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

SB 252 (Wiener)
Version: March 15, 2021
Hearing Date: April 6, 2021
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, unless conducted for specified purposes. This bill subjects violations 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 each testing facility from conducting a canine or feline toxicological experiment in California unless the experiment is conducted for one of a series of purposes laid out in the bill. These exclusions include carve outs for medical research and specified testing of medical devices, drugs, and pesticides. It also excludes testing or experimentation of products intended solely for use in nonhuman animals, such as animal vaccines, animal medicine, or flea and tick products intended to be applied only to nonhuman animals. Violations are subject to only public enforcement.

This bill is sponsored by the Humane Society of the United States. It is supported by various groups advocating for the welfare of animals. It is opposed by Biocom California and the California Life Sciences Association.

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 unless the experiment is conducted for the following purposes:
    a) medical research;
    b) to comply with federal requirements pertaining to the approval or maintenance of a medical device, as defined;
    c) to achieve discovery, approval, or maintenance of a drug, pursuant to a testing requirement imposed by the United States Food and Drug Administration (FDA), as specified, or any binding agency regulation promulgated upon notice and comment thereunder, if the FDA has not otherwise expressly authorized drug manufacturers to use alternative test methods;

d) to achieve discovery, approval, or maintenance of a biologic, pursuant to a testing requirement imposed by the United States Department of Agriculture (USDA), as specified, or any binding agency regulation promulgated upon notice and comment thereunder, if the USDA has not concluded that waivers shall be granted for the experimentation or studies or expressly indicated acceptance of alternative test methods;
e) to achieve discovery, approval, registration, or maintenance of a pesticide, pursuant to a testing requirement imposed by the United States Environmental Protection Agency (EPA), or any binding agency regulation promulgated upon notice and comment thereunder, if the EPA has not concluded that waivers shall be granted for such experimentation or studies or expressly indicated acceptance of alternative test methods;
f) to comply with a requirement to conduct the experiment under the Toxic Substances Control Act, if the EPA has not concluded that waivers shall be granted for such experimentation or studies or expressly indicated acceptance of testing methods alternative to laboratory animal testing, including, but not limited to, in vitro, in silico, and in chemico approaches for identifying skin sensitization hazards.

3) Exempts from this prohibition testing or experimentation conducted for the purpose of developing, manufacturing, or marketing any product intended solely for use in nonhuman animals, including, but not limited to, animal vaccines, animal medicine, or flea and tick products intended to be applied only to nonhuman animals.

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;
   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;
   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; and
   d) "medical research" means research related to the causes, progression, diagnosis, treatment, control, or prevention of physical or mental diseases and impairments or chronic conditions of humans or animals or related to the development of biomedical products or devices, as defined.

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 occurred, to bring a civil action for injunctive relief pursuant to this paragraph. If the court determines that the Attorney General, district attorney, or city attorney is the prevailing party in the enforcement action, the 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 section. These are the exclusive remedies for violations of this section.

COMMENTS

1. Stated intent of the bill

According to the author:

> 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. SB 252 ends this type of testing, which does not make humans any safer. Specifically, SB 252 prohibits all California testing facilities from using dogs and cats in toxicity tests, unless required by federal law. SB 252 does not impact medical research.

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."[1]

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

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[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. 16, 2021]. All further internet citations are current as of March 16, 2021.

> 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 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] However, Biocom California argues in opposition that the ban implemented by this bill is overly broad and would "adversely affect biomedical research in California."

This bill expedites an earnest examination of alternatives to toxicological testing on cats and dogs by instituting a ban on such experiments by testing facilities. Although the definition of testing facilities is broad, the prohibition on the testing contains various exemptions. Toxicological testing on cats and dogs can still take place when the experiment serves a wide host of purposes. This includes for medical research, defined as "research related to the causes, progression, diagnosis, treatment, control, or prevention of physical or mental diseases and impairments or chronic conditions of humans or animals or related to the development of biomedical products or devices, as defined under Section 321(h) of Title 21 of the United States Code [the Federal Food, Drug, and Cosmetic Act]." The term specifically excludes research related to the development of "drugs" as defined in the Federal Food, Drug, and Cosmetic Act. However, it also exempts any experiment conducted to achieve discovery, approval, or maintenance of a drug, biologic, or pesticide pursuant to a testing requirement imposed by certain federal agencies.

