graduate Research Supervisor, 1986 – 1992

- **Research**: Elucidated regulatory elements in a complicated network controlling the expression of genes involved in central metabolism and identified an essential gene involved in the developmental process of sporulation
- **Graduate Research Supervisor:** Demonstrated proficiency in the supervision of graduate students conducting original research in a laboratory setting

GRADUATE EDUCATION

TUFTS UNIVERSITY, Urban & Environmental Policy, Medford, MA
Certificate in Community Environmental Studies, 2002

UNIVERSITY of CALIFORNIA, Davis, CA
Ph.D. in Genetics, 1992, McKnight Graduate Fellow
Dissertation: Characterization of Elements Regulating Transcription of the *Enolase* Genes of *Saccharomyces cerevisiae &* the Mechanism of *GCR1 C*ontrol

Master of Science in Genetics, 1986, McKnight Graduate Fellow
Thesis: Isolation and Characterization of the *wetA* Locus from *Aspergillus nidulans*

PRINCIPAL INVESTIGATOR GRANTS

- 2005 **NSF SBIR 2-03-535** "Environmental neurotoxicity using zebrafish' $750,000
- 2005 **NIH SBIR 2R44EY015335-02** "A new model for eye disease" $1,015,677
- 2005 **NIH SBIR 1R43EY016916-01** "An ocular neovascularization model" $180,000
- 2004 **NIH SBIR 1R43CA112672-01** "Zebrafish assay for identifying endocrine disruptors' $150,000
- 2004 **NSF SBIR 03-535** "Environmental neurotoxicity using zebrafish' $80,000
- 2003 **NIH SBIR 2R44CA88575-02A**1 "Zebrafish assays for vasculogenesis/ hematopoiesis' $ 1,278,234
- 2002 **NIH SBIR 1R43CA/DK/DA932** "Assay for Determining Drug Toxicity" $216,000
- 2002 **NIH SBIR 1R43CA89774-01** "Assay for Identifying Angiogenic Drug Targets" $150,000
- 2002 **NIH SBIR 1R43CA/GM/ES/Trans-NIH91605-01** "New animal Model for Human Tumor Cell Xenograft" $150,000
- 2001 **NIH SBIR 1R43CA/HL88575-01** "Zebrafish Assay for Vasculogenesis/ Angiogenesis" $200,000
- 2001 **NIH SBIR 2R44CA83556-02** "Novel Method for Organ Toxicity" $850,000
- 2000 **NIH SBIR 1R43CA86181-01** "Pharmacogenomics of Carcinogenesis in Whole Animals" $105,000
- 2000 **NSF SBIR 9960650** "Transcription Profiling for Environmental Toxicity" $105,000

ADVISORY BOARDS AND PANELS

- Royal Dutch Shell Animal Testing External Panel, 2014 - present
- The Institute for In Vitro Sciences – Scientific Advisory Board, 2012 – present
- The International QSAR Foundation, 2006 – 2012

PROFESSIONAL/ACADEMIC ORGANIZATIONS

- Associate Member, Society of Toxicology, 2004 – present
- Society of Environmental Toxicology and Chemistry, 2010 – present
- American Society for Cellular and Computational Toxicology 2011 - present
- European Society for Alternatives to Animal testing, 2011 - present
- Panelist and Facilitator, Office of the Provost's Workshops on Scientific Integrity, MIT, 1997 - 1999
- Representative, Women's Advisory Group, MIT, 1995 - 1998
- Chair, MIT Association for Postdoctoral Women, 1995 - 1996
- Genetics Committee Liaison to the Graduate Council, appointed by Dean of Graduate Division, UC Davis, 1990 - 1991

TEACHING EXPERIENCE

Instructor:	MIT course 7.341: Advanced Undergraduate Seminar in Evolution and Development of the Immune System, 9/96-12/96
Laboratory Supervisor:	Undergraduate Research Supervisor, MIT, 3/93 - 9/98 Graduate Research Supervisor, UC Davis, 9/90 - 9/92
Teaching Assistant:	Immunology, MIT, 9/93 - 12/93 Introductory Biochemistry, UC Davis, 1/90-6/92 General Genetics, UC Davis, 7/89 - 9/89 Fungal Molecular Biology, UC Davis, 9/86 -12/86 General Genetics, UC Davis, 1/86 - 4/86 Bacterial Genetics, UC Davis, 9/85 - 12/85

