

## Cruelty Free International Student Resource

London - April 2018

Thank you for getting in touch and for choosing such an important topic for your study!

We receive an incredibly high volume of similar queries from students all over the world and as a small organisation, with limited resources, we aren't usually able to respond to them individually. We hope you can understand that we direct as much of our resources as possible working to put an end to animals suffering in laboratories. We also hope that this resource will prove useful for your academic project and answer any queries you may have.

### Facts and Figures on Animal Testing

Millions of animals are used and killed in the name of progress every year.

#### Global Animal Experiments

- Research by Cruelty Free International and the Dr Hadwen Trust suggests that at least 115 million animals may be used in experiments worldwide each year<sup>i</sup>.
- We estimate that the top 10 animal testing countries in the world are the USA, Japan, China, Australia, France, Canada, the UK, Germany, Taiwan and Brazil, in that order.
- Animal experiments are sadly not in decline, and in many parts of the world are on the increase (e.g. China) or remain at the same level as they were in the 1980s or 1990s (e.g. the UK, Europe).

#### European Union Animal Experiments

- The latest official report from the European Commission shows that in 2011, almost 11.5 million animals were used in experiments across Europe, only a slight decrease on 2008<sup>ii</sup>.
- However, we have conducted a more recent analysis based on reports from EU countries. According to our analysis published in alternatives journal, Altex, the number of experiments has risen to 13.1 million per year across the 28 member states of the European Union, an increase of 14% in 2014<sup>iii</sup>.
- The UK is now the biggest reported user of animals in the EU with 3.9 million experiments reported in 2014. Germany is the second highest user with 2.8 million and France third with 1.8 million.
- In 2014, it is estimated that there were 318,259 experiments on rabbits, 3,851 on cats, 11,250 on horses and 22,967 on dogs.
- There were also 8,898 experiments on primates. The use of new world monkeys (marmosets, tamarins) has increased by 8% and the use of old world monkeys (macaques and baboons) increased by 49%.

- Baboons were used in France (149 experiments), Spain (32 experiments) and Germany (2 experiments).
- Austria (10%), Belgium (15%), Bulgaria (27%) and Ireland (40%) reported the highest levels of severe suffering. Testing of botulinum toxin on animals is a significant activity in Austria and Ireland which might account for this as the test is an LD50 test which causes severe suffering and death to at least 50% of the animals in each and every experiment.

## UK Animal Experiments

- According to the latest Government figures (for 2016), a total of 3.9 million experiments were completed in Great Britain during 2016<sup>iv</sup>.
- Of these, 1.9 million (49%) related to the creation or breeding of genetically altered animals who were not used in further experiments.
- The remaining 2.0 million (50%) were other experiments on animals.
- Almost 700,000 animals were subjected to experiments that even the researchers considered had caused them moderate or severe suffering.
- Animals used in the UK included mice (1.2 million experiments), rats (238,841 experiments), birds (149,97 experiments), rabbits (15,431 experiments), guinea-pigs (26,186 experiments), monkeys (3,569 experiments), dogs (4,932 experiments), cats (190 experiments), horses (8,948 experiments), sheep (47,904 experiments), pigs (5,358 experiments), and fish (286,600 experiments).
- Of the 2.0 million experiments conducted on animals, 55% (1.1 million experiments) were in the area of basic research – much of it driven by the curiosity of university researchers.
- 49% of experiments were conducted in universities, often using taxpayers' funds.
- Only 13% of experiments were apparently required by regulators.
- In 2016, 89% of [experiments conducted on monkeys used animals who were imported from outside the EU](#).
- Experiments are still being conducted for toxicological tests where there are valid non-animal alternatives available. This includes:
  - skin irritation (252 tests in 2016)
  - eye irritation (128 tests in 2016)
  - acute lethal toxicity tests (11,530 tests in 2016)
  - pyrogenicity (fever) tests (2,472 tests in 2016) on live rabbits.

## Arguments Against Animal Testing

### Animal experiments are cruel, unreliable, and even dangerous

The harmful use of animals in experiments is not only cruel but also often ineffective. Animals do not get many of the human diseases that people do, such as major types of heart disease, many types of cancer, HIV, Parkinson's disease, or schizophrenia. Instead, signs of these diseases are artificially induced in animals in laboratories in an attempt to mimic the human disease. Yet, such experiments belittle the complexity of human conditions which are affected by wide-ranging variables such as genetics, socio-economic factors, deeply-rooted psychological issues and different personal experiences.

