

# National Toxicology Program Director's Report

Linda Birnbaum, Ph.D., D.A.B.T., A.T.S.  
Director  
National Institute of Environmental Health Sciences  
National Toxicology Program

NTP Board of Scientific Counselors Meeting  
December 7-8, 2017





# Congressional Appropriations Comparison Table

	FY 2015 Omnibus Appropriation	FY 2016 Omnibus Appropriation	FY 2017 Omnibus Appropriation	FY 2018 President's Request	FY 2018 House-Passed Appropriations	FY 2018 Senate Appropriations Committee
<b>NIEHS</b>	\$ 667,333,000 <sup>a/</sup>	\$ 693,533,000 <sup>a/</sup>	\$ 714,261,000	\$ 533,537,000	\$ 725,387,000	\$ 737,727,000
<b>Ebola (via CDC)<sup>b/</sup></b>	\$ 10,000,000					
<b>NIH (LHHS)<sup>c/</sup></b>	\$30,084,000,000	\$32,084,000,000	\$34,084,000,000	\$26,701,103,000	\$35,184,000,000	\$36,084,000,000
<b>Common Fund<sup>d/</sup></b>	\$ 545,639,000	\$ 675,639,000	\$ 695,456,000	\$ 454,423,000	\$ 695,580,000	\$ 587,890,000 <sup>e/</sup>
<b>Superfund</b>	\$ 77,349,000	\$ 77,349,000	\$ 77,349,000	\$ 59,607,000	\$ 76,349,000	\$ 77,349,000
<b>NIEHS/DOE Training</b>	\$ 10,000,000	\$ 10,000,000	\$ 10,000,000			Report Language

a/ Reduced by \$169,000 transfer to the NIH Office of AIDS Research.

b/ Transfer from CDC Ebola Emergency Response appropriation to NIEHS to remain available through FY 2019.

c/ Excludes Mandatory Type 1 Diabetes Research and Superfund.

d/ Includes addition of \$12.6 million for the Gabriella Miller Kids First Act pediatric research initiative.

e/ Excludes \$60 million "All of US" Precision Medicine funding which the committee moved to the NIH OD.



## FY2018 Appropriations – Key Decision Points

- **Resolution Needed on “Budget Caps”** –
  - Sets “Topline Numbers” for the 12 appropriations bills
  - House and Senate versions differ on “topline numbers”
  - “Budget Control Act of 2011” (BCA) still law

FY2018 Budget	Defense Spending	Non-Defense Spending
<b>BCA Cap</b> (current law)	\$549.5 billion	\$516 billion
<b>FY18 House Budget Resolution</b>	\$621.5 billion	\$511 billion
Δ	<b>\$72 billion over (↑)</b>	\$5 billion under (↓)

- Absent amendment to the BCA, Sequestration Triggered
- Negotiations are in progress with goal to conclude by Dec. 22



## FY2018 Appropriations

### How NIEHS fits in the big picture...

- **Resolution Needed on “Budget Caps”**
  - Amendment to *Budget Control Act* to avoid Sequestration
- **Reconciliation of 12 appropriations bills**
  - Likely Passage in form of an “Omnibus”

FY2018 Proposals	House Bill	Senate Bill	Δ Between House and Senate
<b>Labor, HHS, Education Bill Topline Amount</b>	\$156 billion (\$5 billion ↓ FY17)	\$164.1 billion (\$3 billion ↑ FY17)	\$8.1 billion
<b>NIH vs FY17 Enacted</b>	\$1.1 billion ↑	\$2 billion ↑	\$0.9 billion
<b>NIEHS vs FY17 Enacted (excludes SRP &amp; WTP)</b>	\$11.126 million ↑	\$23.466 million ↑	\$12.34 million

- **Debt Ceiling Deadline – Extended until ~March 2018**
- **3rd Disaster Relief Supplemental Appropriations ?**



