ISSUE BRIEF

Can AI End Animal Testing? The FDA Thinks So

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"Beasts of Burden" have plowed fields since the dawn of the agrarian age. They have transported people and heavy loads for even longer. While the advent of the steam engine and mastery of mechanics lessened the toll on beasts of burden, science made sure animals were not off the hook. In the name of science or product safety, a host of animals (from beagles to bunnies and Rhesus monkeys to rats) have been subjected to experiments and often cruel testing. While the benefits to humans are well documented, the details are often gruesome.

Artificial intelligence may soon end that practice if the recent announcement by the Food and Drug Administration (FDA) reaches fruition. This April, the FDA announced that animal testing may be reduced, refined, and potentially replaced by AI-models.[1]

This brief examines the history of animal testing for cosmetic and drug development and explores how AI and machine learning can revolutionize drug development and offer ethical alternatives to reduce animal suffering and eliminate the need for laboratory cages.

History of Animal Testing for Drugs

Throughout history, animals have been frequently used as subjects in biomedical research. Ancient Greek physician-scientists like Aristotle (384 – 322 BC) and Erasistratus (304 – 258 BC) conducted experiments on live animals. Similarly, Galen (129 – 199/217 AD), a prominent Greek physician in Rome, used animal experiments to enhance knowledge in

anatomy, physiology, pathology, and pharmacology. In the twelfth century, Ibn Zuhr (Avenzoar), an Arab physician in Moorish Spain, pioneered the use of animal testing to trial surgical procedures before applying them to humans.

The significance of animal testing in drug development became evident in the twentieth century. In 1937, a U.S. pharmaceutical company created 'Elixir Sulfanilamide' using diethylene glycol (DEG) as a solvent. Unaware of DEG's toxicity to humans, the company's chief pharmacist added raspberry flavoring to the sulfa drug dissolved in DEG and marketed it, leading to a mass poisoning and over a hundred deaths. The public outrage from this and similar incidents led to the 1938 Federal Food, Drug, and Cosmetic Act, mandating safety testing on animals before drugs could be sold.

In recent times, the use of animals in biomedical research has faced strong opposition from animal protection groups. Various countries have enacted laws to make the practice more humane but the ethical debate over animal testing has been ongoing since the seventeenth century.[2]

Animal Testing and Cosmetics

The Federal Food, Drug, and Cosmetic (FD&C) Act, passed by Congress in 1938, gave the FDA the power to ensure the safety of food, drugs, medical devices, and cosmetics. While the Act did not mandate animal testing for cosmetic safety or require FDA premarket approval for cosmetics, the FDA has advised manufacturers to use appropriate and effective testing methods to verify product safety. Manufacturers are responsible for proving the safety of both ingredients and final cosmetic products before they are sold. When animal testing is used, the FDA encouraged obtaining the most scientific information possible from the fewest animals while using the most humane methods available within scientific limits.[3]

While the Act did not mandate animal testing for cosmetic safety or require FDA premarket approval for cosmetics, the FDA has advised manufacturers to use appropriate and effective testing methods to verify product safety.

Scientists who conduct research with animals must follow the applicable laws, regulations and standards regarding the treatment and care of animals used in research and testing.

These include:

- The Animal Welfare Act and Animal Welfare Act Regulations from the U.S. Department of Agriculture (USDA).
- The Public Health Service Policy of Humane Care and Use of Laboratory Animals from the National Institutes of Health Office of Laboratory Animal Welfare (OLAW).
- The Guide for the Care and Use of Laboratory Animals from the National Research Council.[4]

"Man's best friend is a dog": With Friends Like These, Who Needs Enemies?

It was closing arguments in a Missouri courthouse in 1870 that introduced the concept that dogs were man's best friend.[5] The truth in that statement may add to the high emotions and ethical debate on the morality and cruelty of animal testing. For example, tens of thousands of beagles are housed daily in factory-farm conditions for drug testing in the United States and the United Kingdom.[6] Animal welfare groups allege the conditions and practices are shocking and inhumane.[7] There are, in fact, many groups dedicated to eradicating the practice once and for all (see timeline).

Beyond the ethical issues of using animals like dogs, mice, rats, rabbits, pigs, and monkeys in painful and often deadly experiments, these tests are also very expensive, time-consuming, and can produce inaccurate results. Developing a new drug costs about $2.6 billion, and companies can lose $500,000 to $1 million in revenue for each day a drug's release is delayed.[8] The process of developing new drugs can take 10-15 years, and over 90% of these drugs fail in clinical trials, mainly because they are unsafe or ineffective for humans. Additionally, some safe and effective drugs might be wrongly discarded due to unreliable animal tests.

FDA Moving Away from Animal Testing

The FDA's efforts to move away from animal testing actually began in 2018, when it made the announcement that due to the development of monoclonal antibody therapies and other drugs, it has been favoring more effective and human-relevant methods. Recent AI advancements have accelerated the plan.

