October 17, 2019

The American Society for Pharmacology & Experimental Therapeutics (ASPET)

In response to the Environmental Protection Agency's (EPA) "Directive to Prioritize Efforts to Reduce Animal Testing," the American Society for Pharmacology and Experimental Therapeutics (ASPET) issued the following statement:

> ASPET opposes Administrator Wheeler's announcement that the EPA will reduce and eventually eliminate its reliance on the use of mammals in toxicological studies conducted to identify environmental contaminants that pose a danger to humans. Alternative models are currently either unable to provide the EPA with the data it needs to protect human health, or do not yet exist. Further, the timeline for phasing out mammalian studies appears to have been decided without consideration for the adverse consequences for human health.
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> Where feasible, ASPET supports replacing animal models with alternative, non-living models. However, an alternative model must yield accurate, reliable results that are at least as informative and predictive as the animal model it replaces. There have been tremendous strides in the development of alternatives to animal models for toxicity testing, but in many areas alternative models are inferior or unable to substitute. Animal models can represent the biological complexity of integrated organ systems. An alternative model may be able to show one specific reaction of an organ/system to a substance, but it is unable to predict how the complex human system will respond.
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> ASPET is also concerned that the timeline for reducing and eliminating mammalian studies was not based on scientific evidence or input. In its directive, EPA provided no justification for its selection of 2035 as the year for ending mammalian studies at the agency. The hard deadline raises a question: if alternative models for current studies cannot be developed by 2035, will the EPA rely on inferior data or the absence of data at the expense of satisfying its mission to protect human health? If the EPA chose this deadline based on input from experts, it should make that information known. Conversely, if scientific experts were not consulted, the EPA should suspend the directive until stakeholders from the scientific community can provide information on the current state of development of alternative research models.
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> To accomplish its mission to protect human health and the environment, the EPA must have the best available data that, in some cases, only animal models can provide. The EPA's directive risks endangering human health by prioritizing the use of less effective methods of toxicological testing.

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The American Society for Pharmacology and Experimental Therapeutics (ASPET) is a 5,000 member scientific society whose members conduct basic and clinical pharmacological research.