## Latest Legislative Developments

---

- *Airplanes Health Impact Study*
  - Folded into “FAA Reauthorization bill”
  - Requires FAA to fund NIEHS grantee for an health impacts study
- *Federal Accountability in Chemical Testing Act (FACT Act)*
  - Requires ICCVAM to publicly report animal use data
  - Pending in House (63 cosponsors)
  - NTP/NICEATM briefing provided in May
- *PFAS Provisions in National Defense Authorization Act (NDAA)*
  - Authorizes DOD-funded CDC health impacts study
  - Requires DOD to remediate contaminated drinking water
  - Requires DOD to work on AFFF replacement chemicals





## Congressional Briefings by Friends of NIEHS:

---

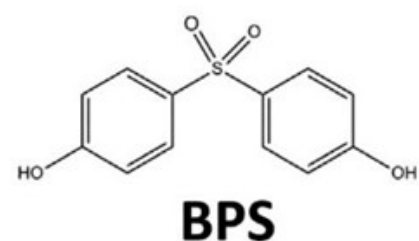
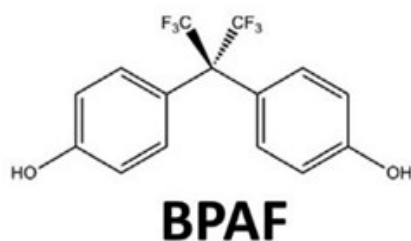
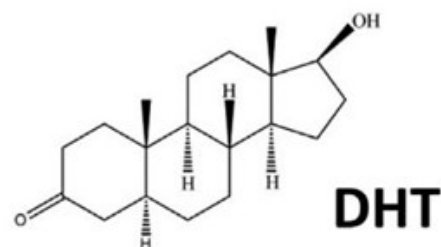
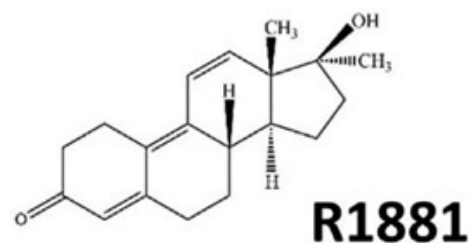
- **Environmental Factors and Autoimmune Diseases**
  - Held on October 12, four speakers:
    - Dr. Rick Woychik, NIEHS Deputy Director
    - Dr. Fred Miller, NIEHS Clinical Research Branch
    - **Dr. Dori Germolec, NIEHS NTP Division**
      - Highlighted PFAS work
    - Dr. John Barnett, NIEHS grantee at WVU
- **Environmental Factors and Neurological Diseases**
  - Planned for March 2018
  - Michael J. Fox Foundation partnering to sponsor



## One NIEHS

### ***Binding of Bisphenol A, Bisphenol AF, and Bisphenol S on the Androgen Receptor: Coregulator Recruitment and Stimulation of Potential Interaction Sites.***

Perera L (DIR), Li Y (DIR), Coons LA, Houtman R, van Beuningen R, Goodwin B, Auerbach SS (DNTP) and Teng CT (DNTP). *Toxicology in vitro* 2017 Oct;44:287-302