It is not surprising to find that treatments showing 'promise' in animals rarely work in humans. Not only are time, money and animals' lives being wasted (with a huge amount of suffering), but effective treatments are being mistakenly discarded and harmful treatments are getting through. The support for animal testing is based largely on anecdote and is not backed up, we believe, by the scientific evidence that is out there.

Despite many decades of studying conditions such as cancer, Alzheimer's disease, Parkinson's disease, diabetes, stroke and AIDS in animals, we do not yet have reliable and fully effective cures.

### Unreliable Animal Testing

- 90% of drugs fail in human trials despite promising results in animal tests – whether on safety grounds or because they do not work<sup>v</sup>
- Cancer drugs have the lowest success rate (only 5% are approved after entering clinical trials) followed by psychiatry drugs (6% success rate), heart drugs (7% success rate) and neurology drugs (8% success rate).<sup>vi</sup>
- Using dogs, rats, mice and rabbits to test whether or not a drug will be safe for humans provides little statistically useful insight, our recent analysis found.<sup>vii,viii</sup> The study also revealed that drug tests on monkeys are just as poor as those using any other species in predicting the effects on humans.<sup>ix</sup>
- Out of 93 dangerous drug side effects, only 19% could have been predicted by animal tests, a recent study found<sup>x</sup>
- Using mice and rats to test the safety of drugs in humans is only accurate 43% of the time, a recent study found<sup>xi</sup>
- Out of 48 cancer drugs approved by the European Medicines Agency from 2009 to 2013 to treat 68 types of cancer, almost half showed no survival benefits according to a recent study. Even in cases where benefits were seen, the difference was judged to be 'clinically insignificant'.<sup>xii</sup>

### Wasteful Animal Testing

- Despite the use of over 115 million animals in experiments globally each year,<sup>xiii</sup> only 46 new medicines were approved in 2017 by the leading drug regulator, the U.S. Food and Drug Administration. Many of these are for rare diseases.<sup>xiv</sup>
- The US drug industry invests \$50 billion per year in research, but the approval rate of new drugs is the same as it was 50 years ago. Only 6% of 4,300 international companies involved in drug development have registered a new drug with the U.S. Food and Drug Administration since 1950.<sup>xv</sup>
- Even those drugs that are approved are not universally effective due to individual reactions - the top ten highest-grossing drugs in the USA only help between 1 in 4 and 1 in 25 people who take them
- Of over 1,000 potential stroke treatments that had been 'successful' in animal tests, only approximately 10% progressed to human trials. None worked sufficiently well in humans.<sup>xvi</sup>
- A review of 101 high impact basic science discoveries based on animal experiments found that only 5% resulted in approved treatments within 20 years.<sup>xvii</sup>

## Dangerous Animal Testing

- Vioxx, a drug used to treat arthritis, was found to be safe when tested in monkeys (and five other animal species) but has been estimated to have caused around 320,000 heart attacks and strokes and 140,000 deaths worldwide.<sup>xviii</sup>
- Human volunteers testing a new monoclonal antibody treatment (TGN1412) at Northwick Park Hospital, UK in 2006 suffered a severe allergic reaction and nearly died. Testing on monkeys at 500 times the dose given to the volunteers totally failed to predict the dangerous side effects.<sup>xix</sup>
- A recent drug trial in France resulted in the death of one volunteer and left four others severely brain damaged in 2016. The drug, which was intended to treat a wide range of conditions including anxiety and Parkinson's disease, was tested in four different species of animals (mice, rats, dogs and monkeys) before being given to humans.<sup>xx</sup>
- A clinical trial of Hepatitis B drug fialuridine had to be stopped because it caused severe liver damage in seven patients, five of whom died. It had been tested on animals first.<sup>xxi</sup>
- Only one third of substances known to cause cancer in humans have been shown to cause cancer in animals.<sup>xxii</sup>

## Animals are Different

- Animals do not get many of the diseases we do, such as Parkinson's disease, major types of heart disease, many types of cancer, Alzheimer's disease, HIV or schizophrenia.
- An analysis of over 100 mouse cell types found that only 50% of the DNA responsible for regulating genes in mice could be matched with human DNA.
- The most commonly used species of monkey to test drug safety<sup>xxiii</sup> (Cynomolgous macaque monkeys), are resistant to doses of paracetamol (acetaminophen) that would be deadly in humans.<sup>xxiv</sup>
- Due to the many important differences between monkeys and humans in brain structure and function, data collected from monkeys used in neuroscience research are misleading and of poor relevance to people, our recent analysis found.<sup>xxv</sup>
- Chocolate, grapes, raisins, avocados and macadamia nuts are harmless in people but toxic to dogs.<sup>xxvi</sup>
- Aspirin is toxic to many animals, including cats, mice and rats and would not be on our pharmacy shelves if it had been tested according to current animal testing standards.<sup>xxvii</sup>

## Alternatives to Animal Testing

Alternatives to animal tests are often cheaper, quicker and more effective

Replacing animal tests does not mean putting human patients at risk. It also does not mean halting medical progress. Instead, replacing animal testing will improve the quality as well as the humaneness of our science.

