

QUESTIONS AND ANSWERS ABOUT U.S. ANIMAL TESTING OF

VACCINES

What are vaccines?

Vaccines are a type of “biological” medicinal product—derived from living organisms—that are used to prevent or treat certain types of infectious or other diseases. Conventional vaccines are produced from dead or inactivated organisms (e.g., viruses) or toxic compounds, or purified products derived from them. However, more recently, several new types of vaccines have also been developed (e.g., recombinant, conjugate and DNA vaccination).

Who regulates vaccines in the U.S. and under what laws?

Vaccines intended for human use are regulated by the Food and Drug Administration (FDA) Center for Biologics Evaluation and Research under the authority of the Public Health Service Act,¹ whereas vaccines intended for use in other animals (e.g., pets and farm) are regulated by the Department of Agriculture (USDA) Center for Veterinary Biologics under the authority of the Virus Serum Toxin Act.²

What animal tests are carried out on vaccines?

“Preclinical” testing in animals is a longstanding requirement for all human and veterinary medicinal products, including vaccines. Specifically, vaccine manufacturers are legally required demonstrate that their products possess the following characteristics:

- ▶ *Purity*, meaning that it is not contaminated with viable bacteria, viruses or fungi
- ▶ *Safety*, meaning that it is not dangerous or harmful (which is usually determined by means of “abnormal toxicity” or similar studies, in which groups of animals are injected with a vaccine and monitored for clinical signs of toxicity)
- ▶ *Potency*, meaning that it is effective in preventing infection (which is usually determined by means of a “challenge study,” in which groups of animals are first inoculated with a vaccine and are then exposed to a virulent strain(s) of the organism against which the vaccine is intended to protect.; animals are then monitored for clinical signs of the infectious disease in question, which may involve considerable pain, suffering, and ultimately, death).

A further pre-marketing requirement for both human and veterinary vaccines is a series of clinical trials in humans or “target” animals to demonstrate safety and effectiveness in the species of ultimate interest. Even after a vaccine has been fully tested and licensed, it is common for manufacturers to conduct additional animal testing of each individual batch of a vaccine, or for an agency to request samples of each vaccine lot to undertake such testing independently.³

¹ <http://www.fda.gov/opacom/laws/phsvact/sec262.htm>

² http://www.aphis.usda.gov/animal_health/vet_biologics/publications/VSTA.pdf

³ <http://www.fda.gov/cber/vaccine/vacappr.htm>

How many animals may be used in vaccine testing?

Unfortunately, laboratory-bred rats and mice and non-mammalian species are not covered under the U.S. Animal Welfare Act standards for animals used in experiments, and as such, statistics concerning their use are not recorded or made publicly available.⁴ However, according to European statistics for 2005, the “production and quality control of products for human medicine and dentistry and for veterinary medicine” consumed approximately 15.3% of all animals used for all experimental purposes that year.⁵

Are animal tests accurate predictors of chemical risks to people?

Not necessarily. In fact, some vaccines have been causally linked to severe adverse reactions in humans (e.g., anaphylactic shock brought on by hepatitis B vaccine; poliomyelitis in a contact of someone who received the oral polio vaccine; arthritis in recipients of the rubella vaccine; death in some recipients of the measles vaccine).⁶ According to FDA, “a new medicinal compound entering Phase 1 testing [in humans], often representing the culmination of upwards of a decade of preclinical screening and evaluation, is estimated to have only an 8 percent chance of reaching the market” because animal studies so often “fail to predict the specific safety problem that ultimately halts development.”⁷

What are some practical alternatives to animal testing?

Relevant alternative methods validated to date include “ELISA” batch potency tests for erysipelas and human tetanus vaccines, as well as a “toxin binding inhibition test” for human tetanus vaccine. The European Centre for the Validation of Alternative Methods has also issued a statement calling for an end to target animal studies for batch safety testing of veterinary vaccines.⁸

What is the Humane Society doing to help animals used in testing?

The Humane Society of the United States and Humane Society Legislative Fund are actively working to end animal testing—permanently. We are working to promote greater reliance on available non-animal testing methods, and are actively supporting the vision of “twenty-first century toxicology” articulated by the U.S. National Research Council, which would see animal tests that are decades old, costly, slow and of dubious relevance to people replaced by ultra-modern, efficient and human-relevant non-animal methods.⁹ We are calling for a “big biology” project to meet this challenge, akin to the Human Genome Project of the 1990s, and are forging an international, multi-stakeholder consortium to help make this landmark vision a reality as quickly as possible.

The Humane Society of the United States is the nation’s largest animal protection organization—backed by more than 10.5 million Americans. For over 50 years, HSUS has worked to reduce suffering and to create meaningful change for animals in laboratories through public education, scientific outreach, legislative advocacy, and strategic partnerships.

Online at HSUS.org/research

The Humane Society Legislative Fund is a social welfare organization incorporated as a separate lobbying affiliate of the HSUS. HSLF works to pass animal protection laws at the state and federal level, to educate the public about animal protection issues, and to support humane candidates for office.

Online at HSLF.org

⁴ <http://www.nal.usda.gov/awic/legislat/awa.htm>

⁵ http://ec.europa.eu/environment/chemicals/lab_animals/pdf/staff_work_doc_sec1455.pdf

⁶ <http://medsafe.govt.nz/Profs/PUarticles/vaccine.htm>

⁷ <http://www.fda.gov/oc/initiatives/criticalpath/whitepaper.html>

⁸ http://ecvam.jrc.it/publication/TargetAnimalSafetyT_statement.PDF

⁹ http://www.hsus.org/animals_in_research/animal_testing/hsus-projects/human_toxicology_initiative.html