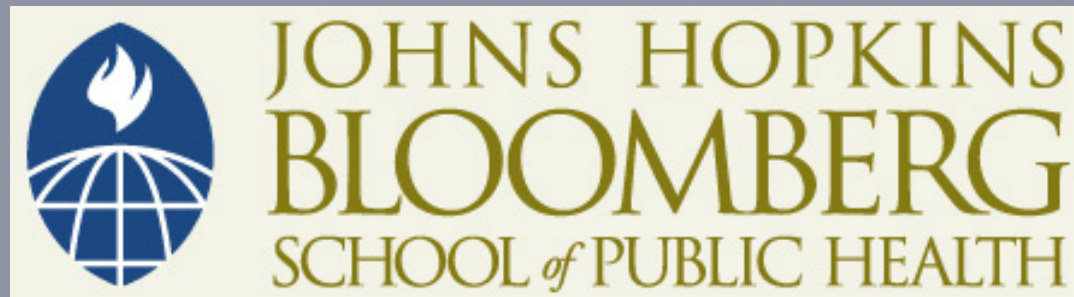


This work is licensed under a [Creative Commons Attribution-NonCommercial-ShareAlike License](https://creativecommons.org/licenses/by-nc-sa/4.0/). Your use of this material constitutes acceptance of that license and the conditions of use of materials on this site.



Copyright 2010, The Johns Hopkins University and Alan M. Goldberg. All rights reserved. Use of these materials permitted only in accordance with license rights granted. Materials provided "AS IS"; no representations or warranties provided. User assumes all responsibility for use, and all liability related thereto, and must independently review all materials for accuracy and efficacy. May contain materials owned by others. User is responsible for obtaining permissions for use from third parties as needed.



JOHNS HOPKINS
BLOOMBERG
SCHOOL *of* PUBLIC HEALTH

International Issues in Humane Science

Alan M. Goldberg, PhD
Johns Hopkins University



JOHNS HOPKINS
BLOOMBERG
SCHOOL *of* PUBLIC HEALTH

Introduction to Alan M. Goldberg, PhD

Paul A. Locke, DrPH, MPH, JD
Johns Hopkins University

Contents

- U.S.
 - Setting the stage
 - ▶ 2006-2008: tipping point

- E.U.
 - Comparison: E.U. vs. U.S.
 - Animal welfare

- Canada
 - CCAC

- Japan
 - Memorial service



JOHNS HOPKINS
BLOOMBERG
SCHOOL *of* PUBLIC HEALTH

Section A

The U.S.

Setting the Stage ...

- Intensive care unit
- Report to Congress
- AAAS 1983 and 2008

Setting the Stage ...

- Intensive care unit
- Report to Congress
- AAAS 1983 and 2008

Why Now?

- Number of chemicals
- Diseases with unknown causes
- Legislative mandate
- Billions of dollars (NIH) for translational research
- More humane, better science

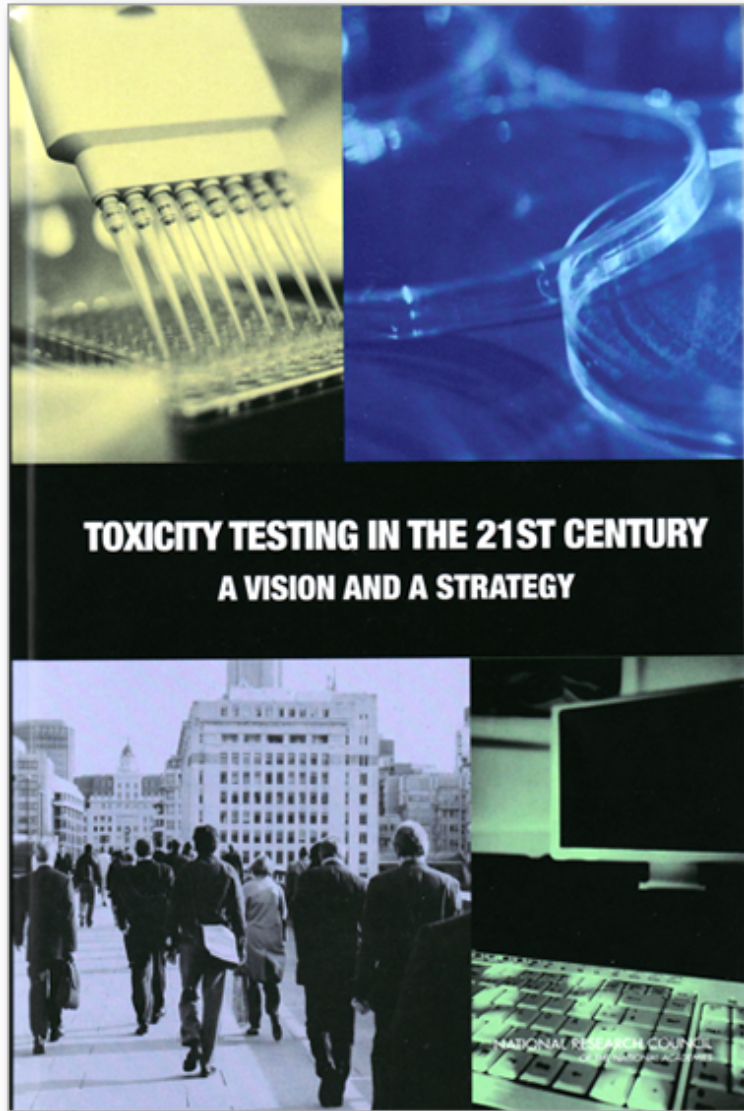
Pre-2000, Post-2000, Currently

- Pre-2000: clinical studies
 - Thirty-five percent of clinical studies failed due to inadequate knowledge of metabolism
- Post-2000: in vitro human cells
 - Five percent of clinical trials failed due to an inadequate knowledge of metabolism
- Currently: FDA requires metabolic studies of human cells in culture

National Toxicology Program

- *A National Toxicology Program: Roadmap for the 21st Century*
 - Specifically identifies the three Rs
 - Cites AWA—minimizing pain and distress
 - Requires training in humane science for all NTP investigators/contractors

2006



- *Toxicity Testing in the 21st Century: A Vision and Strategy*
 - Animal studies—time consuming and expensive
 - Lack of predictability of animal tests
 - Use of human cells in culture
 - Systems biology and pathways = mechanisms

EPA-NIH Memorandum of Understanding

- “We propose a shift from primarily in vivo animal studies to in vitro assays, in vivo assays with lower organisms, and computational modeling for toxicity assessments”

Animal Testing Won't Disappear Overnight

“Animal testing won't disappear overnight, but the agencies' work signals the beginning of the end.”

– *Elias Zerhouni, Director of NIH*
February 2008