ASSEMBLY THIRD READING
AB 357 (Maienschein)
As Amended May 25, 2023
Majority vote

SUMMARY

Updates the provisions of California's prohibition on testing on animals when an alternative exists.

Major Provisions

1) Defines "alternative test method or strategy" to mean a test method, including a new or revised method, that fulfills all of the following criteria:

    a) Does not use animals;

    b) Provides information of equivalent or better scientific quality and relevance compared to traditional animal test methods and includes, but is not limited to, computational toxicology and bioinformatics, high-throughput screening methods, testing of categories of chemical substances, tiered testing methods, in vitro studies, and systems biology; and

    c) Has been identified and accepted for use by a federal agency or program within an agency responsible for regulating the specific product or activity for which the test is being conducted.

2) Defines "medical research" to mean research related to the causes, diagnosis, treatment, control, or prevention of physical or mental diseases and impairments of humans and animals or related to the development of biomedical products, devices, or drugs as defined in United States Code Title 21, Section 321(g)(1). Medical research does not include the testing of an ingredient that was formerly used in a drug, tested for the drug use with traditional animal methods to characterize the ingredient and to substantiate its safety for human use, and is now proposed for use in a product other than a biomedical product, medical device, or drug.

3) Defines "traditional animal test method" to mean a process or procedure using animals to obtain information on the characteristics of a chemical or agent and that generates information regarding the ability of a chemical or agent to produce a specific biological effect under specified conditions.

4) Prohibits manufacturers and contract facilities from using traditional animal test methods within this state for which an appropriate alternative test method or strategy exists, or a waiver has been granted by the agency responsible for regulating the specific product or activity for which the test is being conducted.

5) Requires, when an alternative test method or strategy does not exist, manufacturers and contract testing facilities to use a traditional animal test method using the fewest number of animals possible and reducing the level of pain, suffering, and stress of an animal used for testing.

6) Provides that nothing in the bill prohibits the use of any nonanimal test method or strategy for the testing of any product, product formulation, chemical, drug, medical device, vaccine, or ingredient, as specified.

7) Provides that nothing in this bill prohibits the use of traditional animal testing to comply with requirements of state or federal agencies.

8) Deletes references in existing law to alternative animal tests scientifically validated and recommended by the Inter-Agency Coordinating Committee for the Validation of Alternative Methods and adopted by the relevant federal agency or agencies and the definition of the Inter-Agency Coordinating Committee for the Validation of Alternative Methods

9) Requires, commencing January 1, 2025, and annually thereafter, a manufacturer or contract testing facility in this state using traditional animal test methods to report to the Department of Public Health the number and species of animals used, the type and number of alternative test methods or strategies used, the number of waivers used, and the purpose of the use of the traditional animal tests, alternative test methods or strategies, and waivers.

10) Requires the Department of Public Health to develop a portal for collecting the information required by 9), above.

11) Provides that a violation of this bill is enforceable through a civil action by the Attorney General, the district attorney of the county in which the violation is alleged to have occurred, or a city attorney of a city or a city and county having a population in excess of 750,000 and in which the violation is alleged to have occurred.

12) Provides that if the court determines that the Attorney General or district attorney is the prevailing party in the enforcement action, the official may also recover costs, attorney's fees, and a civil penalty not to exceed $5,000 in that action.

COMMENTS

In 2000, California became the first state in the nation to enact a widespread prohibition on needless testing of consumer products on animals when the Legislature enacted SB 2082 (O'Connell), Chapter 476, Statutes of 2000. That measure prohibited animal testing if an alternative test were approved by the Interagency Coordinating Committee on the Validation of Alternative Methods. In the intervening years, the Interagency Coordinating Committee on the Validation of Alternative Methods has ceased validating alternatives to animal testing. Also, new methods and strategies for alternatives to animal testing developed. Accordingly, this measure revises, recasts, and updates the 2000 law to ensure that no animals will needlessly suffer because of an antiquated statutory prohibition on animal testing.