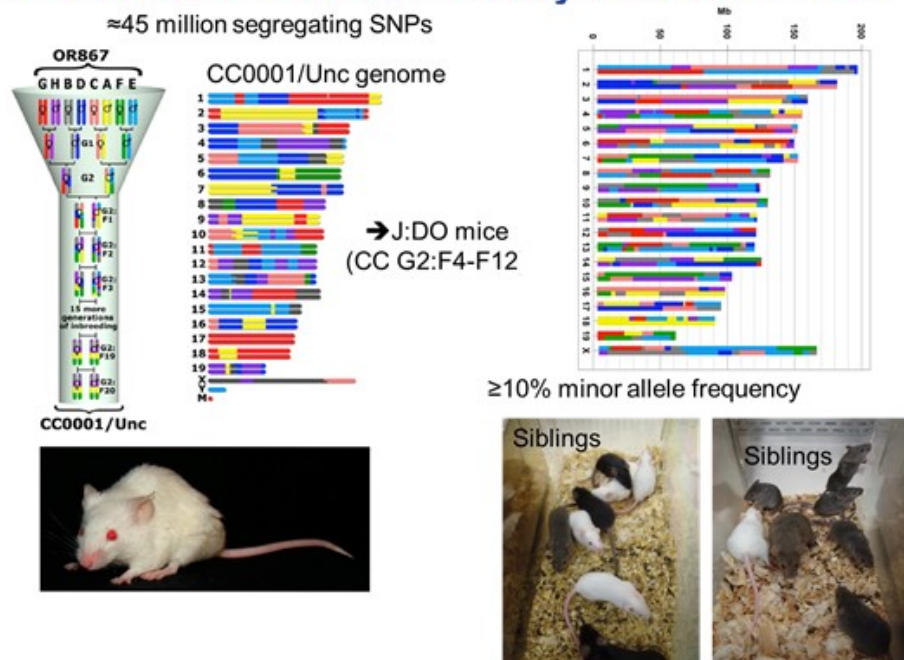


## One NIEHS

***New rodent population models may inform human health risk assessment and identification of genetic susceptibility to environmental exposures.***

Harrill AH (DNTP) and McAllister KA (DERT). *Environ. Health Perspect.* 2017 Aug 15;125(8):086002. [ePub]

### Collaborative Cross & Diversity Outbred models



Exposure  
Assessment

Hazard ID

Dose Response

Mode of Action





### DNTP

**Systematic Review of Community Health Impacts of Mountaintop Removal Mining.** Boyles AL (DNTP), Blain RB, Rochester JR, Avanası R, Goldhaber SB, McComb S, Holmgren SD (DNTP), Masten SA (DNTP) and Thayer KA. *Environment International* (2017) v. 107 pp. 163-172. (SP Goal 4, 5, 7)

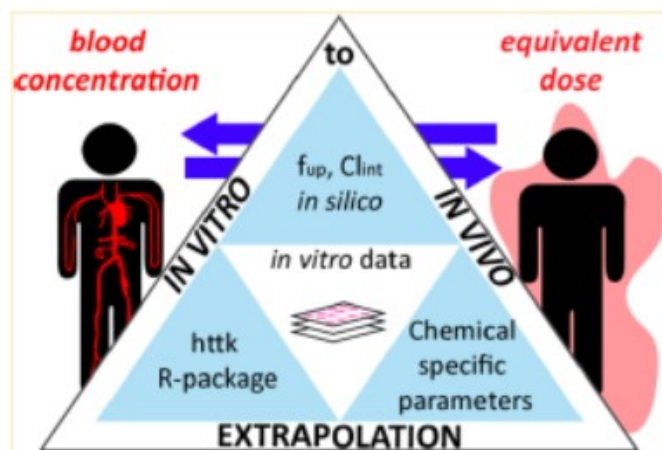




### DNTP

- An Intuitive Approach for Predicting Potential Human Health Risk with the Tox21 10k Library.***

Sipes NS (DNTP), JF Wambaugh, R Pearce, SS Auerbach (DNTP), BA Wetmore, JH Hsieh (DNTP), AJ Shapiro (DNTP), D Svoboda, MJ DeVito (DNTP) and SS Ferguson (DNTP). *Environ Sci Technol.* **2017**, 51 (18), pp 10786–10796





### DNTP

- ***Three-Dimensional (3D) HepaRG Spheroid Model with Physiologically Relevant Xenobiotic Metabolism Competence and Hepatocyte Functionality for Liver Toxicity Screening.***

Ramaiahgari SC, S Waidyanatha, D Dixon, MJ DeVito, RS Paules and SS Ferguson. *Toxicol Sci* (2017) v. 159 (1): pp. 124-136

