

Congress of the United States
Washington, DC 20515

July 22, 2020

The Honorable Dr. Stephen M. Hahn
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993

Dear Commissioner Hahn:

We are writing to request information about FDA policies mandating that drug companies conduct testing on dogs to fulfill regulatory requirements. We understand from recent reports that in these tests, dogs—even small puppies—are made to ingest or inhale large doses of drugs for months on end before being killed and dissected. Several companies, including those developing vaccines and treatments for COVID-19, have questioned the need for these animal tests typically mandated by the FDA.

The chief medical officer of Moderna Therapeutics, whose COVID-19 vaccine candidate recently passed Phase 1 human trials after the FDA allowed it to avoid some animal testing, told media, “I don’t think proving this in an animal model is on the critical path to getting this to a clinical trial.”^{1,2} Likewise, Vanda Pharmaceuticals, which also has a potential COVID-19 treatment in clinical trials, has stated, “The animal studies the FDA demands...have been considered routine in the pharmaceutical industry for decades, despite the growing body of evidence discrediting such studies’ scientific value.”^{3,4}

We are concerned by reports that the FDA has sometimes not allowed companies to use alternatives to animal testing that are more accurate, cost-effective and efficient.⁵ However, we are encouraged by the FDA’s ongoing efforts to replace regulatory testing on dogs for human food additives and veterinary drugs, and would like to see the same thing happen for pharmaceutical testing.^{6,7} Such a move would save time, money and dogs, and accelerate medical innovation. Recent polling shows that a majority of Americans support eliminating the FDA’s dog testing mandate for pharmaceuticals.

¹Boodman, Eric. “Coronavirus Vaccine Clinical Trial Starting without Usual Animal Data.” *STAT*, 11 Mar. 2020,

www.statnews.com/2020/03/11/researchers-rush-to-start-moderna-coronavirus-vaccine-trial-without-usual-animal-testing.

² Cohen, Elizabeth. “Moderna Coronavirus Vaccine: Early Results from Trial Show Participants Developed Antibodies against the Virus.” *CNN*, 18 May 2020, edition.cnn.com/2020/05/18/health/coronavirus-vaccine-moderna-early-results/index.html.

³ “Open Letter to the Food and Drug Administration.” *Vanda Pharmaceuticals*, https://mma.prnewswire.com/media/818251/Open_Letter.pdf

⁴ “Vanda Initiates Study of Tradipitant in Hospitalized Patients with Severe COVID-19 Pneumonia.” *American Pharmaceutical Review*, 7 Apr. 2020, www.americanpharmaceuticalreview.com/1315-News/562883-Vanda-Initiates-Study-of-Tradipitant-in-Hospitalized-Patients-with-Severe-COVID-19-Pneumonia.

⁵ Bellotti, Anthony and David Clement. “Outdated Regulations are Hampering A Coronavirus Cure.” *Washington Examiner*, 18 June 2020, <https://www.washingtonexaminer.com/opinion/op-eds/outdated-regulations-are-hampering-a-coronavirus-cure>

⁶ FDA. “Update on CFSAN Toxicology Activities.” 3 Dec. 2019, <https://www.fda.gov/media/132933/download>

⁷ “FDA Proposes Study to Eliminate Use of Dogs in Some Types of Research.” *U.S. Food and Drug Administration*, 16 Nov. 2018, www.fda.gov/animal-veterinary/cvm-updates/fda-proposes-study-intent-eliminating-use-dogs-certain-types-research.

Please provide our offices with the following information:

1. List all relevant laws, regulations and guidances that FDA relies on to require or recommend dog testing by drug makers and the date each was last updated.
2. When did the FDA last evaluate the scientific necessity of its various dog testing requirements and recommendations for pharmaceuticals? Please provide any formal or informal FDA reports.
3. Has the FDA reviewed past drug applications to assess how well dog tests predicted human outcomes? If so, when? Please provide the results of any such reviews.
4. What is the estimated cost and timeline of the various dog tests required or recommended by the FDA for pharmaceuticals?
5. Has the FDA assessed the accuracy of dog testing versus available alternative methods? If so, when? Please provide the results of any such reviews.
6. What is the FDA currently doing to advance the regulatory acceptance of data from organs-on-a-chip and other innovative and more efficient methods for drug testing that companies can use to replace dog tests?

You are likely aware that the House Appropriations Committee included language we supported in its FY21 FDA funding bill that also addresses this issue.⁸

We want to ensure that unnecessary FDA animal testing red tape does not pose obstacles to medical innovation or slow development of safe and effective drugs, including COVID-19 vaccines and therapies that are desperately needed to restore public health and fully re-open the economy.

Thank you for your cooperation.

Sincerely,



Brendan F. Boyle
Member of Congress



Scott Perry
Member of Congress

⁸ Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Bill, 2021, <https://appropriations.house.gov/sites/democrats.appropriations.house.gov/files/Ag%20Report%20received%207-2-20.pdf>

Matt Gaetz
Member of Congress

Eleanor Holmes Norton
Member of Congress

Brian Fitzpatrick
Member of Congress

Peter A. DeFazio
Member of Congress

Marcy Kaptur
Member of Congress

Madeleine Dean
Member of Congress

Deb Haaland
Member of Congress

Lucille Roybal-Allard
Member of Congress

Dina Titus
Member of Congress

Richard E. Neal
Member of Congress

Alcee L. Hastings
Member of Congress

Steve Cohen
Member of Congress

Suzanne Bonamici
Member of Congress

Ann McLane Kuster
Member of Congress

Cindy Axne
Member of Congress

Earl Blumenauer
Member of Congress