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February 17, 2022

Robert Califf, M.D.
Commissioner
U.S. Food and Drug Administration

Via e-mail: commissioner@fda.hhs.gov

Dear Dr. Califf:

We are writing on behalf of PETA Science Consortium International e.V.,[1] an organization that advances reliable, non-animal toxicology testing approaches. We applaud you for taking on a leadership role during this challenging time. As the FDA works toward solutions related to the current pandemic and future emergency preparedness, we urge the agency to review its policies on preclinical safety testing and ensure that the most reliable data along with core scientific principles are used during the drug development process. Permitting safe and effective drugs to reach patients quickly is critical to addressing the challenges of our time, and the FDA achieved success in bringing COVID-19 vaccines to market with great speed, in part by allowing vaccine developers to leverage human-relevant data and restrict their reliance on preclinical animal tests. Given your commitment to scientifically sound data, we look forward to a stronger focus on human-relevant data gathered from sources such as real-world evidence, *in vitro* techniques, and *in silico* analyses as drugs are assessed for safety and efficacy. This shift in focus is crucial, given that about 95% of new drugs that pass the currently required preclinical animal tests fail in humans, and 10 to 15 years are generally needed to bring a new therapy to market under the existing paradigm.[2]

During your confirmation hearings, we appreciated your support for shifting toward the use of non-animal methods to enable more efficient pre-clinical development and evaluation of new drugs and devices. A reaffirmed commitment to demonstrate the FDA's support of modern approaches to safety and efficacy assessment without the use of animals will generate a more human-relevant understanding of toxicity and efficacy while expediting the availability of treatments to patients. While under your leadership, **we urge the agency to take the following actions in order to continue modernizing the drug approval process**:

- **Support the FDA Modernization Act.**[3]
  This bill strengthens the FDA's movement to adopt modern science by clearly noting that non-animal test methods—including cell-based assays, organs-on-chips and microphysiological systems, sophisticated computer modeling, and other human biology–based test methods—can be used to show that new treatments are safe and effective.

- **Integrate successful policies from the Coronavirus Treatment Acceleration Program (CTAP)[4] more broadly.**
  - Under CTAP, the FDA has delivered new treatments to patients as quickly as possible, while ensuring that patients are protected by the best modern science. Vaccines were allowed to enter clinical trials without first completing the routine suite of animal tests, a tremendous step forward for both "speed to patient" and human-relevant science.
  - CTAP success can be expanded to all the agency's product review divisions by reducing requirements for animal tests when modern, human-relevant safety and efficacy test methods are available and by increasing access to clinical trials for companies prioritizing the use of data from non-animal toxicological tests.

- **Prioritize an official database of preclinical data.**
  You suggested this concept as a counterpart to ClinicalTrials.gov during your previous time as commissioner, and we agree that the much-needed increase in transparency of both successful and abandoned drugs would revolutionize new drug development.

- **Support non-animal methods through programs and funding.**
  Initiatives like the Innovative Science and Technology Approaches for New Drugs Pilot Program[5] and the Medical Device Development Tools program[6] are helpful steps in non-animal method implementation, and we strongly recommend continued support for these programs and the introduction of others that provide test method developers with a systematic approach for engaging with agency reviewers. This would ensure that the FDA's needs are represented in critical aspects of test development.

- **Ensure that at least one representative from each FDA center participates in relevant Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) meetings.**
  - ICCVAM meetings provide a forum for sharing information on emerging approaches that would meet regulatory needs, and increased FDA participation would ensure that all centers remain informed of new approaches that they are likely to encounter within regulatory submissions.
  - This action would assist the agency in meeting goals put forth in several FDA policies[7,8,9] centered around the replacement of animal tests with new tools that reliably promote human health and safety.

We commend the agency for its role in advancing human-relevant science and look forward to the evidence-based actions that you will take during your term. By moving away from a reliance on animal tests while shifting toward modern, human-relevant techniques, the FDA will bring safer and more effective drugs to the public in a timely manner.

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We ask that you or someone from your staff contact April Naab at 406-231-9707 or AprilN@thepsci.eu so that we can discuss these important matters. Thank you kindly for your time and consideration.

Sincerely,

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cc: Julia C. Tierney, J.D., Chief of Staff, Office of the Commissioner (julia.tierney@fda.hhs.gov)

[1]PETA Science Consortium International e.V. Available at: https://www.thepsci.eu
[2]National Institutes of Health. National Center for Advancing Translational Sciences. "About the National Center for Advancing Translational Sciences." Available at: https://ncats.nih.gov/about
[3]H.R. 2565. FDA Modernization Act of 2021. Available at: https://www.congress.gov/bill/117th-congress/house-bill/2565?s=1&r=76
[4]FDA. Coronavirus Treatment Acceleration Program (CTAP). Available at: https://www.fda.gov/drugs/coronavirus-covid-19-drugs/coronavirus-treatment-acceleration-program-ctap
[5]FDA Center for Drug Evaluation and Research. Innovative Science and Technology Approaches for New Drugs (ISTAND) Pilot Program. Available at: https://www.fda.gov/drugs/drug-development-tool-ddt-qualification-programs/innovative-science-and-technology-approaches-new-drugs-istand-pilot-program
[6]FDA Center for Devices and Radiological Health. Medical Device Development Tools (MDDT). Available at: https://www.fda.gov/medical-device/science-and-research-medical-devices/medical-device-development-tools-mddt
[7]FDA. "FDA's Predictive Toxicology Roadmap." Available at: https://www.fda.gov/science-research/about-science-research-fda/fdas-predictive-toxicology-roadmap
[8]National Toxicology Program. "A Strategic Roadmap for Establishing New Approaches to Evaluate the Safety of Chemicals and Medical Products in the United States." Available at: https://ntp.niehs.nih.gov/whatwestudy/niceatm/natl-strategy/index.html
[9]FDA. "Advancing New Alternative Methodologies at FDA." Available at: https://www.fda.gov/science-research/about-science-research-fda/advancing-alternative-methods-fda

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