Congress of the United States

Washington, DC 20510

June 22, 2022

Robert Califf, M.D.
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Commissioner Califf:

Thank you for prioritizing the reduction of animal testing that is required by the Food and Drug Administration (FDA) and seeking to launch a dedicated new program focused on achieving this goal.[1,2] Allowing the regulated community to utilize high-tech alternatives to inhumane and wasteful animal tests to fulfill FDA requirements will save time, money, and animals' lives, and will expedite drug development.

To this end, we are writing to request that the FDA develop and release Guidance for Industry on alternatives to animal testing.

In recent years, concerns have been raised about the use of thousands of dogs annually in painful and deadly tests undertaken for FDA approval of human drugs and medical devices.[3] Reports have even documented how National Institutes of Health (NIH) divisions involved in drug development have spent millions of taxpayer dollars to commission tests to gain FDA approval that involve dogs, including puppies, being de-barked, force-fed experimental drugs, and even injected with cocaine.

The FDA appears to be sending mixed messages about animal testing requirements. For instance, the FDA has stated it "does not mandate that human drugs be studied in dogs."[4] On the other hand, the NIH and private companies have argued that the FDA required them to conduct tests on dogs.

We are aware that FDA guidance documents released in recent years contain the following brief footnote stating that the FDA will consider alternatives to animal testing for regulatory purposes:

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[1] Califf, Robert. Testimony Before the U.S. House of Representatives Appropriations Subcommittee on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies, May 19, 2022, https://docs.house.gov/meetings/AP/AP01/20220519/114643/HHRG-117-AP01-20220519-SD001.pdf

[2] "FDA Seeks $8.4 Billion to Further Investments in Critical Public Health Modernization, Core Food and Medical Product Safety Programs." FDA.gov, March 28, 2022, https://www.fda.gov/news-events/press-announcements/fda-seeks-84-billion-further-investments-critical-public-health-modernization-core-food-and-medical

[3] Taylor, Scott. "Drug-testing on puppies: new report asks for alternative testing at FDA labs." WJLA, July 11, 2021, https://wjla.com/features/i-team/animals-drug-testing-fda-labs-animals

[4] Taylor.

> *"We support the principles of the "3Rs," to reduce, refine, and replace animal use in testing when feasible. We encourage sponsors to consult with us if they wish to use a non-animal testing method they believe is suitable, adequate, validated, and feasible. We will consider if such an alternative method could be assessed for equivalency to an animal test method."*[5]

Unfortunately, the actual process by which sponsors can engage with the FDA and gain approval to use alternatives to animal tests for regulatory purposes is not clearly defined.

To eliminate unnecessary government-mandated animal testing and facilitate greater use of modern alternative methods, we request that the FDA develop and release Guidance for Industry on how alternatives to animal testing can be used to meet regulatory requirements. Furthermore, we ask the FDA to detail a transparent process by which sponsors can engage with the agency on this issue and gain approval for non-animal testing methods.

We hope you will consider enacting these measures as soon as possible to promote alternatives to animal testing. Thank you for your leadership on this issue and consideration of our request.

Sincerely,

Dina Titus
Member of Congress

Brian J. Mast
Member of Congress

Eleanor Holmes Norton
Member of Congress

Brian Fitzpatrick
Member of Congress

Nicole Malliotakis
Member of Congress

Albio Sires
Member of Congress

[5] "Sponsor Responsibilities—Safety Reporting Requirements and Safety Assessment for IND and Bioavailability/Bioequivalence Studies." FDA.gov, June 2021, https://www.fda.gov/media/150356/download

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