UNITED STATES ICCVAM Advancing alternatives to animal testing

Interagency Coordinating Committee on the Validation of Alternative Methods

Creating a 3Rs Roadmap and Strategy for the United States

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NIEHS / NTP

SACATM Meeting, September 2, 2015
Research Triangle Park, NC

Agency for Toxic Substances and Disease Registry • Consumer Product Safety Commission • Department of Agriculture
Department of Defense • Department of Energy • Department of the Interior • Department of Transportation
Environmental Protection Agency • Food and Drug Administration • National Institute for Occupational Safety and Health
National Institutes of Health • National Cancer Institute • National Institute of Environmental Health Sciences
National Library of Medicine • Occupational Safety and Health Administration

Why?

NTP Strategy document *"A Roadmap for the Future*" (2004)

"The strategy will also provide a long-term vision that **moves toxicology away from an animal-based enterprise**, including developing non-mammalian models."

NAS Report, Toxicity Testing in the 21st Century: A Vision and a Strategy (2007)

"Moving Toxicology from observational to predictive science" Advances in toxicogenomics, bioinformatics, systems biology, epigenetics, and computational toxicology could **transform toxicity testing from a system based on whole-animal testing** to one founded primarily on in vitro methods that evaluate changes in biologic processes using cells, cell lines, or cellular components, preferably of human origin.

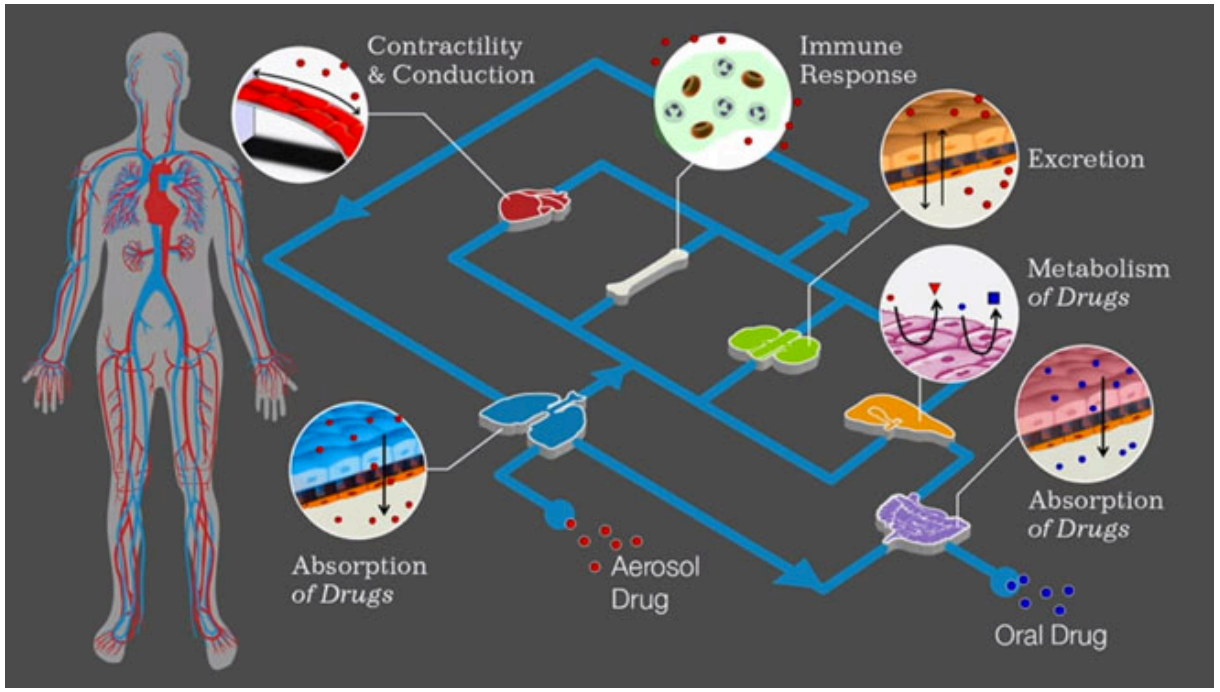
Tox21 Interagency Collaboration, (2008-present)

"Tox21 researchers aim to develop better toxicity assessment methods to **quickly and efficiently test whether certain chemical compounds have the potential to disrupt processes in the human body** that may lead to negative health effects."

Why?

Significant investments being made by Federal Government.