There is no doubt that the use of animals in scientific and product research has significantly benefitted human beings. However, many product developers and scientific observers are increasingly concerned that animal experimentation is based on scientifically flawed premises and that in many cases, animal testing retains its acceptability only because clear alternatives have not been identified. For example, dramatically rising costs and extremely high failure rates in drug development have led many to re-evaluate the value of animal studies. A study found that only about 12% of pharmaceuticals pass preclinical testing to enter clinical trials. Of those, only 60% successfully complete phase I trials. Overall, approximately 89% of novel drugs fail

human clinical trials, with approximately one-half of those failures due to unanticipated human toxicity. (Gail Van Norman, *Limitations of Animal Studies for Predicting Toxicity in Clinical Trials: Is it Time to Rethink Our Current Approach?* (November 2019) JACC: Basic to Translational Science, at p. 849.)

One prominent, and recent, example of the potential deficiencies in using dogs to test the safety of products can be found in the Environmental Protection Agency's (EPA's) most recent review of the herbicide Glyphosate, more commonly known as Round Up. In 2017, the EPA required both 90-day and chronic toxicity tests on dogs; and based on the results, the EPA eventually permitted the product to keep its registration. (United States EPA Office of Pesticide Programs Draft Human Health Risk Assessment in Support of Registration Review (December 12, 2017) at. pp. 30-31.) That same year, however, the California Office of Environmental Health Hazard Assessment required Round Up to be added to the list of chemicals necessitating a warning pursuant to Proposition 65 due to the carcinogenic risks posed by the product. (https://oehha.ca.gov/public-information/press-release/press-release-proposition-65/glyphosate-be-added-proposition-65.) Although the state and federal government are presently contesting the validity of various agency findings, the ongoing debate would seem to validate the studies that call into question the veracity of the results obtained by testing the chemicals on dogs.

Further, despite the deeply rooted assumption that animal models accurately predict human toxicity, even cursory examination of the concordance of animal and human trials raises concerns. An analysis of 2,366 drugs concluded that, "results from tests on animals (specifically rat, mouse and rabbit models) were highly inconsistent predictors of toxic responses in humans." Similar results were found for nonhuman primates and dogs, where the author argued that canine data indicating an absence of toxicity would only increase the probability that the compound would show no toxic effects in humans from 70% to 72% - a very small, almost negligible effect that comes at huge costs. (Bailey, et. al, An Analysis of the Use of Animal Models in Predicting Human Toxicology and Drug Safety, (2014), Alternatives to Laboratory Animals Journal, available at https://journals.sagepub.com/doi/abs/10.1177/026119291404200306.)

Recognizing the need to move away from cruel and inaccurate tests on animals, California has been a national leader in eliminating needless animal testing. As noted in 2000, the state was a national leader in prohibiting most animal tests when an alternative existed. Building upon that legislation, in 2018 California enacted SB 1249 (Galgiani) Chapter 899, Statutes of 2018 to prohibit the use of animal testing in the development of cosmetic products starting in 2020. Additionally, last year the Legislature approved SB 879 (Wiener) Chapter 551, Statutes of 2022, to prohibit unnecessary toxicological testing on dogs and cats. Furthermore, California was a national leader in ending the practice of sending shelter pets to be used for animal research, thus ensure these pets could be adopted to loving homes and not used to test consumer products. (AB 2269 (Waldron) Chapter 568, Statutes of 2016.)

As noted above, some aspects of California's 23-year old prohibition on animal testing when an alternative exists have become unworkable, particularly those aspects of the law which are related to the obsolete Interagency Coordinating Committee on the Validation of Alternative Methods and their approval of alternatives. This bill revises, recasts, and modernizes the 2000 law to address current scientific realities. First, this measure eliminates the references to the Interagency Coordinating Committee on the Validation of Alternative Methods and instead prohibits animal tests when a viable non-animal method or strategy exists. Furthermore, recognizing the growing prevalence of biomedical research, the bill specifically defines that term

to mean, "the investigation of the biological processes and causes of disease or research conducted to increase fundamental scientific knowledge, and to expand the understanding about how processes in living organisms develop and function but does not include traditional animal test methods done to assess the safety or efficacy of chemicals, ingredients, drugs, medical devices, vaccines, product formulations, or products."