Thankfully, the development of alternative methods is growing. Due to innovations in science, animal tests are being replaced in areas such as toxicity testing, neuroscience and drug development. But much more needs to be done.

The reasons why animal testing persists are often not scientific. Instead it can be due to conservatism within the scientific establishment – it is easier and more comfortable to simply do what has always been done. Test results on animals can be easily compared to earlier tests on animals to give confidence to scientists. Regulators can adopt a ‘tick box’ approach, divorced from the needs of the real world.

Once new alternatives have been developed, there are also massive bureaucratic hurdles to implementing and enforcing their use. One of the most important jobs the Cruelty Free International science team does is encourage regulators to accept and promote alternative methods to animal testing.

## Types of Alternatives

### Cell Cultures

Almost every type of human and animal cell can be grown in the laboratory. Scientists have even managed to coax cells to grow into 3D structures, such as miniature human organs, which can provide a more realistic way to test new therapies.

Human cells have been used to create innovative little devices called ‘organs-on-chips’. These can be used instead of animals to study biological and disease processes, as well as drug metabolism. Devices have already been produced that accurately mimic the lung, heart, kidney and gut. The ultimate goal is to use these chips to create a whole ‘human-on-a-chip’.

Cell cultures have been central to key developments in areas such as cancers, sepsis, kidney disease and AIDS, and are routinely used in chemical safety testing, vaccine production and drug development.

### Human Tissues

Both healthy and diseased tissues donated from human volunteers can provide a more relevant way of studying human biology and disease than animal testing.

Human tissue can be donated from surgery (e.g. biopsies, cosmetic surgery and transplants). For example, skin and eye models made from reconstituted human skin and other tissues have been developed and are used to replace the cruel rabbit irritation tests. Companies such as Episkin, Mattek and CellSystems GmbH now produce these tests in easy to use kits for companies to use to test their cosmetics and other substances.

Human tissue can also be used after a person has died (e.g. post-mortems). Post-mortem brain tissue has provided important leads to understanding brain regeneration and the effects of Multiple Sclerosis and Parkinson’s disease.

## Computer Models

With the growing sophistication of computers, the ability to 'model' or replicate aspects of the human body is ever more possible.

Computer models of the heart, lungs, kidneys, skin, digestive and musculoskeletal systems already exist. They can be used to conduct virtual experiments based on existing information and mathematical data.

## Volunteer Studies

Rapid advances in technology have allowed for the development of sophisticated scanning machines and recording techniques that can be used to safely study human volunteers.

Brain imaging machines that can 'see' inside the brain can be used to monitor the progression and treatment of brain disease. They can help researchers understand the causes by comparing with healthy volunteers.

An innovative technique called microdosing can also be used in volunteers to measure how very small doses of potential new drugs behave in the human body. These microdoses are radio-labelled, injected into human volunteers and measured (usually in blood samples) using a very sensitive measuring device called an accelerator mass spectrometer.

Less high-tech studies for nutrition, drug addiction and pain can also be carried out on consenting humans in the interest of advancing medical science. These studies can help replace animal tests.

## Human Medical Breakthroughs

- We are told that insulin therapy would not have been discovered unless animal researchers had removed the pancreas from dogs in the 1920s. But like other areas of medical research, the important clues actually came much earlier from observations of human patients.<sup>xxviii</sup>
- Brain surgery in Parkinson's patients identified the best place for Deep Brain Stimulation electrodes to be placed in the brain to improve symptoms, decades before a claimed 'discovery' in monkeys.<sup>xxix</sup>
- Alois Alzheimer first described the main features of Alzheimer's disease in 1906 by studying brain segments from patients after they had died.<sup>xxx</sup>
- Human population studies led to the discovery that smoking causes cancer. Smoking does not cause cancer in mice and rats.<sup>xxxi</sup>
- An Australian doctor used himself in an experiment to discover the main cause of stomach ulcers. He drank a culture of bacteria and became sick before curing his symptoms with antibiotics.<sup>xxxii</sup>
- A German chemist tested the effects of aspirin on himself after an accidental discovery that it helped relieve pain in a patient with toothache.<sup>xxxiii</sup>