DARPA / NIH ~$145M



http://thenewstack.io/organs-on-chips-emulates-human-organs-for-better-biomedical-testing/

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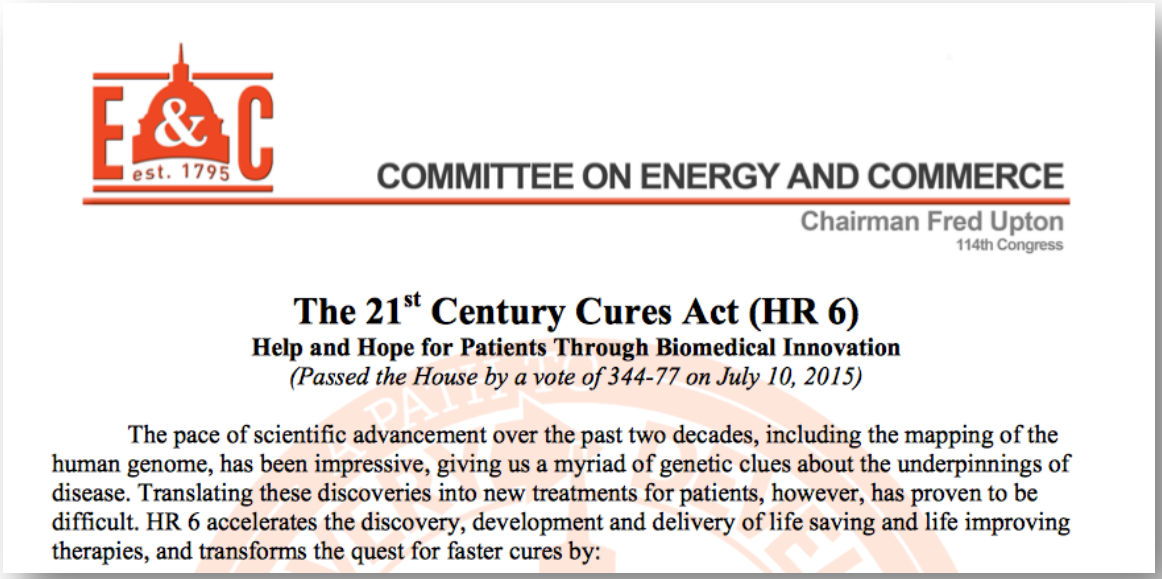

COMMITTEE ON ENERGY AND COMMERCE

Chairman Fred Upton

114th Congress

The 21st Century Cures Act (HR 6)

Help and Hope for Patients Through Biomedical Innovation

(Passed the House by a vote of 344-77 on July 10, 2015)

The pace of scientific advancement over the past two decades, including the mapping of the human genome, has been impressive, giving us a myriad of genetic clues about the underpinnings of disease. Translating these discoveries into new treatments for patients, however, has proven to be difficult. HR 6 accelerates the discovery, development and delivery of life saving and life improving therapies, and transforms the quest for faster cures by:

CBO estimates that implementing the legislation would cost **$106.4 billion over the 2016-2020** period

H.R. 6 would authorize appropriations for the National Institutes of Health (NIH), the Food and Drug Administration (FDA), and other agencies within the Department of Health and Human Services (HHS) for programs aimed at **promoting the discovery and development of drugs and other technologies that prevent, diagnose, and treat disease** or to support activities authorized by the legislation. The bill also would make related changes to those agencies' programs.

What are the drivers?

Public Health

Economics

Ethics

Core Principle

Development, validation, and adoption of predictive, human-based, test methods requires multiple stakeholders all working with specific intent.

Challenges

- Coordination
- Animals as the gold standard / access to human data
- Institutional inertia favors animal models
- Developing a transition plan
- Funding Strategic Investments

Stakeholders

- US Gov / Agencies (HHS)
- Industry (Pharma)
- NGOs
- International Partners
- Many others

Questions for SACATM

- Is a national 3Rs strategy and roadmap needed?
- If so, what process should be considered for developing a national strategy and what government agencies, industries, NGOs and other organizations should be involved?
- What mechanisms (public-private partnerships, strategic funding, international activities, new metrics, etc.) should be considered for leveraging United States-based activities to help advance the 3Rs?

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Duties of ICCVAM

- (1) Review and evaluate new, revised, or alternative test methods
- (2) Facilitate appropriate interagency and international harmonization of toxicological test protocols that encourage the reduction, refinement, or replacement of animal test methods.
- (3) Facilitate and provide guidance on the development of validation criteria, validation studies and processes for new or revised or alternative test methods and help facilitate the acceptance of such scientifically valid test methods and awareness of accepted test methods by Federal agencies and other stakeholders.
- (4) Submit ICCVAM test recommendations for the test method reviewed by the ICCVAM, through expeditious transmittal by the Secretary of Health and Human Services, to each appropriate Federal agency
- (5) Consider for review and evaluation, petitions received from the public that—
  - (A) identify a specific regulation, recommendation, or guideline regarding a regulatory mandate; and
  - (B) recommend new or revised or alternative test methods and provide valid scientific evidence of the poten tial of the test method.
- (6) Make available to the public final ICCVAM test recommendations to appropriate Federal agencies and the responses from the agencies regarding such recommendations. (7) Prepare reports to be made available to the public on its progress under this Act. The first report shall be completed not later than 12 months after the date of the enactment of this Act, and subsequent reports shall be completed biennially thereafter.