AN INTERNATIONAL ORGANIZATION DEDICATED TO PROTECTING THE RIGHTS OF ALL ANIMALS

PETA

PEOPLE FOR THE ETHICAL TREATMENT OF ANIMALS

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May 5, 2020

Stephen Hahn, M.D.
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993-0002

Sent via email to Stephen.Hahn@fda.hhs.gov

Dear Dr. Hahn,

On behalf of People for the Ethical Treatment of Animals (PETA) and our more than 6.5 million members and supporters, we strongly support the U.S. Food and Drug Administration's (FDA) policies that aim to expedite the development of safe, effective COVID-19 therapies using modern, human-relevant testing strategies. Beyond fostering the rapid development of treatment and diagnostic tools for addressing this pandemic, the Coronavirus Treatment Acceleration Program (CTAP) presents an opportunity to improve the processes used by industry and regulatory agencies to develop new medical treatments across the agency.

Prioritize human-relevant methods

With CTAP, the FDA has set a goal of delivering new treatments to patients as quickly as possible, while ensuring that the patients who participate in the more than 70 ongoing clinical trials of potential therapies for COVID-19 are protected by the best modern science. These clinical trials represent a shift in the historical order of procedures and highlight the inadequacies of using animals to model human disease, safety, and treatment efficacy in the development and evaluation of new therapies. The FDA's review of the investigational new drug application for the COVID-19 vaccine candidate jointly developed by Moderna and the U.S. National Institutes of Health, which allowed the vaccine to enter clinical trials without first completing the routine suite of animal tests, is a tremendous step forward in meeting CTAP's goals.

The FDA has carefully considered and enacted policies to make a systematic transition away from reliance on animal testing. In 2017, the FDA published its Predictive Toxicology Roadmap to help bring medical products to market faster by replacing reliance on animal testing with new tools and technology that better predict human responses. In 2018, the FDA's Strategic Policy Roadmap took up these ideas, making it an agency-wide priority to leverage innovation that facilitates efficient access to novel medical products.

We urge the FDA to expand the modifications made under CTAP to all of the agency's product review divisions. Reducing requirements for animal tests when modern, human-relevant safety and efficacy test methods are available and increasing access to clinical trials for companies prioritizing modern non-animal

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toxicological tests over traditional animal-based tests will help the agency meet the goals established in its roadmap policies.

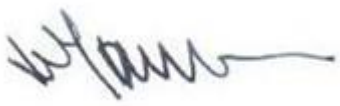
Avoid falling back on old methods

Regulatory agencies around the world are responding to the urgency of this crisis by granting new drug sponsors the flexibility to propose innovative strategies that would replace animal use. Going forward, we urge the agency to use the lessons learned during the coronavirus pandemic to expedite acceptance of modern toxicological methods designed to ensure that new therapies are safe, effective, and accessible. In tandem with the rapid advancement toward clinical trials of vaccines and therapies such as human convalescent plasma, the FDA must also seize the opportunity to take decisive action to support its goals of modernizing and accelerating drug development by pivoting toward the use of the most current, human-relevant, animal-free test methods available.

Using the current process, more than 95% of new drugs that pass the currently required animal tests ultimately fail in humans. The coronavirus pandemic has emphasized the need to replace the lengthy, animal-intensive drug development process with an approach that both effectively and efficiently identifies life-saving treatments for humans. We applaud the FDA's role in furthering humane science during this pandemic and call on the agency to continue and to expand prioritization of human-relevant science well beyond the COVID-19 crisis.

At your earliest convenience, please do let me know the FDA's plans to integrate these recent COVID-19 policy changes into the agency's broader approach to the development and testing of new therapies. If you are available to schedule a teleconference to discuss this important matter, I can be reached by phone at 310-437-8003, or via e-mail at JeffreyB@peta.org. I look forward to hearing from you.

Sincerely,



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