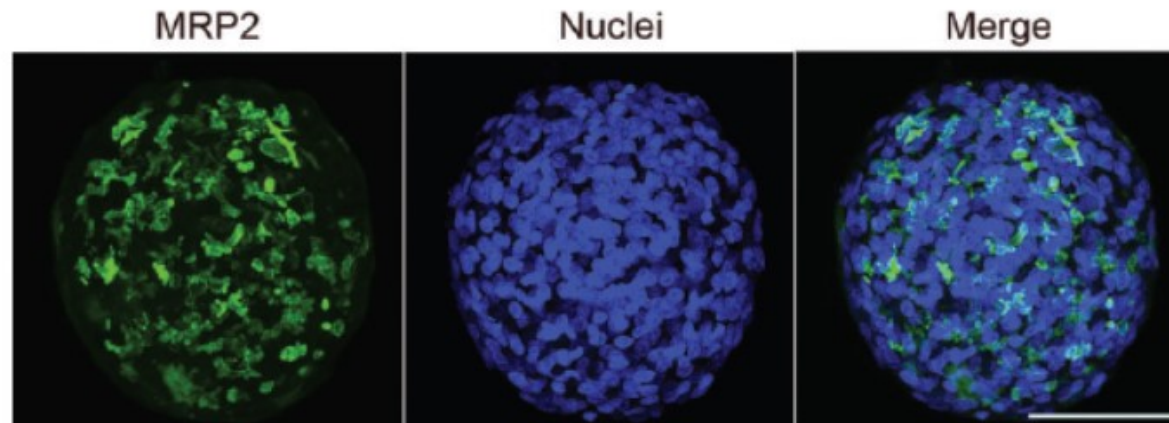


Figure 3. MRP2 localization in HepaRG spheroids. Immunofluorescent staining of MRP2 (green) and nuclei (blue) on HepaRG spheroids (scale bar 100  $\mu$ m).

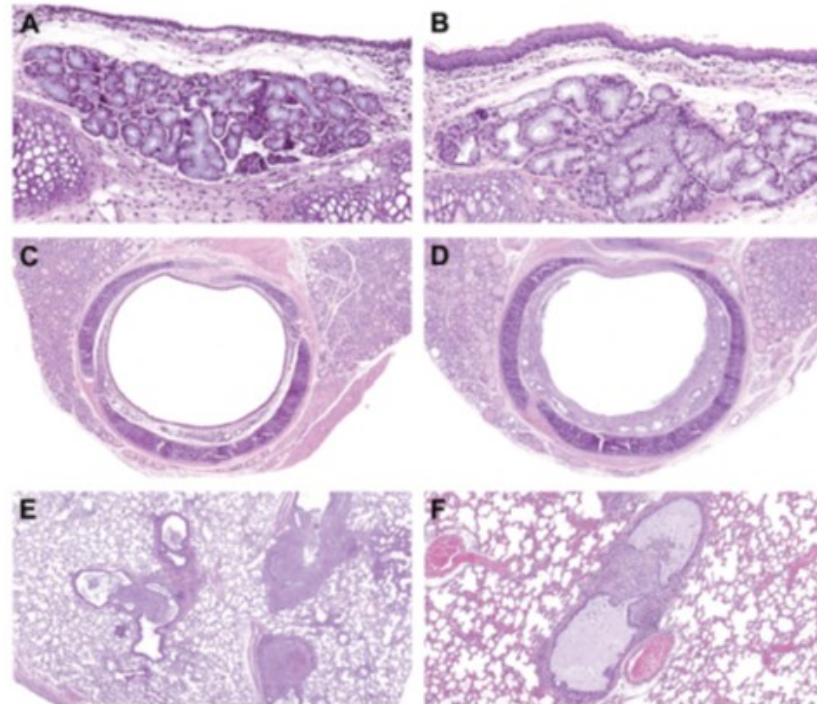




### DNTP

**Evaluation of the respiratory tract toxicity of ortho-phthalaldehyde, a proposed alternative for the chemical disinfectant glutaraldehyde.**

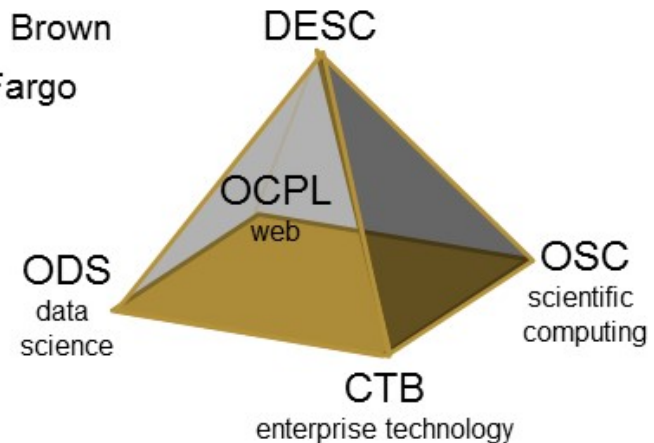
Catlin NR (DNTP), Willson CJ, Stout M (DNTP), Kissling GE (DNTP), Waidyanatha (DNTP), Baker GL, Hayden BK, and Wyde M (DNTP). *Inhal Toxicol* (2017) v. 29 pp. 414-427.