- The anaesthetic effect of laughing gas was discovered when someone accidentally cut their leg while under the influence of the gas. An American dentist then confirmed the effects on himself while having a tooth removed.<sup>xxxiv</sup>

### Alternatives are Better

- Crude skin allergy tests in guinea pigs only predict human reactions 72% of the time. But a combination of chemistry and cell-based alternative methods has been shown to accurately predict human reactions 90% of the time.<sup>xxxv</sup>
- The notorious Draize skin irritation test in rabbits can only predict human skin reactions 60% of the time. But using reconstituted human skin is up to 86% accurate.<sup>xxxvi,xxxvii</sup>
- The standard test on pregnant rats to find out if chemicals or drugs may harm the developing baby can only detect 60% of dangerous substances.<sup>xxxviii</sup> But a cell-based alternative (EST) has 100% accuracy at detecting very toxic chemicals.<sup>xxxix</sup>
- The cruel and unreliable shellfish toxin testing on live mice has now been fully replaced with a far superior analytical chemistry method that is better at protecting humans.

### The Leaping Bunny

Leaping Bunny certifications are part of our international cruelty free programme, symbolised by the iconic Leaping Bunny logo. The Leaping Bunny logo provides shoppers with the best assurance that no animal testing has taken place for certified products.

Leaping Bunny certified companies have worked hard to obtain either or both of our current certifications in the programme:

- Leaping Bunny certification for cosmetics (and personal care) products
- Leaping Bunny certification for household and cleaning products

### What criteria does a company need to meet to become Leaping Bunny certified?

To become Leaping Bunny certified companies must:

- Guarantee that no animal testing takes place at any stage of their supply chain (i.e. on their finished products, on the raw materials or ingredients these products are made up of). This includes animal testing by the company, its laboratories, manufacturers or suppliers after a **fixed cut-off date**;
- Actively **monitor their supply chains**, maintaining ongoing up-to-date records and assurances that no animal testing has been conducted after their fixed cut-off date;
- Agree to ongoing **independent audits** to ensure their continued compliance with Leaping Bunny criteria.

