



Modernizing Biomedical Research and Regulatory Policies to Advance Human Health

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INTRODUCTION

The use of animals to try to understand human disease has long been the dominant paradigm in biomedical research. Approximately 47% of research funding from the U.S. National Institutes of Health (NIH) goes toward animal experimentation and the U.S. Food and Drug Administration requires that novel drugs be tested in animals.

“Preclinical research, especially work that uses animal models, seems to be the area that is currently most susceptible to reproducibility issues.” –

U.S. National Institutes of Health (NIH) Director, Dr. Francis Collins

DRUG DEVELOPMENT:

10-15 yrs. for drug to reach market

R&D Cost > \$2bil

Fail 95% of time

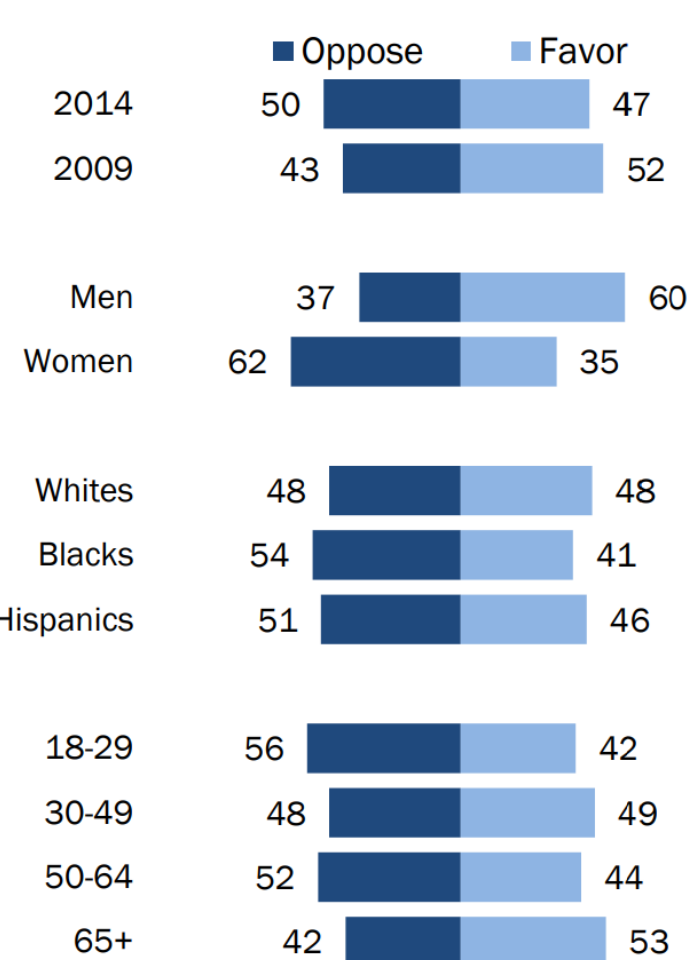
CONSIDER:

- Systematic reviews published in peer-reviewed journals document limitations in translating results from studies using animals to humans for numerous disease areas. Fewer than 10 percent of highly promising basic science discoveries enter routine clinical use within 20 years.

- Between 50 and 89 percent of preclinical research is not reproducible, resulting in approximately \$28 billion per year spent on research that is misleading. Animal experimentation is implicated as a serious problem area.

Use of Animals in Scientific Research

% of U.S. adults saying they favor/oppose the use of animals in scientific research



Survey of U.S. adults Aug. 15-25, 2014, Q24a. “Don’t know” responses not shown. Whites and blacks include only non-Hispanics; Hispanics are of any race.

PEW RESEARCH CENTER

- A 2014 Pew Research report indicates that a majority of Americans now oppose taxpayer-funded animal experiments.



Additionally, the unnatural, confined laboratory life imposed upon animals used for experimentation causes physical and psychological stress, altering their physiology and neurobiology and making them incomparable to their wild counterparts, inherently, to other species. A mouse in a laboratory will not respond to a drug in the same way as a mouse in a field would. **One then has to ask, how does this biologically distinct mouse reliably represent the biology of human beings?** There is a clear need to identify strategic priorities to eliminate the use of animals as the dominant paradigm in biomedical research and regulatory testing.



OBJECTIVES

- Describe a strategy for replacing the use of animals in biomedical research with human-relevant, non-animal methods.
- Conduct a critical review of the literature to determine the areas of research and regulatory testing where the use of animals can be ended immediately, either because it is unproductive, untranslatable, or because the harms to animals do not outweigh the benefits to humans.

