



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. However, now the transition away from research relying on the use of animals to model human disease or as tools to predict human responses to drugs or other substances and towards human biology-based methods is changing policy and practice around the globe.

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 (€25 billion, or £22 billion) per year spent on research that is misleading. Animal experimentation is implicated as a serious problem area.
- Recent polls indicate that a majority of people are in favour of ending 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.



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METHODOLOGY

Conduct a literature review to identify the ways in which the use of animals has hindered biomedical research, drug discovery, and economic advancement, 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.

CONTACT INFO AND LINKS

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Full reports with references linked within these webpages:

PETA US RMD: www.peta.org/RMD

PETA EU RMD: <http://petauk.org/rmd>

PETA India RMD: <https://www.petaindia.com/RMD>

RESULTS

STRATEGY FOR REPLACING EXPERIMENTS USING ANIMALS WITH SUPERIOR, HUMAN-RELEVANT METHODS

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 harm-benefit analysis system (US and India) and/or transparent, robust prospective and retrospective evaluations (EU).

4

Harmonize and promote international acceptance of non-animal testing methods for regulatory toxicity testing requirements.

5

Redirect funds away from animal experiments and toward sophisticated human-relevant, animal-free research methods.

AREAS WHERE THE USE OF ANIMALS CAN BE ENDED IMMEDIATELY OR DRAMATICALLY REDUCED

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/Eye Irritation/Corrosion
- Acute Systemic Toxicity
- Endocrine Disruption
- Developmental and Reproductive Toxicity
- Exposure-Based Assessment
- Aquatic Toxicity Testing



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CONCLUSIONS

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. This will also alleviate the unimaginable suffering of millions of animals.