# Sharks, Monkeys, and Horseshoe Crabs Targeted in COVID Vaccine Chase

*The race to develop a COVID-19 vaccine is putting animals through a meat grinder in our laboratories to meet the FDA's archaic animal-testing requirements.*


WASHINGTON, DC, UNITED STATES, October 8, 2020 /EINPresswire.com/ -- Wayne Pacelle of Animal Wellness Action and Tamara Drake of the Center for Responsible Science released the following statement on the race for a COVID-19 vaccine and its impact on wildlife across the globe:

"The race to develop a COVID-19 vaccine, with the runners sent down the wrong path by the Food and Drug Administration's (FDA) archaic animal-testing regulatory requirements, is putting wild animals through a sort of meat grinder in our laboratories. Researchers may kill upwards of 500,000 sharks for a single moon-shot vaccine, while hundreds of other laboratories are injecting and sickening troops of monkeys for their own experimental vaccines. The vaccine quest — which every sane person agrees is critical for the public and economic health — is even contributing even more adverse effects in our marine ecosystems because of stepped-up collecting of horseshoe crabs for their distinctive blood type.

> One exploitative form of animal use (chaotic live-wildlife markets in China) has triggered yet more forms of controlled and calculated animal exploitation in global laboratories."
>
> *Wayne Pacelle*

In short, laboratories in the United States and throughout the world have repurposed their operations to develop a vaccine and to take advantage of billions in government dollars thrown their way, and it's causing an unmistakable surge in laboratory animal use. Their other animal-testing work does not seem to have abated, so the expansion of animal-based laboratory work is additive to the existing toll.

The Monkey Business

There is a shortage of monkeys in the United States because of surging demands for their use in vaccine development  “We can’t find any rhesus [monkeys] any longer,” according to Mark Lewis, the CEO of contract research firm Bioqual. “They’ve completely disappeared.”

With the government putting tens of billions into the hands of vaccine developers, Mr. Lewis need not fret. Charles River Laboratories and other businesses that specialize in breeding animals for labs will undoubtedly step up their work and churn out more animals.

While the government is funding the surge in activity in vaccine development, its regulatory framework is guiding the researchers to use animals in their protocols. The Federal Food Drug and Cosmetics Act (FFDCA) requires the use of animals to test the safety and efficacy of drugs and vaccines before they enter human clinical trials, and the FDA has long been heavy-handed in applying the rule. These archaic requirements include the use of at least two species of animals (rodent and non-rodent), and non-human primates are often the choice for the secondary experiments. This reflexive use of animals for new drug development continues despite data revealing that 95 percent of drugs fail in human clinical trials after animal tests purportedly show safety and efficacy.  The reality is, the responses in animals treated with experimental drugs are typically not predictive of the human response.

Take the case of the search for a vaccine for HIV/AIDS, a pandemic that got rolling in the 1980s and has claimed more than 30 million lives since that zoonotic disease jumped the species barrier. Data assembled in 2008 revealed that out of 85 potential AIDS vaccines that were tested in 197 human trials, only seven reached Phase III trials, which involve a large group of human volunteers, and not one vaccine was successful after passing muster in chimpanzees.  If you were a batter in baseball, and you didn’t get a hit in 85 appearances at the plate, you might wonder what’s fundamentally wrong with your swing.

Just last month, in an AstraZeneca Phase III clinical trial for a COVID-19 vaccine, a study participant experienced neurological illness after receiving the vaccine, putting the brakes on the movement of experimental therapies into clinical trials. The FDA has refused to allow trials in the US to resume pending further review.  AstraZeneca conducted innumerable monkey tests for this vaccine.  We can surmise that the tests on monkeys didn’t pick up the safety risk that may have afflicted the human participant.  This is a major flaw in the current drug development testing paradigm: animal tests do not forecast the reaction in humans.

Sharks At Risk from More Than Finning

Because of finning for use in soup in some Asian nations, sharks aren’t safe in the oceans. But the non-marine environments aren’t safe for them either. Sharks are being collected and cut up for COVID-19 vaccines. Hammerheads, great whites, and whale sharks are among the targets in the unsustainable quest for a substance called “squalene.”

Many vaccines use adjuvants to stir the human immune response. The bad news for sharks is that their livers are reservoirs for squalene. Already, up to 3 million sharks are killed each year for squalene for cosmetics and vaccines. The race for the vaccine has compounded the number of sharks used in research, with a half-million shark victims could be used for a single experimental vaccine project.

In this case, there are known, widely accepted plant-based alternatives, including a sustainable sugarcane-derived alternative.

Here again, some researchers repeat the bromide that they'd use alternatives to animal use when available if available, but they aren't using one right under their noses.

Horseshoe Crab Use Ripples Through Marine Ecosystems

Researchers are also tapping horseshoe crabs for one of their bodily attributes: their blood.

FDA requires that drugs, vaccines, and medical devices must be tested for endotoxins. Between 1940 and 1970, researchers used rabbits hundreds of thousands each year — to attempt to screen for this bacterial contaminant. In 1970 they found a new method — using the blue blood of the horseshoe crab after discovering that the crab had a highly sensitive immune response to endotoxins. Each year pharmaceutical companies capture about a half-million Atlantic horseshoe crabs, bleed them, and toss them back into the ocean. Half of them don't survive the trauma.

Over the past few decades, this practice along with the overharvesting of crabs for bait for fishing has reverberated through the marine ecosystem in on the Atlantic and Gulf coasts. Bass, flounder, and other fish species have experienced steep population declines, with scientists speculating that reduced crab populations are part of the cause. Same for some migratory shorebirds. Six species of shorebirds time their northern migration to eat the eggs of spawning horseshoe crabs. In fact, the red knot was listed under the U.S. Endangered Species Act in 2014 due to the dwindling population of horseshoe crabs.

But are these ecological consequences something we must endure because the use of horseshoe crabs is essential for vaccine development and other human public health and welfare imperatives? Well, almost certainly not. In 2012 the FDA issued guidance on the acceptability of a synthetic alternative to the horseshoe crab blood test, recombinant factor C (rFC). In 2016, rFC was approved as an alternative in Europe. But because of bureaucratic inertia, the U.S. Pharmacopeia — which sets scientific standards for drugs in the U.S. — refused to place rFC on its list of acceptable tests. As a consequence, manufacturers must go through a burdensome validation process of the rFC unlike the streamlined versions of validation used for other methods in the Pharmacopeia, which hinders the use of rFC.

The global COVID-19 crisis has put a spotlight on the problems with the animal-testing paradigm

that drives the behavior of regulators and pharmaceutical companies. In this case, one exploitative form of animal use (chaotic live-wildlife markets in China that delivered the novel coronavirus into the human body) has triggered yet more forms of controlled and calculated animal exploitation in global laboratories.

The magnification of animal testing, due to the COVID crisis, is a wake-up call for our movement to demand that FDA's archaic regulations be revamped. Researchers should use the best methods of testing rather than being required to use animals even when they don't yield reliable results. Typically, non-animal testing methods that are more reliable, faster, and less costly than animal experiments.  When researchers can use the best tools, they generate the best scientific outcomes, often sparing animals and saving human lives in the process."

Marty Irby
Animal Wellness Action
+1 202-821-5686
email us here
Visit us on social media:
Facebook
Twitter

---