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OF ANIMALS

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Martin Makary, MD, MPH
Commissioner
U.S. Food and Drug Administration

Via e-mail*:* Commissioner@fda.hhs.gov

Dear Commissioner Makary:

Congratulations on your confirmation as Commissioner of the Food and Drug Administration (FDA). We are hopeful you will guide the FDA to ensure that the best science is used to get medicines to patients efficiently and without undue agency or regulatory burden.

While previous statements from the agency have indicated strong support for implementing efficient and effective non-animal methods, in practice, the FDA has largely failed to grab the low-hanging fruit. Instead, the FDA has created roadblocks to the use of non-animal methods, including stalling the use of existing well-characterized methods, overlooking the disadvantages of tests on animals, failing to provide transparency to the regulated industry and consumers, and ignoring calls for accountability.

This is why PETA scientists, along with nearly 47,000 supporters (signatures enclosed), are urging the new FDA leadership to right the wrongs of its predecessors by applying the most reliable and relevant testing approaches to best protect human health. In your new role, we hope you will consider the following five actions that are ready to roll:

1. Instead of insisting that manufacturers test sunscreens using unreliable animal tests, embrace modern tools, such as using existing human information and non-animal test methods.
2. Update a decades-old policy for assessing toothpastes and other fluoridated over-the-counter products with available, human-relevant and reliable methods that industry prefers to use because of their demonstrated effectiveness.
3. Enact a policy to accept human tissue models to assess the skin irritation potential of medical devices, joining scientists from around the world in replacing the test on rabbits.
4. Replace tests on animals to identify toxins in shellfish with well-established non-animal methods that can better protect human health.
5. Accept the use of human tissue models to evaluate personal lubricant products instead of the outdated rabbit vaginal irritation test.

As *Blind Spots* posits, when modern medicine issues recommendations based on good scientific studies, it shines. As someone who understands the importance of accountability and transparency, we are hopeful you will align the FDA with

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public interest and practical, sensible toxicology testing. As you reference in *Blind Spots*, misleading groupthink can harm millions. Right now, you have the power to turn off the faucet of bad ideas by embracing human-relevant, forward-thinking science.

We would appreciate a meeting with you and any members of your FDA team to further discuss how the agency can tackle these issues and bring about a new and improved testing paradigm. Thank you for your continued efforts, and I look forward to the positive changes you will accomplish.

Sincerely,

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