### NIEHS IT Leadership – Office of Environmental Science Cyberinfrastructure (OESC)

- Interim Director of Environmental Science Cyberinfrastructure (DESC), Jeff Shilling (NCI)
- Interim DESC provides matrix leadership for the “**Group of Four**”
  - **Computer Technology Branch (CTB)**, Bernard Brown
  - **Office of Scientific Computing (OSC)**, David Fargo
  - **Office of Data Science (ODS)**, Stephanie Holmgren (Acting Director)
  - **Office of Communication and Public Liaison (OCPL)**, Christine Flowers



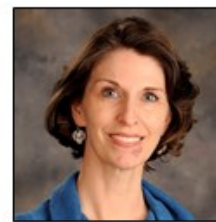
Jeff Shilling  
OESC



Bernard Brown  
CTB



David Fargo  
OSC



Stephanie Holmgren  
ODS



Christine Flowers  
OCPL (Web)





## NIEHS Highlights

### Relmagine HHS Initiatives

- Restoring Market Forces
- Putting People at the Center of HHS Programs
- Leveraging the Power of Data
- Turning HHS into a More Innovative and Responsive Organization
- Generating Efficiencies through Streamlined Processes
- Moving to a 21<sup>st</sup> Century Workforce



Former HHS Director,  
Tom Price



Acting Assistant  
Secretary for  
Health,  
Don Wright



Acting Secretary and  
Deputy Secretary of HHS,  
Eric D. Hargan



### Hiring “Freeze” Update

- Limited Authorities:
  - Exempted positions necessary to meet national security/ cybersecurity, public safety, critical infrastructure, direct patient care
  - Lateral Reassignments and Details
  - Pathways and Presidential Management Fellows
  - PHS Commissioned Corps
  - Very limited NIH-wide needs (contract specialists)





## HHS Approved Selection

---

### Incoming Associate Director of NTP and Scientific Director of DNTP



Dr. Brian Berridge, D.V.M., Ph.D, D.A.C.V.P.



### Strategic Planning Current Status

- **New NIEHS Strategic Plan**

- NIEHS Leadership currently reviewing input, establishing organization of the new Plan
- Publication of draft framework and objectives for the new Plan scheduled for end of January 2018
- Draft will be posted on the NIEHS Website and comments accepted until early March
- Text will be subsequently finalized and shared with advisory committees
- Publication of new Plan anticipated in Fall 2018





### **Recent Events:**

- Peer Review of the Draft RoC Monograph on Haloacetic Acids found as Water Disinfection By-Products, NIEHS, July 24
- 4th International Symposium on Systematic Review and Meta-Analysis of Laboratory Animal Studies, NIEHS, August 24-25
- North Carolina Society of Toxicology Annual Meeting, October 30
- Understanding Pathways to a Paradigm Shift in Toxicity Testing and Decision Making, November 20-21







### **Upcoming Events:**

- The Promise of Genome Editing Tools to Advance Environmental Health Research, Jan 10-11
- Peer Review of the Draft Report on Carcinogens Monograph on Antimony Trioxide, Jan 24
- Informing Environmental Health Decision Through Data Integration, Feb 20-21
- Building a Better Epithelium: Breaking the Barrier to the Next Generation of Toxicity Testing, March 10
- Society of Toxicology 57<sup>th</sup> Annual Meeting and ToxExpo, March 11-15
- Keystone Symposia on Molecular and Cellular Biology: Organs-and Tissues-on-Chips, April 8-12

# Thank You!

