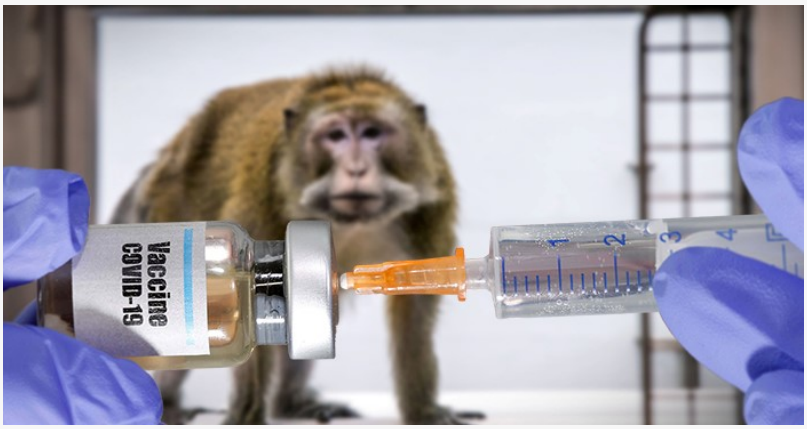
Animal Wellness Action: Are FDA's Onerous Regulations Hindering A Vaccine for COVID-19?

With COVID-19 Surging Across the Country, No Time to Waste on Revamping Drug Development Regulations



FDA TESTING | Photo Credit: Craig Swanson

WASHINGTON, DC, UNITED STATES, July 15, 2020 /EINPresswire.com/ -- by Wayne Pacelle and Tamara Drake

There are 536 counties in the U.S. with COVID-19 case densities that are equal to or exceeding New York City's peak in April. Our national crisis has not only been severe, but enduring.

What started as mainly a respiratory virus, according to medical accounts, has now morphed into a pathogen that can damage the heart, blood vessels, kidneys, and gastrointestinal and neurological systems.

Face masks and social distancing, as important as they are, can only get us so far. Those tools help us with the strategy of containment. But we need a strategy that puts the virus into all-out retreat, and that's where vaccines and therapies are critical.

Yet our national system for developing and testing new vaccines and drugs is archaic. One major deficiency: the U.S. Food and Drug Administration's mandate for extensive animal testing – for rodents and for non-rodents – even when animals cannot acquire the disease or even manifest symptoms. In the case of COVID-19, animals don't get the virus like people do.

The data are overwhelming in demonstrating that animal tests are not predictive of the human response to new drugs. Ninety-five percent of drugs that pass the test in animals fail in humans. That is not only a colossal waste of animal life and a terrible diversion of time and talent, but it drags out the process and means that patients must wait to get life-saving or life-enhancing drugs. It sends researchers, as a regulatory reflex, scrambling to infect animals that aren't generally susceptible to the virus. "The ideal animal model," according to the World Health

Organization, “for studying routes of virus transmission, pathogenesis, antiviral therapy, vaccine and immune responses has yet to be found.”

FDA regulations and statutes require outdated animal tests for product submission, to the exclusion of more predictive tests. Even in the best of circumstances, developing a vaccine is difficult. With these regulatory burdens, it further complicates the path. And to ask for a vaccine in months, rather than in years or decades, is shooting for the moon.

Animal-free, human-relevant test methods are crucial to speeding up the fight against this pandemic and other diseases that need cures. Modern human-based technologies are put to work in the drug discovery stage and to repurpose existing drugs. Human mini-organs (organoids), organs-on-chips provide a way to discover how the virus infects the human body and the subsequent damage to various organs and systems. These technologies, available for safety and efficacy testing as well as batch testing for vaccines, are typically less expensive than animal tests.

Innovations are allowing us to investigate how COVID-19 infects the different organ systems and to screen potential therapies for safety and efficacy.

- A team John’s Hopkins University is using human mini-brains (organoids) to investigate the brain’s susceptibility to COVID-19.
- Researchers at Hubrecht Institute used organoids to see how COVID-19 directly infects cells in the intestine and replicate. They found that the virus easily infects the “mini guts” and quickly replicated. Organoids are also being used to speed up the search for effective COVID-19 therapies.
- The U.S. Defense Advanced Research Projects Agency (DARPA) has invested $16 M over the next year for Wyss Institute to identify FDA approved drugs to prevent and treat COVID-19 using lung and intestinal organ chips.
- Human-on-a-Chip in vitro systems, using the immune-system-on-a-chip is being used to uncover how severe COVID-19 directly affects multi-organ systems. As the global pandemic of COVID-19 continues to grow, this system has the potential to quickly evaluate antiviral and repurposed drugs to help combat this devastating disease.
- The Human Emulation System comprised of organ-chips, hardware and apps, offers researchers a new standard for predicting human response to therapies and vaccines with greater precision and control than cell culture or animal-based test methods.
- A human ventricular cardiac organoid chamber is being used by drug companies to test COVID-19 therapies on the heart. The miniature hearts allow researchers to observe mechanisms by which drugs cause arrhythmias without testing in humans. These models also provide an avenue to study COVID-19’s direct effect on the heart.

FDA has to grant an exception – rather than embracing the strategies from the get-go – to recognize the use of these modern methods in regulatory submissions. This is a burden for researchers who have the know-how and capacity to use superior methods. It is a form of

institutional medical malpractice to require researchers to use decades-old, failed tools when there are far better means of examining disease.

The nation wants researchers to take us to the moon in record time. But FDA is giving researchers a horse to get there.

The Center for Responsible Science (CRS) and seventeen co-petitioners petitioned FDA to modernize its regulations to include the use of non-animal, human-relevant technology in preclinical testing. FDA has not provided a substantive response. Fortunately, as a first important step, the House Appropriations Committee has included language in the Fiscal Year 2021 Agriculture-FDA spending bill urging FDA to update its regulations to allow for the use of human-relevant non-animal test methods. A similar effort is underway in the U.K. to urge regulatory bodies to update regulations to accelerate the use of human-relevant test methods, without the use of animals for all diseases in the wake of the pandemic.

CRS, the Center for a Humane Economy, Animal Wellness Action, and the Animal Wellness Foundation are teaming up to act as catalysts for long-overdue regulatory reforms. This pandemic has cast a kleig light on the deficiencies of our drug development paradigm. FDA regulations and the Federal Food Drug and Cosmetics Act must be updated if we want to help people and restore the economy.

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