

FOR IMMEDIATE RELEASE

Contact: Jim Newman, jim@amprogress.org

Comments from Americans for Medical Progress on the FDA Modernization Act

General Statements

- It is important to note that before the FDA Modernization Act was passed, the Food and Drug Administration already had tremendous discretion when it comes to the use of both animal and nonanimal alternatives in the critically important task of safety testing new medications prior to their approved use in humans.
- The FDA has always required drug developers to provide evidence that safety and efficacy has been shown. And while the previous version of the law referenced the use of animal studies to do this, it did not expressly require them. This is a claim that has been put forward by animal research opponents but is not actually reflected in the law's prior language.
- In essence, the FDA Modernization Act made relatively minor changes to the existing statute. These edits added and expanded references to nonanimal alternatives, technologies that did not exist in any great extent when the previous law was written.
- While these updates to the law will not lead to transformative changes to the biomedical research process, passage of the FDA Modernization Act will likely increase dialogue amongst scientists, Congress and the public about the development and funding for new methods to test medications before they approval for human use.

Comments About the Use of Nonanimal Alternatives

- The entire research community is fully and enthusiastically supportive of adopting nonanimal alternatives that can reduce or replace animal research. We would all like to lessen the need for animal studies. Just like most other Americans, the research community - which is made up of scientists, veterinarians and other dedicated animal care employees - loves and appreciates animals.
- However, it's also vitally important for the public to understand that computer models, organs-on-a-chip and organoids are not able to replace animal studies in most cases because these technologies are still in their infancy. As a result, they only provide a limited amount of information required in the drug safety testing process and also in other health research areas.
 - For example, organs-on-a-chip can provide helpful data as to how a single organ might respond to a yet-to-be-approved medication. However, we are complex beings made up of a vast assortment of organs, tissues, and not-yet-fully understood systems that interact and rely on one another. This is why the study of entire living systems remains necessary.
 - We must also remember that when we ingest medications, they are broken down into their components and processed by the body. The study of living systems

(aka animal models) is crucial as it allows us to observe and monitor this process closely and learn what happens in a living, breathing body.

- Finally, alternative models (such as computer models) can only mimic what we already understand about the human body. As a result, there are many areas where we have a tremendous amount to learn.
- With this important context in mind, the biomedical research community regularly embraces the use of nonanimal alternatives as they become available. In fact, these methods are already being used in university and company settings in a variety of ways.

Examples include:

- Using computer databases and models to identify promising medication possibilities for future testing.
- Nonanimal models might be used to simulate how individual organs might respond to test medications and other compounds.
- Nonanimal alternatives are also frequently employed before animal studies are used, to provide initial safety data when assessing whether a candidate medication may cause severe illness, harm or even death.

The Broader Context of Health Research Involving Animals

- The biomedical research community recognizes that health science discovery is an incredibly broad and complex topic. As a result, there is much more work to be done to better inform the public about why and how animals are studied.
- The use of animals for medication safety testing is important. But they also play a vital role in other portions of the discovery process. And in many of these areas, the use of nonanimal alternatives is less of an option and at times, impossible.
 - One example is basic science. Animals are often involved in this monumentally important form of research, which helps us understand the building blocks of life. This includes the study of things like cell function, genetics; and the various ways our bodies regulate weight, heartbeat and breathing. Obtaining this knowledge helps us understand the many diseases that impact these vital processes. It also unearths new treatment and cure strategies we never would have known about otherwise. Our world history is filled with advancements across various scientific fields where basic, foundational research led to pivotal lifesaving and life improving achievements such as cancer therapies, heart and blood pressure medications and vaccines to name a few.
 - Another area where animals have repeatedly played a pivotal role in advancing human and veterinary health is in the development of therapies. The powerful new technology behind the mRNA COVID-19 vaccines was created in the 1990s through studies in rodents. If that research did not occur, our ability to fight the COVID-19 pandemic would most certainly have been severely delayed and the death toll for this disease would be much, much higher.
- At the end of the day, we must use valid, scientifically proven methods for fighting disease and also for ensuring that our medications are safe and effective. And while we're all excited about the development of nonanimal alternatives, the adoption of these

technologies will take significant time as these methods can currently only be used in a small percentage of cases.

About Americans for Medical Progress

[Americans for Medical Progress](#) (AMP) is a nonprofit, health research advocacy group that supports the advancement of human and animal medicine through responsible and highly regulated research in animals. AMP informs the public about animal-based research through outreach events like [Biomedical Research Awareness Day](#), news and opinion articles, social media interactions and various online and printed publications. AMP is a 501(c)3 nonprofit charity supported by the nation's top universities, private research facilities, research-related businesses, scientific and professional societies, as well as by foundation grants and contributions by individuals. AMP's Board of Directors is composed of physicians, researchers, veterinarians and university officials.

###