AWARDS AND HONORS

- Postdoctoral Fellow, NIH Research Service Award, 1995
- Postdoctoral Fellow, Immunology Training Grant, MIT, 1992-1994
- McKnight Graduate Fellow, UC Davis, 1984 - 1989
- Received B.S. with High Honors, N.M.I.M.T. 1982
- Regent's Scholar, N.M.I.M.T., 1981-1982
- Tri Beta Society (Biology Honorary), 1981-1982
- Presidential Scholar, U.N.M., 1978 -1980

SELECTED PRESENTATIONS and PUBLICATIONS

Bishop, P.L. and **C.E. Willett**. 2013. The Use and Acceptance of Other Scientifically Relevant Information (OSRI) in the U.S. Environmental Protection Agency (EPA) Endocrine Disruptor Screening Program. Birth Defects Res B Dev Reprod Toxicol. Oct 22, 2013. doi: 10.1002/bdrb.21077. [Epub ahead of print].

Vinken M, Landesmann B, Goumenou M, Vinken S, Shah I, Jaeschke H, **Willett C**, Whelan M, Rogiers V. (2013) Development of an adverse outcome pathway from drug-mediated bile salt export pump inhibition to cholestatic liver injury. Toxicological Sciences: published online August 14, 2013 doi:10.1093/toxsci/kft177.

Daland J, Borghoff S, Becker RA, Casey W, Hartung T, Holsappl, M, Marty S, Mihaich E, Van Der Kraak G, Wade MG, **Willett, K.,** Andersen M, Borgert C, Coady K, Di, D, Dourson M, Gray E,Lamb J, Ortego L, Schug T, Toole C, Zorrilla L, Kroner O, Patterson J, Rincke L, and B Jones (2013). Workshop Report: Lessons Learned, Challenges, and Opportunities: The U.S. Endocrine Disruptor Screening Program, ALTEX. 2013 Oct 10. pii: S1868696X1309271X. [Epub ahead of print].

Jacobs, M.N., Laws, SC.**, Willett, K.,** Schmieder, P., Odum, J., Bovee, T.F. 2013. *In vitro* metabolism and bioavailability tests for endocrine active substances: What is needed next for regulatory purposes? ALTEX. 30(3):331-51.

Kleensang A, Maertens A, Rosenberg M, Fitzpatrick S, Lamb J, Auerbach S, Brennan R, Crofton K, Gordon B, Fornace A, Gaido K, Gerhold D, Haw R, Henney A, Ma'ayan A, McBride M, Monti S, Ochs M, Pandey A, Sharan R, Stierum R, Tugendreich S, **Willett C,** Wittwehr C, Xia J, Patton GW, Arvidson, Bouhifd M, Hogberg HT, Luechtefeld T, Smirnova L, Zhao L, Adeleye Y, Kanehisa M, Carmichael P, Andersen M, Hartung T. 2013. t4 workshop report: Pathways of Toxicity ALTEX. 2013 Oct 15. pii: S1868696X1309261X. [Epub ahead of print].

Willett, C. 2013. Pathway-based Approaches to Safety Assessment: Development and Use. Presented at the IVTIP Spring 2013 Meeting '2013: State of the art on alternatives from an industrial point of view: ready for regulation?' May 15-16, 2013, Southampton, UK.

Willett, C. Evolving Approaches to AOP Development: Observations from MOA Frameworks to Systems Biology. SEURAT-1 Workshop: Liver Toxicity Adverse Outcome Pathways, 25-26 October 2012, Ispra, Italy.

Willett, C. 2012. The AOP Approach Applied to REACH axlr8-progress-report-2012, in: Alternative Testing Strategies: Progress Report 2012 & AXLR8-3 Workshop Report on a 'Roadmap to Next Generation Safety Testing Under Horizon 2020,' eds. Troy Seidle and Horst Spielmann, AXLR8 Consortium, 2012.

Willett, C. 2012. Highlighting the Need for AOPs in Streamlining Hazard Assessment Methods for Cancer Assessment. Presented at the 2nd McKim Workshop on Reducing Data Redundancy in Cancer Assessment, May 8 – 12, 2012, Baltimore, MD

Bishop PL, Manuppello JR, **Willett CE, JT** Sandler. 2012. Animal use and lessons learned in the US High production volume chemicals challenge program. Environ Health Perspect. 2012 Dec;120(12):1631-9

Willett, C., Bishop, P., and K. Sullivan. 2011. Application of an Integrated Testing Strategy to the US EPA Endocrine Disruptor Screening Program. Tox. Sci. 123(1):15-25.