According to the Author

California is a scientific and technological leader in non-animal alternatives. Science is rapidly moving away from outdated animal tests as many faster, less expensive, and more human-relevant alternative methods become available. This legislation would ensure that companies in California are taking advantage of these new testing strategies as soon as they are available and appropriate for use.

AB 357 would require companies and their contract testing facilities to use test methods that replace animal testing when they are available and provide information of equivalent or better scientific quality and relevance for the intended purpose. The bill would also require a manufacturer or contract testing facility using traditional animal testing methods to report annually to the Attorney General information regarding their use of animal testing.

Arguments in Support

This bill is sponsored the Humane Society of the United States and is supported by a half-dozen animal rights organizations. The Humane Society notes:

It is estimated that more than 50 million animals are used in experiments each year in the United States. Thousands may be used for a single test, and experiments are often excruciatingly painful for the animals and can vary in duration from days to months to years. In some instances, animals are not given any kind of pain medication to help relieve their suffering or distress during or after the experiment on the basis that it could affect the experiment. Animals are often killed once an experiment is over so that their tissues and organs can be examined, although it is not unusual for animals to be used in multiple experiments over many years.

Animal testing is costly, time-consuming, and often poorly predictive of toxicity in humans. Non-animal alternatives can provide more efficient as well as more effective chemical safety assessments. Human cell-based tests and advanced computer models, for example, deliver human-relevant results in hours or days, unlike some animal tests that can take months or years.

By minimizing animal testing and focusing on the use of faster, cost effective, and more reliable testing methods, companies can save lives, time, and money. This legislation would ensure companies take advantage of those new testing strategies as soon as they are approved for use.

Arguments in Opposition

As noted this bill is opposed by several biomedical and biotechnical research organizations. In opposition to the bill California Life Sciences and Biocom California jointly write:

The use of animals in testing for drug, device, vaccine, or chemical development products has long been a matter of public debate. The life sciences industry, however, is unable to fully eliminate the use of all animals in research. While the life science industry adheres to

both the 3Rs principles and rigorous ethical guidelines governing the use of laboratory animals – including review of all activities by an Institutional Animal Care and Use Committee (IACUC), as mandated by PHS (Public Health Service) Policy, USDA Regulations, and voluntary accreditation bodies, such as AAALAC international – its reliance on some degree of animal research is indispensable for ensuring the safety and efficacy of drugs, medical devices, and vaccines. By excluding these forms of safety testing from its definition of "biomedical research", AB 357 would hamstring the life sciences industry's ability to ensure the safety and efficacy of these medical products.

FISCAL COMMENTS

According to the Assembly Appropriations Committee, ongoing costs to the Department of Justice (DOJ) (General Fund) in the hundreds of thousands of dollars annually. DOJ reports costs of $47,000 in fiscal year (FY) 2023-24, $319,000 in FY 2024-25, and $555,000 in FY 2025-26 and ongoing. DOJ's Consumer Protection Section anticipates adding three positions beginning in 2025 to enforce the provision so the bill, and DOJ's California Justice Information Services Division anticipates staffing costs to initiate and support the online reporting requirements of this bill.

VOTES

ASM JUDICIARY: 8-0-3
YES: Maienschein, Connolly, Haney, Kalra, Pacheco, Papan, Reyes, Robert Rivas
ABS, ABST OR NV: Essayli, Dixon, Sanchez

ASM APPROPRIATIONS: 12-2-2
YES: Holden, Bryan, Calderon, Wendy Carrillo, Dixon, Mike Fong, Hart, Lowenthal, Papan, Pellerin, Weber, Ortega
NO: Megan Dahle, Mathis
ABS, ABST OR NV: Robert Rivas, Sanchez

UPDATED

VERSION: May 25, 2023

CONSULTANT: Nicholas Liedtke / JUD. / (916) 319-2334 FN: 0000991