SENATE THIRD READING
SB 879 (Wiener)
As Amended May 19, 2022
Majority vote

SUMMARY

Prohibits the unnecessary testing of specified substances on dogs and cats when an alternative test method has been scientifically validated and recommended by the Inter-Agency Coordinating Committee for the Validation of Alternative Methods.

Major Provisions

1) Defines the following terms:

   a) "Alternative test method" means a test method that does not use animals, or in some cases reduces or refines the use of animals, for which the reliability and relevance for a specific purpose has been established by validation bodies, including, but not limited to, the Interagency Coordinating Committee for the Validation of Alternative Methods and the Organization for Economic Co-operation and Development. Alternative test methods include, but are not limited to, high-throughput screening methods, testing of categories of chemical substances, tiered testing methods, in vitro studies, and systems biology;

   b) "Application or exposure" includes, but is not limited to, oral ingestion, skin or eye contact, or inhalation;

   c) "Canine or feline toxicological experiment" means any test or study of any duration that seeks to determine the effect, if any, of the application or exposure, whether internal or external, of any amount of a chemical substance on a dog or cat;

   d) "Cat" means any member of the species Felis catus;

   e) "Chemical substance" means, generally, any organic or inorganic substance of a particular molecular identity, including any combination of such substances occurring in whole or in part as a result of a chemical reaction or occurring in nature and any element or uncombined radical and includes pesticides.

   f) "Medical research" means 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 drugs or devices but does not include experimentation or testing of a chemical substance or ingredient proposed for use in a product other than a biomedical drug or device;

   g) "Pesticide" means any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest; any substance or mixture of substances intended for use as a plant regulator, defoliant, or desiccant; and any nitrogen stabilizer, except that the term "pesticide" does not include any article that is a "new animal drug" within the meaning determined by the United States Secretary of Health and Human Services not to be a new animal drug by a regulation establishing conditions of use for the article, or that is an animal feed or containing a new animal drug; and

h) "Testing facility" means any partnership, corporation, association, school, institution, organization, or other legal relationship, whether privately or government owned, leased, or operated, that tests chemicals, ingredients, product formulations, or products in this state.

2) Prohibits, notwithstanding any other law, a testing facility from conducting a canine or feline toxicological experiment in this state to achieve discovery, approval, maintenance of approval, notification, registration, or maintenance of a pesticide or chemical substance, unless the experiment is conducted pursuant to any of the following:

   a) To satisfy an express requirement imposed by the United States Environmental Protection Agency under the authority of the Federal Insecticide, Fungicide, and Rodenticide Act;

   b) To support an application to the United States Environmental Protection Agency for a waiver of the requirements of a), above, provided that testing is conducted solely to reduce the total number of animals needed for experiments to achieve discovery, approval, maintenance of approval, notification, registration, or maintenance of a pesticide or chemical substance; and

   c) To satisfy an express requirement imposed by the Food and Drug Administration per the Federal Food, Drug, and Cosmetic Act or any binding agency regulation promulgated upon notice and comment thereunder.

3) Provides that 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 city and county having a population in excess of 750,000 and in which the violation is alleged to have occurred, may bring a civil action for injunctive relief and that if such relief is granted, the prosecuting party may also recover costs, attorney fees, and a civil penalty not to exceed $5,000 for each day that each dog or each cat is used in a canine or feline toxicological experiment in violation of the provisions of this bill.

4) Exempts testing of the following from the prohibitions in this bill:

   a) Medical research; and

   b) Testing or experimentation conducted for the purpose of developing, manufacturing, or marketing any product intended for beneficial use in dogs or cats.

5) Provides that the bill may be referred to as the Protection of Dogs and Cats from Unnecessary Testing, or PET, Act.

COMMENTS

In recent years, several studies have called into question the effectiveness of testing the toxicity of certain consumer pesticides and medications on dogs and cats. These studies suggest that prolonged animal studies tend to lead to high rates of false-negatives, whereby a product appears safe in the animal but is subsequently found to be potentially harmful to humans. At the same time, dogs and cats may be adversely impacted by such unnecessary and ineffective testing.