Writing in opposition, the California Life Sciences Association specifically highlights concerns with the exclusion of research related to the development of drugs as defined in the Federal Food, Drug, and Cosmetic Act. It states that it is "unclear as to why the

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[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.

understanding of what constitutes medical research would now exclude research into such critical therapies for patients, especially given the current circumstances of our nation." It asserts that the bill must be amended to specifically exempt from the ban toxicological testing on dogs and cats for drug development for human and animal health to "prevent the disruption of critical research into patient therapies in California, including those for infectious diseases, and to otherwise alleviate unnecessary confusion around permissible medical research." Opponents highlight a series of successful drugs that were tested on dogs on their way to market, including Nexium, Crestor, Nasonex, and Viagra.

It should be noted that the bill exempts testing to achieve discovery, approval, or maintenance of a drug where it is "pursuant to a testing requirement imposed by the [FDA]" pursuant to federal law, as specified, or pursuant to "any binding agency regulation promulgated upon notice and comment thereunder, if the FDA has not otherwise expressly authorized drug manufacturers to use alternative test methods." Therefore, if the FDA expressly requires testing a drug on dogs or cats, the bill exempts it from the ban.

In addition, some concerns have been raised about the ban potentially impacting medical research in connection with vaccines. Although the bill language likely already allows for such research, the author has agreed to take the following amendment:

> Amendment
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> Add the following to the end of Section 1834.9.3(b)(6): "except that the term 'medical research' shall include any vaccine, as defined under Section 4132(a)(2) of Title 26 of the United States Code."

Responding to concerns raised when a nearly identical bill was being heard last session, AB 2059 (Kamlager, 2020), this bill also does not apply the ban to "testing or experimentation conducted for the purpose of developing, manufacturing, or marketing any product intended solely for use in nonhuman animals, including, but not limited to, animal vaccines, animal medicine, or flea and tick products intended to be applied only to nonhuman animals." In opposition to this bill, the California Life Sciences Association also requests that a clarifying amendment be taken to include registration and licensing in the exemption found in Section 1834.9.3(a)(4) regarding biologics. In response, the author has agreed to take such an amendment.

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. State. Twenty years ago, the state passed legislation that mandated the use of non-animal test methods validated by the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) for certain products. In 2018, California also became 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. Alternative testing methods are not only more affordable, but they are more effective and less harmful.

A coalition of groups in support of the bill make the case:

> Dogs that undergo toxicity testing suffer terribly and are kept in empty steel cages, often alone. They may be force-fed drugs, pesticides, or other substances and are observed for harmful effects such as heart failure, signs of cancer, or even death. Some tests involve administering chemicals at extremely high doses to dogs over a prolonged period, causing slow and horrific deaths. Dogs and cats are often killed after studies so that their tissues and organs can be examined.
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> Despite this needless suffering, dog tests do not ensure human safety and have scientific limitations that never will improve. An expanding body of analysis is showing that dogs are extremely unreliable at predicting human reactions to toxic substances and that predictions of toxicity based on canine data are little better than a coin toss. Alternative testing methods are more affordable, more predictive, and clearly less harmful to animals. As we move closer to the time when no animals are used for toxicity testing, we can take a big step in that direction now by enacting SB 252 and ending dog and cat toxicity testing that is not federally required.

The California Life Sciences Association writes in opposition:

> [W]hile we appreciate the inclusion of more United States regulatory agencies and processes in the recent amendments to [SB] 252, we remain concerned as to the impact of the bill on the life sciences industry's ability to maintain compliance with international regulatory authorities. Such actions necessary to maintain compliance internationally may include, for instance, circumstances where a vaccine or pharmaceutical has been licensed in the European Union with data from the United States, requiring the use of canine studies to satisfy European Medicines Agency requirements.

The association requests an amendment exempting toxicological testing on dogs and cats when it is done in order "to comply with a requirement to gain approval of a compound for export to a foreign entity."

SUPPORT

Humane Society of the United States (sponsor)
Alternatives Research & Development Foundation
Animal Legal Defense Fund
Cruelty Free International
Humane Society Legislative Fund
Humane Society Veterinary Medical Association
National Anti-Vivisection Society
Physicians Committee for Responsible Medicine
Rise for Animals
Social Compassion in Legislation
Over 500 individuals

OPPOSITION

Biocom California
California Life Sciences Association

RELATED LEGISLATION

Pending 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 is currently in the Senate Judiciary Committee.

AB 1282 (Bloom, 2021) establishes new procedures governing community blood banks for animals and imposes new requirements on veterinarians engaged in the production of animal blood and blood component products. This bill is in the Assembly Business and Professions Committee.

Prior Legislation:

AB 2059 (Kamlager, 2020) was substantially identical to this bill, 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 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.

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