SENATE JUDICIARY COMMITTEE Senator Thomas Umberg, Chair 2021-2022 Regular Session

SB 879 (Wiener)

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Fiscal: Yes Urgency: No

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SUBJECT

Toxicological testing on dogs and cats

DIGEST

This bill prohibits certain facilities from conducting toxicological experiments on dogs and cats for specified purposes. This bill subjects those in violation to civil penalties to be assessed in actions brought by the Attorney General or other, local prosecutors, as specified.

EXECUTIVE SUMMARY

Animal testing has long been used in pharmaceutical and industrial research to predict human toxicity. This includes the use of dogs and cats. However, proponents of the bill point to a growing body of research calling into question the effectiveness of such testing. Many suggest that animal subjects are poor predictors of toxicity in humans and that better alternatives should be explored, not just for ethical reasons, but for economic and practical reasons as well.

This bill prohibits testing facilities from conducting canine or feline toxicological experiments in California for certain purposes related to pesticides and other chemical substances, as specified. There are a number of exemptions, including where federal agencies require such testing. Violations are subject to only public enforcement.

This bill is sponsored by the Humane Society of the United States. There is no known opposition.

PROPOSED CHANGES TO THE LAW

Existing law:

- 1) Prohibits manufacturers and contract testing facilities from using traditional animal testing methods within this state when an appropriate alternative test method has been scientifically validated and recommended by the Inter-Agency Coordinating Committee for the Validation of Alternative Methods or other specified agencies. However, this does not prohibit the use of animal tests to comply with the requirements of state agencies; or federal agencies when the federal agency has approved an alternative nonanimal test, as specified above, and the federal agency staff concludes that the alternative nonanimal test does not assure the health or safety of consumers. (Civ. Code § 1834.9.)
- 2) Makes it unlawful for a manufacturer to import for profit, sell, or offer for sale in this state, any cosmetic, if the cosmetic was developed or manufactured using an animal test that was conducted or contracted by the manufacturer, or any supplier of the manufacturer, on or after January 1, 2020. (Civ. Code § 1834.9.5.)
- 3) Prohibits an animal shelter entity or other person that accepts animals from the public or takes in stray or unwanted animals from selling, giving, or otherwise transferring a living animal to a research facility, an animal dealer, or other person for the purpose of research, experimentation, or testing. In reverse, a research facility, animal dealer, or other person shall not procure, purchase, receive, accept, or use a living animal for the purpose of research, experimentation, or testing if that animal is transferred from, or received from, an animal shelter entity or other person that accepts animals from the public or takes in stray or unwanted animals. (Civ. Code § 1834.7.)

This bill:

- 1) Establishes the Protection of Dogs and Cats from Unnecessary Testing Act.
- 2) Prohibits 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 conducted pursuant to any of the following:
 - a) to satisfy an express requirement imposed by the United States Environmental Protection Agency (EPA) under the authority of the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. § 136 et seq.); the Toxic Substances Control Act (15 U.S.C. § 2601 et seq.); including any EPA rule, regulation, or order;
 - b) to support an application to the EPA for a waiver from any requirement, provided that the 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; or
- c) to satisfy an express requirement imposed by the Food and Drug Administration (FDA) per the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 301 et seq.) or any binding agency regulation promulgated upon notice and comment thereunder.
- 3) Exempts from this prohibition testing or experimentation conducted for the purpose of developing, manufacturing, or marketing any product intended for beneficial use in dogs or cats.
- 4) Provides definitions for its core terms, including:
 - 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) "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. "Application or exposure" includes, but is not limited to, oral ingestion, skin or eye contact, or inhalation. "Application or exposure" does not include testing of veterinary products for canine or feline health; and
 - c) "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.
- 5) Authorizes 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, to bring a civil action for injunctive relief pursuant to this paragraph. A prevailing official 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 this law. These are the exclusive remedies for violations of this law.

COMMENTS

1. Stated intent of the bill

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.

2. A ban with exemptions

Proponents of the bill point to various studies showing the lack of evidence that toxicological testing on dogs and cats is warranted and effective.

One study specifically addressed the issue of how well-suited toxicological testing on dogs is, given the predictive results. Its analysis found the results of the studies "show that the absence of toxicity in dogs provides virtually no evidence that adverse drug reactions (ADRs) will also be absent in humans."

