Of Mice and Mandates: Animal Experiments, Human Cancer Risk, and Regulatory Policies

By ACSH Staff — July 1, 1998

Executive Summary

Laboratory animals have been used for many years to determine whether chemicals in foods, pharmaceuticals, and other products might cause cancer and other health problems in human beings; and animal testing continues to play a role in determining the safety of products for human use. Yet an increasingly sophisticated understanding of cancer formation (carcinogenesis) along with growing doubts about how confidently we can infer human health effects from test results in quite different animal species has begun to change both scientific assessment practices and the legal and regulatory requirements based on them.

In the real world people constantly encounter many known carcinogens, both synthetic and natural, without developing cancer. These substances appear in air, water, and foods; indeed, some are generated naturally within the human body itself. Five hundred years ago the Swiss physician Paracelsus introduced the basic toxicological concept that a substance’s poisonous capacity depends on the dose. Vitamin A, for example, is necessary in small quantities for vision but at much higher doses is toxic to the liver and heart.

This concept is often lost sight of in the interpretation of results from animal tests involving very high doses of a single test agent. A new perspective is warranted in light of the huge cost of animal testing and in light of the all-too-common misinterpretations of the results of animal tests with respect to their predicting of human health risk. In developing that new perspective, we should consider the following points:

- Toxicity testing using animals plays an essential role in the development of drugs, industrial and agricultural chemicals, consumer products, food additives, and cosmetics. When properly conducted and interpreted, animal testing will continue to be a valuable source of information on the potential toxicity of chemicals to humans.
- Differences in physiology and anatomy between humans and mice, rats, and other species often make it difficult to apply animal results confidently and directly to human health. Animal testing should not be viewed as sufficient, in the absence of additional supporting data, to predict risk to humans.
- Some products have been labeled carcinogenic solely as a result of unrealistically high doses having been force fed to laboratory animals. Excessive focus on unrealistic, theoretical carcinogenicity risks of some products diverts resources and attention from documented threats to human health.
- Improved means of interpreting animal test data along with emerging testing alternatives, increasing understanding of the process of cancer causation, and changes in risk-
assessment methodology will permit a more critical, real-world view of risks to human health.


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