METHODOLOGY

Conduct a literature review to identify the ways in which the use of animals has hindered biomedical research, drug discovery, and economic advancement in the U.S., enumerate the areas of research where the use of animals has been most problematic, and define a strategy for shifting resources towards the implementation of non-animal, human-relevant methods.

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RESULTS

The shifting consensus away from the use of animals in experimentation can be observed in a number of arenas, including publications documenting the limited predictive value of research on animals, increased awareness of animal cognition and sentience, and fast eroding public support for the enterprise. These shifts also direct us toward opportunities for economic advancement, where a move away from animal-based research will allow for significant growth in the science and technology sectors and for faster return on investment in drug research and development. Importantly, an evolution of research funding priorities toward human-relevant methods will get treatments to the patients who need them more safely and likely in less time.

STRATEGY FOR REPLACING EXPERIMENTS USING ANIMALS WITH SUPERIOR, HUMAN-RELEVANT METHODS IN THE UNITED STATES

1

Immediately eliminate animal use in areas for which animals have already been shown to be poor and unreliable predictors for humans and have impeded progress.

2

Conduct critical scientific reviews of animal use to identify the areas in which the use of animals has failed to advance human health and should therefore be phased out.

3

Implement ethical cost/benefit analysis system to identify areas where suffering endured by animals eclipses any hypothetical benefit to humans.

4

Promote international harmonization and acceptance of non-animal testing methods for regulatory toxicity testing requirements among government agencies and research bodies.

5

Redirect funds from animal studies to the development of non-animal methods.

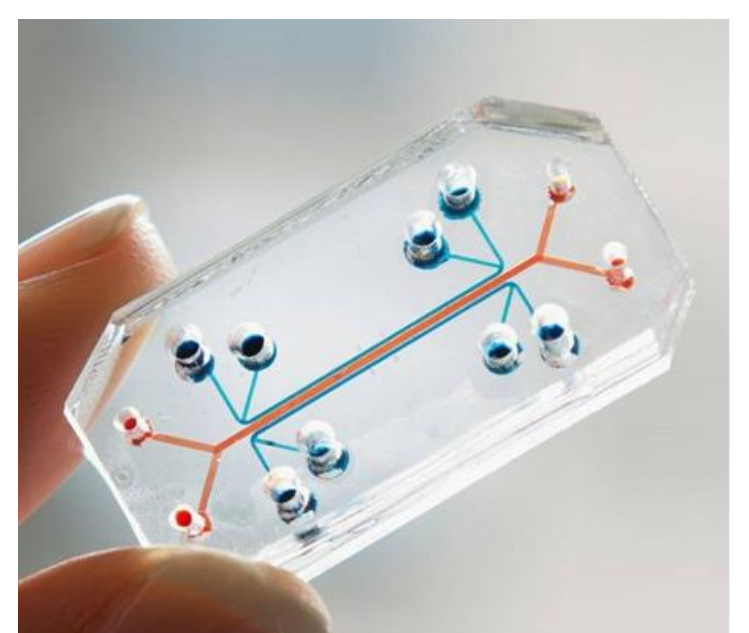
AREAS OF RESEARCH WHERE THE USE OF ANIMALS CAN BE ENDED IMMEDIATELY

Non-regulatory Research

- Cancer
- HIV/AIDS
- Cardiovascular Disease
- Stroke
- Diabetes
- Neurodegenerative Diseases
- Nerve Regeneration
- Sepsis
- Inflammation and Immunology
- Neuropsychiatric Disorders
- Substance Abuse
- Trauma and Shock
- Forensic Sciences
- Medical Training

Regulatory Testing

- Tobacco Testing
- Pyrogenicity
- Genotoxicity
- Carcinogenicity
- Biologic Drugs
- Antibody Production
- Fetal Bovine Serum
- Skin Sensitization
- Skin Irritation/Corrosion
- Eye Irritation/Corrosion
- Acute Systemic Toxicity
- Endocrine Disruption
- Developmental and Reproductive Toxicity
- Exposure-Based Assessment



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CONCLUSIONS

Astonishing advances in human-relevant research technologies hold tremendous promise to revolutionize biomedical research and usher in the age of personalized medicine. Regulatory and funding agencies must redirect the public's funds to more relevant research that has real potential to help humans. With greater investment in exciting and innovative non-animal methods and bold policy initiatives, far more promising cures and treatments for humans can be developed. This will also alleviate the unimaginable suffering of millions of animals.