- <sup>i</sup> Estimates for worldwide laboratory animal use in 2005. (2008). ATLA, 36: 327-342.
- <sup>ii</sup> Seventh report on the statistics on the number of animals used for experimental and other scientific purposes in the member states of the European Union, European Commission: <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52013DC0859&from=EN>
- <sup>iii</sup> EU statistics on animal experiments for 2014. (2016). ALTEX, 33(4); 463-46.
- <sup>iv</sup> Annual statistics of scientific procedures on living animals in Great Britain 2016, UK Home Office: [https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/627284/annual-statistics-scientific-procedures-living-animals-2016.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/627284/annual-statistics-scientific-procedures-living-animals-2016.pdf)
- <sup>v</sup> Clinical Development Success Rates 2006-2015. Biotechnology Innovation Organization: <https://www.bio.org/sites/default/files/Clinical%20Development%20Success%20Rates%202006-2015%20-%20BIO,%20Biomedtracker,%20Amplion%202016.pdf>
- <sup>vi</sup> Clinical Development Success Rates 2006-2015. Biotechnology Innovation Organization: <https://www.bio.org/sites/default/files/Clinical%20Development%20Success%20Rates%202006-2015%20-%20BIO,%20Biomedtracker,%20Amplion%202016.pdf>
- <sup>vii</sup> An analysis of the use of animal models in predicting human toxicology and drug safety. (2014). ATLA, 42: 181-199.
- <sup>viii</sup> An analysis of the use of dogs in predicting human toxicology and drug safety. (2013). ATLA, 41: 335-350.
- <sup>ix</sup> Predicting human drug toxicity and safety via animal tests: can any one species predict drug toxicity in any other, and do monkeys help? (2015). ATLA, 43: 393-403.
- <sup>x</sup> The ability of animal studies to detect serious post marketing adverse events in limited. (2012). Regulatory Toxicology & Pharmacology, 64: 345-349.
- <sup>xi</sup> The future of teratology research is in vitro. (2005). Biogenic Amines, 19:97-145.
- <sup>xii</sup> Availability of evidence of benefits on overall survival and quality of life of cancer drugs approved by European Medicines Agency: retrospective cohort study of drug approvals 2009-13. (2017). British Medical Journal, 359: j4530.
- <sup>xiii</sup> Estimates for worldwide laboratory animal use in 2005. (2008). ATLA, 36: 327-342.
- <sup>xiv</sup> Novel Drug Approvals for 2017. U.S. Food & Drug Administration: <https://www.fda.gov/drugs/developmentapprovalprocess/druginnovation/ucm537040.htm>
- <sup>xv</sup> Lessons from 60 years of pharmaceutical innovation. (2009). Drug Discovery, 8: 959-968.
- <sup>xvi</sup> 1,026 experimental treatments in acute stroke. (2006). Annals of Neurology, 59: 467-477.
- <sup>xvii</sup> Translation of highly promising basic research into clinical applications. (2003). American Journal of Medicine, 114: 477-484.
- <sup>xviii</sup> The FDA exposed: an interview with Dr. David Graham, the Vioxx whistleblower. (2005). Natural News: [http://www.naturalnews.com/011401\\_Dr\\_David\\_Graham\\_the\\_FDA.html](http://www.naturalnews.com/011401_Dr_David_Graham_the_FDA.html)
- <sup>xix</sup> Expert group on phase one clinical trials: independent report to the Secretary of State for Health. (2006). The Stationery Office, London UK. P.65.
- <sup>xx</sup> Fatal French clinical trial failed to check data before raising drug dose. (2016). Nature News: <http://www.nature.com/news/fatal-french-clinical-trial-failed-to-check-data-before-raising-drug-dose-1.21190>
- <sup>xxi</sup> Hepatic failure and lactic acidosis due to fialuridine, an investigational nucleoside analogue for chronic hepatitis B. (1995). The New England Journal of Medicine, 333: 1099-1105.
- <sup>xxii</sup> Chemicals causing mammary gland tumours in animals signal new directions for epidemiology, chemicals testing, and risk assessment for breast cancer prevention. (2007). American Cancer Society, Cancer supplement, 109 (12): 2635-2666.
- <sup>xxiii</sup> Genomics: mice in the ENCODE spotlight. (2014). Nature, 515: 346-347.
- <sup>xxiv</sup> Metabolism by conjugation appears to confer resistance to paracetamol (acetaminophen) hepatotoxicity in the cynomolgus monkey. (2014). Xenobiotica, Oct 22: 1-8.
- <sup>xxv</sup> Non-human primates in neuroscience research: the case against its scientific necessity. (2016). ATLA, 44: 43-69.
- <sup>xxvi</sup> Top 10 dog poisons. WebMD: <http://pets.webmd.com/dogs/guide/top-10-dog-poisons?page=2>
- <sup>xxvii</sup> New test methods can reduce amount of animal testing. (2013). Medical Xpress, May 2013.
- <sup>xxviii</sup> M. Bliss. The Discovery of Insulin. Chicago University Press; 25<sup>th</sup> anniversary edition, 5 Feb 2009.
- <sup>xxix</sup> Ligation of the anterior choroidal artery for involuntary movements: parkinsonism. (1953). The Psychiatric Quarterly, 27(2): 317-319.
- <sup>xxx</sup> Alzheimer's disease fact sheet. NIH: <https://www.nia.nih.gov/health/alzheimers-disease-fact-sheet>
- <sup>xxxi</sup> A review of chronic inhalation studies with mainstream cigarette smoke in rats and mice. (1998). Toxicologic Pathology, 26(3): 307-314.



- 
- <sup>xxxii</sup> *Helicobacter pylori*: a nobel pursuit? (2008). *Canadian Journal of Gastroenterology*, 22 (11): 895-896.
- <sup>xxxiii</sup> Snaeder W. *Drug Discovery: A History*. Wiley, 2005.
- <sup>xxxiv</sup> Snaeder W. *Drug Discovery: A History*. Wiley, 2005.
- <sup>xxxv</sup> Intralaboratory validation of four in vitro assays for the prediction of the skin sensitizing potential of chemicals. (2011). *Toxicology in Vitro*, 25: 1162-1168.
- <sup>xxxvi</sup> In vitro acute skin irritancy of chemicals using the validated EPISKIN model in a tiered strategy: results and performances with 184 cosmetic ingredients. (2007). *AATEX 14, Special Issue*, 351-358.
- <sup>xxxvii</sup> Comparison of human skin irritation and photo-irritation patch test data with cellular in vitro assays and animal in vivo data. (2007). *AATEX 14, special issue*, 359-365
- <sup>xxxviii</sup> Proposal for a tiered approach to developmental toxicity testing for veterinary pharmaceutical products for food producing animals. (2003). *Food & Chemical Toxicology*, 41: 611-619.
- <sup>xxxix</sup> AXLR8. Alternative testing strategies progress report 2010. AXLR8 Consortium Report: [www.AXLR8.eu](http://www.AXLR8.eu)