

## **ANIMAL TESTING IN BIOMEDICAL RESEARCH**

### **Fact Sheet**

The use of animals in biomedical research is essential to the development of new and more effective methods for diagnosing and treating disease. In fact, virtually every major medical advance of the last century has derived, in part, from research with animals. Animal research is conducted to investigate physiological processes that can only be studied in living organisms, and to assure the safety of new medical treatments before they can be tested in humans. Such testing is mandated – by law – by health regulatory agencies worldwide to protect the health and safety of patients and consumers. For example:

- In the United States (U.S.), the U.S. Food and Drug Administration (FDA) expressly requires that laboratory animal tests be conducted both for prescription drugs and over-the-counter drugs before these products can be tested further in humans.
- In the European Union (EU), regulatory agencies demand proof of safety before they will license a new drug, including toxicological assessment “some of which can only be obtained from animal testing.”<sup>1</sup>

### **Regulations Governing Animal Testing**

Researchers are deeply concerned about the welfare of the animals they study, for a range of humane, compassionate and scientific reasons. The pharmaceutical industry sets high standards for the ethical treatment of animals. It adheres to strict rules and regulations set by government agencies, industry and professional organizations to ensure that animals used in research and testing receive responsible, humane treatment.

In the United States:

- The **Animal Welfare Act (AWA)**, a federal law enforced by the **U.S. Department of Agriculture (USDA)**, strictly regulates the care, treatment and use of animals in research facilities. The AWA sets comprehensive standards for cleanliness and care, including appropriate veterinary care, housing, feeding, handling, sanitation, ventilation and sheltering. Research institutions must ensure that pain and distress are minimized, and must consider alternatives to any procedures using animals. USDA inspectors conduct unannounced visits to all research facilities at least once a year.
- In addition, the USDA requires all research institutions to establish an **Institutional Animal Care and Use Committee (IACUC)** comprised of veterinarians, researchers, representatives of the scientific community and at least one community member who is not affiliated with the research facility. The IACUC is charged with ensuring that animals used in its institution’s research

programs are treated ethically and humanely in accordance with AWA regulations. IACUC also require researchers to justify the need for animals, select the most appropriate species and use the fewest number of animals possible to answer a specific question.

- The **U.S. Public Health Service Act** requires all institutions receiving research funds from the National Institutes of Health, the FDA, or the Centers for Disease Control to adhere to stringent animal welfare standards set forth in the *Guide for the Care and Use of Laboratory Animals*.
- The vast majority of research facilities voluntarily seek accreditation from professional associations that require additional standards for laboratory animal care such as the **Association for Assessment and Accreditation of Laboratory Animal Care International**. In addition, appropriate research personnel are trained and certified through the **American Association for Laboratory Animal Science**.

Worldwide:

- Regulations on toxicity testing for new drugs and medicines are being harmonized internationally through the **International Conference on Harmonization (ICH)**. Better harmonization has already led to a reduction in animal use. For example, instead of three very similar sets of tests being carried out for a new drug to be licensed in the EU, the United States and Japan, now only one set of tests needs to be carried out which is accepted by the regulatory authorities in all three jurisdictions.<sup>2</sup>

### **The “3R” Principles: Refinement, Reduction and Eventual Replacement of Laboratory Animals**

Allergan shares the pharmaceutical industry’s goal of reducing or eliminating animal testing wherever possible, and we are committed to the “3R” principles of refinement, reduction and eventual replacement of laboratory animals in product testing. For instance, for several years we have focused on reducing and refining our assay process used in the final manufacturing stages of BOTOX<sup>®</sup> (botulinum toxin type A), leading to FDA approval in September 2006 of a revised assay and tightened acceptance criteria for product release that is enabling us to further substantially reduce the number of animals involved in the assay by approximately 50 percent. In the first quarter of 2007, Allergan has submitted two Prior Approval Supplements to the FDA that would further reduce the routine use of animals without decreasing quality assurance.

Industry-wide, great progress has been made – the number of animals used in research has actually decreased over the last two decades.

### **Alternatives to Animal Testing**

According to the FDA, “many procedures intended to replace animal tests are still in various stages of development...While the best means may begin with valuable adjunct tests, ultimately testing must progress to a whole intact, living organism – an animal.”<sup>3</sup>

For example, the use of research methods like computer models and cell and tissue cultures to screen and determine the toxic potential of a substance in the early stages of investigation have substantially reduced the number of animals required for testing. But these methods cannot yet replace experiments conducted in actual living organisms where complex biological processes between cells, tissues and organs can be studied before a new treatment is tested in humans.

The pharmaceutical industry is actively committed to the search for animal testing alternatives and is providing significant support to both internal and external efforts to develop and evaluate non-animal testing methods and procedures.

### **For Additional Information on Animal Testing**

Americans for Medical Progress

<http://www.amprogress.org/Issues/issuesmain.cfm>

*Non-profit organization whose mission is to protect society's investment in research, promote public understanding of and support for the appropriate role of animals in biomedical research.*

California Society for Biomedical Research

<http://www.ca-biomed.org/csbr/index.html>

and

California Biomedical Research Association

<http://www.ca-biomed.org/index.html>

*Membership and education organizations that advocate for the continued advancement of human and animal health through biomedical research, teaching and testing; promote public understanding, education, and support of biomedical research; and participate in legislation at the local and state level.*

Coalition for Medical Progress

<http://www.medicalprogress.org>

*Bridging the information gap on biomedical research involving animals.*

Foundation for Biomedical Research

<http://www.fbresearch.org/>

*The nation's oldest and largest organization dedicated to improving human and animal health by promoting public understanding and support for the humane and responsible use of animals in medical and scientific research.*

Incurably Ill for Animal Research

<http://www.iifar.org>

*iIFAR consists largely of incurably ill patients who support animal research and was founded to remind the public that all medical research is being conducted to help society with better, longer lives for people and animals.*

International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH)

<http://www.ich.org>

*The International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) is a unique project that brings together the regulatory authorities of Europe, Japan and the United States and*

*experts from the pharmaceutical industry in the three regions to discuss scientific and technical aspects of product registration.*

*The purpose is to make recommendations on ways to achieve greater harmonisation in the interpretation and application of technical guidelines and requirements for product registration in order to reduce or obviate the need to duplicate the testing carried out during the research and development of new medicines.*

*The objective of such harmonisation is a more economical use of human, animal and material resources, and the elimination of unnecessary delay in the global development and availability of new medicines whilst maintaining safeguards on quality, safety and efficacy, and regulatory obligations to protect public health.*

*This Mission is embodied in the [Terms of Reference of ICH](#).*

National Association for Biomedical Research

<http://www.nabr.org/>

*Only national, nonprofit organization dedicated solely to advocating sound public policy that recognizes the vital role of humane animal use in biomedical research, higher education and product safety testing.*

States United for Biomedical Research

<http://statesforbiomed.org/>

*Providing hope for those suffering from illnesses for which there are still no cures. Members include colleges and universities, research hospitals, voluntary health associations and bioscience companies, who honor the many successes achieved by medical and biomedical research toward improving the lives of humans and animals.*

###

---

<sup>1</sup> Directive 2001/83/EC of the European Parliament and of the Council of the 6 November 2001 on the Community code relating to medicinal products for human use, as amended

<sup>2</sup> ICH Safety guidelines: <http://www.ich.org/cache/compo/276-254-1.html>

<sup>3</sup> U.S. Food and Drug Administration. Statement to the Maryland Governor's Task Force to Study Animal Testing, April 17, 1989. Quote available at: [www.nabr.org](http://www.nabr.org). Accessed: May 11, 2007.

*Revised: July 2007*