The FDA plans to utilize computer modeling and artificial intelligence (AI) to predict a drug's behavior and promote the use of lab-grown human organoids (small, self-organized 3D tissue cultures derived from stem cells) and organ-on-a-chip systems that replicate human organs for drug safety testing. The new strategy is designed to improve drug safety and speed up the evaluation process. It also aims to reduce animal testing, cut research and development expenses, and consequently lower drug prices.[9]

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FDA Commissioner Martin A. Makary, M.D., M.P.H., described the new initiative as a paradigm shift in drug evaluation, promising to accelerate cures and meaningful treatments for Americans while reducing and hopefully eliminating animal use entirely in the future. By leveraging AI-based computational modeling, human organ model-based lab testing, and real-world human data, the FDA aims to get safer treatments to patients faster and more reliably, while also reducing costs and drug prices. Makary highlighted additional benefits for patients including a more efficient pipeline for novel treatments as well as an added margin of safety, since human-based test systems may better predict real-world outcomes.

Thousands of animals, including dogs and primates, could eventually be spared each year as these new methods are established, representing a major step toward ending the use of laboratory animals in drug testing.

Not Out of the Woods Yet

Others have argued that there is not yet a high-tech complete replacement for animals within the realm of biomedical research and drug testing, and that humane animal testing is still crucial to testing prospective drugs for humans. "We all want better and faster ways to bring lifesaving treatments to patients," National Association for Biomedical Research President Matthew R. Bailey said in a press release provided to Fox Digital. "But no AI model or simulation has yet demonstrated the ability to fully replicate all the unknowns about many full biological systems. That's why humane animal research remains indispensable."[10]

Balancing the requirements of biomedical research with the humane treatment of animals is not a static process. It takes scrutiny, oversight, strict adherences to guidelines and a committed effort from regulators and the medical and consumer industries. The relationship between technological innovation and ethical responsibility continues to shape the future of scientific research, with the hope that one day, animals can be liberated from testing, reflecting the broader impact of ever evolving technological advancement on society.

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Animal Welfare Protest Timeline

Below is a brief tailored historical timeline of the Animal Rights Movement[11] (events include those predominately relating to animal testing rather than the slaughter or consumption of animals).

Early Events and Legislation

1635: First known animal protection legislation passes, in Ireland, "An Act against plowing by the tayle, and pulling the wool off living sheep."

19th CENTURY

1822: British Parliament passes "Act to Prevent the Cruel and Improper Treatment of Cattle."

1824: The first Society for the Prevention of Cruelty to Animals is founded in England by Richard Martin, Arthur Broome, and William Wilberforce.

1835: The first Cruelty to Animal Act is passed in Britain.

1866: The American Society for the Prevention of Cruelty to Animals (ASPCA) is founded by New Yorker Henry Bergh.

20th CENTURY

1980: People for the Ethical Treatment of Animals (PETA) is founded; “Animal Factories” by attorney Jim Mason and philosopher Peter Singer is published.

1989: Avon stops testing its products on animals; In Defense of Animals launches their campaign against Proctor & Gamble’s animal testing.

1990: Revlon stops testing its products on animals.

1992: Animal Enterprise Protection Act is passed.

1993: General Motors stops using live animals in crash tests; The Great Ape Project is founded by Peter Singer and Paola Cavalieri.

1997: PETA releases an undercover video showing animal abuse by Huntingdon Life Sciences.

21st CENTURY

2009: The European Union bans cosmetic ingredients testing and bans the sale or import of seal products.

2011: National Institutes of Health stops funding of new experiments on chimpanzees; President Barack Obama and Congress lift ban on USDA funding for horse inspections.

2014: India bans cosmetic testing on animals, the first Asian country to do so.

2019: The Environmental Protection Agency (EPA) announces plans to reduce and eventually eliminate the use of mammals to test the toxicity of chemicals.

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[1] https://www.fda.gov/news-events/press-announcements/fda-announces-plan-phase-out-animal-testing-requirement-monoclonal-antibodies-and-other drugs#:~:text=The%20FDA's%20animal%20testing%20requirement,Approach%20Methodologies%20or%20NAMs%20data).

[2] https://pmc.ncbi.nlm.nih.gov/articles/PMC3123518/

[3] https://www.fda.gov/cosmetics/product-testing-cosmetics/animal-testing-cosmetics

[4] https://www.fda.gov/consumers/consumer-updates/animal-welfare-testing-and-research-fda-regulated-products

[5] https://historicmissouri.org/items/show/2

[6] https://headlines.peta.org/breeding-misery/

[7] https://www.peta.org/blog/beagle-factory-farm/

[8] https://www.pcrm.org/news/news-releases/fdas-plan-replace-animal-testing-begins-new-era-drug-testing-says-doctors-group

[9] https://www.fda.gov/news-events/press-announcements/fda-announces-plan-phase-out-animal-testing-requirement-monoclonal-antibodies-and-other-drugs

[10] https://www.yahoo.com/news/peta-animal-rights-groups-praise-154748818.html

[11] https://www.treehugger.com/historical-timeline-of-animal-rights-movement-127594