K. Sullivan, K., Beck, N., C. Sandusky and **C. Willett**. 2011. A discussion of the impact of us chemical regulation legislation on the field of toxicity testing. Toxicology in Vitro. Sep;25(6):1231-6.

Willett, C., Bishop P., K. Sullivan. 2011. A Strategy for Reducing Animal Use in the U.S. EPA's Endocrine Disruption Screening Program. 8th World Congress on Alternatives & Animal Use in the Life Sciences, August 21 – 25. Montreal, Canada.

Beck N, Sullivan, K., and **C. Willett**. Options for Increased Regulatory Oversight of Cosmetics in the U.S. 50th Annual Meeting of the Society of Toxicology, March 6 - 10, 2011. Washington, DC.

Ankley, G., Embry, M., Gourmelon, A., Iguchi, T., Maack, G., Matthiessen, P., Musset, L., Touart, L., Wheeler, J., and **C. Willett**. The OECD fish testing framework project: Summary of workshop recommendations. 21st SETAC Europe Annual Meeting, 15 – 19 May, Milan, Italy.

Willett C., Beck, N., Brown, J., Manuppello, J., and K. Sullivan. Fulfilling Data Requirements for the U.S. EPA Endocrine Disruptor Screening Program using Existing and Non-Traditional Data. 49th Annual Meeting of the Society of Toxicology, March 7 - 11, 2010. Salt Lake City, Utah.

Sullivan, K. Beck, N., **Willett, C.** and C. Sandusky. An Examination of New Chemical Regulation Policies as a Means to Revolutionize Toxicity Testing. 7th World Congress on Alternatives & Animal Use in the Life Sciences, August 31 – September 3, Rome, Italy.

Manuppello, J., **Willett, C.** and J. Sandler. The U.S. Environmental Protection Agency's High Production Volume Challenge Program: Lessons Learned. 7th World Congress on Alternatives & Animal Use in the Life Sciences, August 31 – September 3, Rome, Italy.

Willett, C. and Rizutto, P. REACH and the Future of Toxics Legislation. Special Libraries Association 2009 Annual Conference & INFO-EXPO, 16 June 2009. Washington, DC

Willett, C.E. and K. Sullivan. Application of an intelligent testing strategy to the US EPA Endocrine Disruptor Screening Program. 48th Annual Meeting of the Society of Toxicology, March 15–19, 2009, Baltimore, Maryland**.**

Willett, C.E., Timm, G. and D. Dietrich. An approach for expedited validation of "me-too" in vitro methods. ESTIV 2008, The 15th International Congress on In vitro Toxicology, September 25 – 28, 2008, Stockholm, Sweden.

Willett, C.E. and S. Gala. Alternative Methods for Use in Medical Training. 6th World Congress on Alternatives & Animal Use in the Life Sciences, August 21 - 25, Tokyo, Japan.

Willett, C.E, Manupello, J. and T. Seidle. Potential economic and animal welfare advantages associated with the use of alternative methods in regulatory safety testing. ILSI/HESI DART In Vitro Assays Workshop, February 27 - 28, 2007, Cary, NC.

Ton. C, Lin Y, and **Willett, C**. 2006. Zebrafish as a model for developmental neurotoxicity testing. Birth Defects Res A Clin Mol Teratol. 76(7):553-567

Willett, C., The Use of Zebrafish in Preclinical Drug Testing. 28th Annual Meeting of the Molecular Biology Society of Japan, December 7 – 11, 2005. Fukuoka, Japan.

Willett, C. and M. Haldi**,** Zebrafish Model of Eye Neovascularization. CHI Discovery on Target, Animal Models, Boston, MA, October 18 – 19, 2005.

Danilova, N., Visel, A., **Willett, C. E**. and L. A. Steiner. 2004. Expression of the winged helix/forkhead gene, foxn4, during zebrafish development. Dev. Brain Res. 153: 115-119.

Danilova, N., Hohman, V. S., Sacher, F., Ota, T., **Willett, C. E**., and L. A. Steiner. 2004. T cells and the thymus in developing zebrafish. Devel. Comp. Immunol. 28(7-8):755-67.