Another study focused on what the limitations of animal studies as a whole are specifically with respect to predicting toxicity in humans. It found:

Although animal toxicity testing has been the stalwart basis of "ensuring" safety of in-human clinical testing and use, examination of the published data raises significant questions about whether it is reliable and should be abandoned or at least significantly curtailed in favor of other potentially more reliable methods. Savings in time and cost for new therapeutics

¹ Jarrod Bailey, Michelle Thew, & Michael Balls, *An analysis of the use of dogs in predicting human toxicology and drug safety*. (November 1, 2013) Alternatives to Laboratory Animals, https://journals.sagepub.com/doi/10.1177/026119291304100504?url_ver=Z39.88-2003&rfr_id=ori:rid:crossref.org&rfr_dat=cr_pub%20%200pubmed [as of Mar. 1, 2022]. All further internet citations are current as of this date.

could be substantial, if the safety of nonanimal preclinical testing is proven. Increasingly, scientific organizations and government regulatory agencies are recognizing that alternative methods may replace animal testing and improve the flow and safety of new therapeutics to human use.²

These studies arguably undermine the basis for the longstanding use of animals for such experimentation. Another study prompted by the U.S. Department of Veterans Affairs concluded that although many investigators cited their experience using dogs and the historical data available in dog models as justification for using dogs in further testing, the "justifications are insufficient alone and constitute a form of circular reasoning that perpetuates the use of laboratory dogs without adequate examination of alternatives."³

This bill expedites an earnest examination of alternatives to toxicological testing on cats and dogs by instituting a ban on certain experiments by testing facilities for certain purposes. The prohibition extends only to testing of pesticides and other chemical substances, as those terms are defined under federal law. Even so, the bill exempts such experiments when conducted pursuant to federal regulatory mandates. In addition, the prohibition does not apply to "testing or experimentation conducted for the purpose of developing, manufacturing, or marketing any product intended for beneficial use in dogs or cats." This exclusion was initially in response to AB 2059 (Kamlager, 2020), a substantially similar bill introduced in 2020. This bill is also modeled after a bill introduced last year by the same author, SB 252 (Wiener, 2021), albeit with a much narrower approach.

In order to ensure there is some repercussion for violating this new law, the bill provides a modest enforcement mechanism. It authorizes the Attorney General and the district attorney or city attorney, as specified, in whose jurisdiction the violation is alleged to have occurred, to bring an action seeking injunctive relief and a civil penalty of no more than \$5,000 for each day that each animal is used in a toxicological experiment in violation of this law. The prosecuting entity may seek to recover costs and attorneys' fees in a successful action.

The Humane Society of the United States, the sponsor of this bill, writes:

California is a trailblazer in the protection of animals with some of the strongest laws and regulations concerning animal welfare of any U.S.

² Gail A. Van Norman, *Limitations of Animal Studies for Predicting Toxicity in Clinical Trials: Is it Time to Rethink Our Current Approach?* (November 25, 2019) JACC. Basic to translational science, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6978558/.

³ National Academies of Sciences, Engineering, and Medicine *Necessity, Use, and Care of Laboratory Dogs at the U.S. Department of Veterans Affairs* (2020) The National Academies Press, https://www.nap.edu/read/25772/chapter/2.

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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.

SUPPORT

Humane Society of the United States (sponsor)

OPPOSITION

None known

RELATED LEGISLATION

<u>Pending Legislation:</u> AB 1881 (Santiago, 2022) enacts the Dog and Cat Bill of Rights and requires certain shelters and rescue groups to post a copy of these rights. This bill is in the Assembly Business and Professions Committee.

Prior Legislation:

SB 585 (Stern, 2021) prohibits a person from removing or disabling a cat's claws by performing a declawing procedure, as defined, except under specified circumstances. It subjects violations to civil penalties imposed in actions brought by the Attorney General or local prosecutors' offices, as specified. This bill died in the Senate Business, Professions, and Economic Development Committee.

AB 1282 (Bloom, Ch. 752, Stats. 2021) establishes guidelines for veterinarians to operate community blood banks for animals that source blood from animals volunteered by their owners. It also establishes conditions on which captive closed-colony canine blood banks are eliminated. The bill allows the importation of animal blood from out-of-state blood banks that comply with California standards. It provides implementation requirements for the Veterinary Medical Board and the California Department of Food and Agriculture.

SB 252 (Wiener, 2020) *See* Comment 2. This bill died in the Assembly Appropriations Committee.

AB 2059 (Kamlager, 2020) was substantially identical to SB 252, applying only to testing on dogs. It died in the Assembly Appropriations Committee.

SB 1249 (Galgiani, Ch. 899, Stats. 2018) makes it unlawful for a manufacturer of cosmetic products to import for profit, sell, or offer for sale in this state, any cosmetic, if the cosmetic was developed or manufactured using an animal test that was conducted or

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contracted by the manufacturer, or any supplier of the manufacturer, on or after January 1, 2020, as specified. This bill provides that violations are punishable by an initial \$5,000 fine and an additional \$1,000 for each day the violation continues.