Accordingly, the author suggests prohibiting the practice in California, unless such testing is required by federal law or if such testing is critical to medical research.

Animal testing has been historically used in pharmaceutical and industrial research to predict human toxicity. Before chemical products or medications are permitted to reach market, government regulators require the products to undergo a myriad of tests to ensure that the products can be used safely. Typically, before human testing can begin, regulators require a product to undergo two rounds of testing in animals, typically a rodent and one larger species, to determine toxicity and pharmacokinetics. (Kobel, *et.al, A 1-year toxicity study in dogs is no longer a scientifically justifiable core data requirement for the safety assessment of pesticides* (2010) Critical Reviews in Toxicology, at p. 1.) Approximately 90,000 dogs are used annually in laboratory tests in the United States and European Union. (Bailey, *et al., An Analysis of the Use of Dogs in Predicting Human Toxicology and Drug Safety* (2013) Alternatives to Laboratory Animals Journal, p. 335.) Frequently, dogs are utilized in chronic exposure studies whereby a dog is exposed to low levels of chemicals for a year or more to determine the hazards of chronic exposure. (Kobel, *et.al, A 1-year toxicity study in dogs, supra*, at p. 2.) Over the past two decades, the effectiveness of long-term exposure testing in dogs has come into significant doubt for many areas of study. Nonetheless, evidence suggests that dogs may still provide the most benefit in testing heart-related drugs or studying the impact to blood pressure, heart rate, and electrocardiograms of other products. (Nuffield Council on Bioethics, *The Ethics of Research Involving Animals* (2005) at pp. 156-161.) Similarly, cats have been a mainstay in research studies of neurological, cardiovascular, and respiratory diseases and the immune system. In particular, they have been valuable models for understanding the function of the neuron (nerve cell), the chemical transmission of nerve impulses, and the functional organization of the brain. Neuroscientists studying cats have provided a map of the circuitry of the vertebral cortex revealing the major pathways that send signals from the eye to the brain. Approximately 21,000 cats were part of research, education or drug and other product safety testing in 2014, as reported by U.S. research facilities to the U.S. Department of Agriculture. (USDA Animal and Plant Health Inspection Service, *Annual Report Animal Usage by Fiscal Year,* (2015), *available at* https://www.aphis.usda.gov/animal_welfare/downloads/7023/Animals%20Used%20In%20Research%202014.pdf.) A growing body of research is suggesting, especially outside of cardiology studies, that dog testing may produce false negative results. With regard to pesticide tests, in 2006, the United States Environmental Protection Agency (EPA) eliminated many mandatory year-long pesticide tests in dogs after reaching a "clear conclusion that a 12-month dog study in addition to a 3-month study is of little value and the requirement for this study should be eliminated from the list of mandatory studies to be performed in the safety assessment for pesticides." (Kobel, *et.al, A 1-year toxicity study in dogs, supra*, at p. 11.) Although the EPA no longer mandates year-long tests for many pesticides, in 2019, an undercover investigation by the United States Humane Society (a supporter of this bill) discovered that Dow Agrosciences was testing fungicides on at least 36 beagles at a facility in Michigan. (Shawna Williams, *Humane Society Successfully Campaigns to End Pesticide Test on Dogs* (2019) The Scientist Magazine.)

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 percent to 72 percent - 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 deficiencies of testing of certain products and medicines on dogs and cats, as well as the horrific cruelty such testing inflicts on innocent animals, this bill prohibits toxicological testing on dogs and cats. Nonetheless, recognizing that certain federal laws require such tests this bill would permit testing to continue on dogs and cats if required to obtain specified approvals in accordance with federal law. Additionally, this bill also exempts testing that is required for medical research, as defined, as well as testing for products intended to be used for dogs and cats. This bill also vests 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 city and county having a population in excess of 750,000 with the ability to seek civil penalties of up to $5,000 per day for violations of this bill. Finally, this bill adopts a severability clause.