Danilova, N., **Willett, C.E**., and Steiner, L.A. 2004. Review: The Immune System of Zebrafish. In: Molecular Biology of B Cells. F.W. Alt, T. Hongo, and M.S. Neuberger, eds.

Ma, C., Parng, C., Seng, W.L., Zhang, C., **Willett, C.**, and McGrath, P. 2003. Zebrafish – an *in vivo* model for drug screening. Innovations in Pharmaceutical Technologies. November: 38-45.

Willett, C., Target Validation in Zebrafish using RNA Interference. Drug Discovery Series: IBC's Inaugural Conference on RNA Interference, San Diego, CA, February 10-11, 2003.

Willett, C., Whole Embryo Assays. CHI Genomics on Target. Genomic Animal Models, Boston, MA, November 18– 21, 2002.

Willett, C., Zebrafish: A Good Model for Drug Screening. Drug Discovery Series. IBC's inaugural Conference on Model Organisms for Drug Discovery, Boston, MA, August 8-9, 2002.

Willett, C., Montgomery, J., Lee, J., Eng, K. and Seng, W.L. Gene profiling angiogenic activity in zebrafish. Fifth International Conference on Zebrafish Development & Genetics, June 12-16, 2002, Madison, WI.

Willett, C. E., Kawasaki, H., Amemiya, C. Lin, S. and L. Steiner. 2001. *Ikaros* expression as a marker for lymphoid progenitors during zebrafish development. *Dev. Dynamics*, **222** (4):694-698.

Willett, C. E., Zebrafish as a Model for Environmental Testing. The Silent Spring Institute, Newton MA. August 16, 2001**.**

Willett, C. E., and W. Seng. Zebrafish as a model for angiogenesis drug screening. National Cancer Institiute, National Institiutes of Health, Bethesda, MD, July 26, 2001.

Willett, C. E., Zebrafish as a Model for Environmental Testing. Menzie-Cura and Associates, Chelmsford, MA, July 16, 2001.

Willett, C. E., Seng, W., and G. Serbedzija. Zebrafish as a model for angiogenesis drug screening. Genzyme Corporation, Framingham, MA, May 30, 2001.

Serbedzija, G. N., Flynn, E. and **C. E. Willett.** 2000. Zebrafish Angiogenesis: a New Model for Drug Screening. *Angiogenesis*, 3 (4):353-359.

Jessen, J., **Willett, C. E.** and S. Lin. 1999. Artificial chromosome transgenesis reveals long-distance negative regulation of *rag1* in zebrafish. *Nature Genetics* **23**:15-16.

Willett, C. E., Cortes, A., Zuasti, A., and A. G. Zapata. 1999. Early hematopoiesis and developing lymphoid organs in the zebrafish. *Dev. Dynamics* **214**:323-336.

Willett, C. E., J. J. Cherry, A. G. Zapata, N. Hopkins and L. A. Steiner. Expression of the *Rag* Genes During Early Development Identifies the Zebrafish Thymus. Presented at the 7th congress of the International Society of Developmental and Comparative Immunology, Williamsburg, VA, July 21 - 25, 1997.

Willett, C. E.. Mutational Analysis of Complexity in Zebrafish Development. Presented at the International Conference on Complex Systems, Nashua, NH, September 22, 1997.

Willett, C. E., A. G. Zapata, N. Hopkins and L. A. Steiner. 1997. Expression of the *Rag* Genes During Early Development Identifies the Zebrafish Thymus. *Dev. Biol*. **182**, 331.

Willett, C. E., J. J. Cherry, N. Hopkins and L. A. Steiner. Early Development of the Zebrafish Immune System. Presented at the course in Developmental Immunology, Hebrew University, April 14 - 19, 1996, Jerusalem, Israel.

Willett, C. E., J. J. Cherry, N. Hopkins and L. A. Steiner. Expression of the *Rag* Genes During Zebrafish Development. Presented at "Zebrafish Development and Genetics", April 24 - 28, 1996, Cold Spring Harbor Lab, Cold Spring Harbor, NY.

Willett, C. E., J. J. Cherry, A. G. Zapata, N. Hopkins and L.A. Steiner. Developmental Biology of the Zebrafish Immune System. Presented at the Institute for Molecular and Genetic Medicine, Medical College of Georgia, Augusta, GA, November 9, 1996.