According to the Author

> The PET Act ends the suffering of cats and dogs by prohibiting these household pets from being used in toxicity tests for specific products such as pesticides, chemical substances and food additives. Toxicity testing on dogs and cats, which includes force-feeding or injecting the animals with chemicals to test for a harmful reaction or even death, is largely ineffective and is not supported by current science. This testing does, however, cause a lot of harm to animals. Common household pets, like dogs and cats, go through unnecessary suffering that has little scientific basis and does not produce useful results. Dogs and cats should not have to undergo unnecessary testing, especially when it is so often highly painful and irreversibly harmful. SB 879 ends this type of testing, which does not make humans any safer. Specifically, SB 879 prohibits all California testing facilities from using dogs and cats in certain toxicity tests, unless required by federal law.

Arguments in Support

This bill is sponsored by the Humane Society of the United States and supported by several other groups that support animal health and well-being. In support of this bill the Humane Society writes:

> Continuing to allow unnecessary toxicity testing on dogs in California is inconsistent with our state's position as a world leader on animal welfare and our role in fostering innovative technological and scientific advancements, including replacements for animal testing. California is a trailblazer in the protection of animals with some of the strongest laws and regulations concerning animal welfare of any U.S. state, including a 2018 law that made it the first state to ban the sale of cosmetics tested on animals. This bill continues to build upon the strides made to improve animal welfare and drive innovation towards more humane and human relevant science.

Arguments in Opposition

No opposition on file.

FISCAL COMMENTS

According to the Assembly Appropriations Committee:

1) Cost pressures (Trial Court Trust Fund) in the low hundreds of thousands of dollars to the trial courts in increased workload. This bill authorizes the Department of Justice, county district attorneys, and city attorneys to file civil injunctive action to enforce the prohibition against contract testing facilities conducting toxicological experiments on dogs. One hour of court time costs approximately $1,000. If DOJ, district attorneys or city attorneys file a total of 20 injunctions statewide requiring an average of 12 hours of court time for each injunction, the cost to the courts would be $240,000. Although courts are not funded on the basis of workload, increased pressure on the Trial Court Trust Fund and staff workload may create a need for increased funding for courts from the General Fund (GF) to perform existing duties.

2) Costs (Legal Services Revolving Fund) to the Department of Justice (DOJ) of $16,000 in fiscal year (FY) 2022-23, $32,000 in FY 2023-24, and $16,000 in FY 2024-25 in additional staff time to bring claims against specified facilities that conduct unauthorized toxicological experiments on dogs and cats. DOJ anticipates receiving enforcement referrals from its clients that conduct inspections, such as the Department of Health Care Services. DOJ anticipates its attorney workload will increase by 177 hours in FY 2021-22, 355 hours in FY 2022-23, and 177 hours in FY 2023-24. This bill will be reimbursable through direct billings to client agencies.

VOTES

SENATE FLOOR: 38-0-2
YES: Allen, Archuleta, Atkins, Bates, Becker, Borgeas, Bradford, Caballero, Cortese, Dahle, Dodd, Durazo, Eggman, Glazer, Gonzalez, Grove, Hueso, Hurtado, Kamlager, Laird, Leyva, Limón, McGuire, Melendez, Min, Newman, Nielsen, Ochoa Bogh, Pan, Portantino, Roth, Rubio, Skinner, Stern, Umberg, Wieckowski, Wiener, Wilk
ABS, ABST OR NV: Hertzberg, Jones

ASM JUDICIARY: 10-0-1
YES: Stone, Cunningham, Bloom, Davies, Haney, Kalra, Maienschein, Reyes, Robert Rivas, Wilson
ABS, ABST OR NV: Kiley

ASM APPROPRIATIONS: 16-0-0
YES: Holden, Bigelow, Bryan, Calderon, Arambula, Megan Dahle, Davies, Mike Fong, Fong, Gabriel, Eduardo Garcia, Levine, Quirk, Robert Rivas, Akilah Weber, McCarty

UPDATED

VERSION: May 19, 2022

CONSULTANT: Nicholas Liedtke / JUD. / (916) 319-2334 FN: 0003368