HORSESHOE CRAB RECOVERY COALITION

Horseshoe Crab Recovery Coalition Celebrates U.S. Pharmacopeia Recognition of Synthetic Alternatives to Horseshoe Crab Blood

July 26, 2024 --The Horseshoe Crab Recovery Coalition (HCRC), a coalition of more than 50 conservation and healthcare organizations, applauds the U.S. Pharmacopeia's (USP) Microbiology Expert Committee for voting to adopt Chapter 86: Bacterial Endotoxins Test Using Recombinant Reagents. This new chapter creates a standard for the biomedical industry's use of a synthetic alternative to horseshoe crab blood in bacterial endotoxin testing.

Horseshoe crabs are facing mounting pressures across the Atlantic Coast. One of those pressures is the biomedical harvest of horseshoe crabs for their blue blood, which is used to create the Limulus amebocyte lysate (LAL) test. Medical devices and injectable drugs are all tested for contaminants—or endotoxins—to ensure safety. Currently, most pharmaceutical companies use LAL. This comes at a high cost to horseshoe crabs and coastwide conservation.

"Shorebirds including the federally threatened Red Knot rely on horseshoe crab eggs during their migratory journeys that span thousands of miles each year. Widespread adoption of synthetic alternatives by the biomedical industry can alleviate harvest pressures and conserve horseshoe crabs," said Annie Chester, Policy Director at the American Bird Conservancy. "This has the dual benefit of advancing bird conservation and human health."

"We are delighted that USP has provided guidance that will help place recombinant testing on equal footing with LAL," added Larry Niles, co-founder of HCRC. "Recombinant testing provides a reliable, sustainable alternative that is critical to horseshoe crab conservation and a healthy ecosystem throughout the Atlantic coast."

In the industry and Congress, there are leaders championing synthetic testing alternatives. These alternatives are safe, effective, and do not come with the ecological cost of LAL. Pharmaceutical company Eli Lilly has been using a non-animal alternative, recombinant Factor C (rFC), since 2016. In Congress, Representative Frank Pallone (D-NJ) and Sen. Cory Booker (D-NJ) have supported the adoption of chapter 86.

"I fully support U.S. Pharmacopeia's new guidelines for synthetic alternatives to horseshoe crab blood for biomedical testing," said **U.S. Congressman Frank Pallone, Jr. (NJ-06)**. "For years, I've been leading the charge in Congress to track horseshoe crabs, study coastal ecosystems, and modernize our biomedical testing guidelines. Horseshoe crabs predate the dinosaurs and are an iconic Atlantic species. They are a crucial part of the local ecosystem and a food source for birds like the critically endangered *rufa* red knot, which famously has one of the longest migrations of any species in the world and stops in my home state of New Jersey to feed. Increasing global demand

for vaccines, and therefore horseshoe crab blood, is straining their populations and threatening biodiversity. Synthetic alternatives offer a viable solution to get these ancient creatures out of the biomedical supply chain and keep them in their natural habitats."

HCRC thanks Representative Pallone and Senator Booker for their leadership. Not only are their efforts conserving horseshoe crabs, they are removing barriers for the pharmaceutical industry.

Support for Chapter 86:

"The health of the Red Knot population is linked to the health of horseshoe crabs, whose eggs the Red Knot rely on for food," said **Bethany Kraft, senior director of coastal and marine resilience at the National Audubon Society**. "A safe and expeditious transition from horseshoe crab blood to a synthetic alternative in the biomedical industry is an important step in protecting shorebirds, horseshoe crabs, and other wildlife."

"The many advantages to using non-animal approaches to test for endotoxins make this policy change, and industry adoption, a no brainer," says **Elizabeth Baker, director of research policy at the Physicians Committee for Responsible Medicine**. "Now, companies can confidently replace their use of horseshoe crabs in testing products without second guessing whether the FDA will accept the test."

"The USP's new guidance will accelerate the transition from horseshoe crab blood to synthetics that are safer, more cost-effective, and more reliable," said **Will Harlan, senior scientist at the Center for Biological Diversity**. "Biomedical safety tests should not depend on the blood of a dwindling natural resource, especially when synthetics are readily available."

"The pharmaceutical industry's continued reliance on horseshoe crab blood has caused a critical decline in the population of this ecologically crucial species," said **Kathleen Conlee, vice president for animal research issues at the Humane Society of the United States**. "Many crabs don't survive after they are captured and have up to half of their blood drained. We welcome the adoption of this new standard, which will enable wider use of the synthetic, non-animal alternative, ensuring the protection of these remarkable creatures from overharvesting while still ensuring that products are safe to use."

"This decision by USP presents a tremendous opportunity for pharmaceutical companies to rise to the occasion and do the right thing," said **Ryan Phelan, co-founder and executive director of Revive & Restore**. Now, there is no excuse to continue using horseshoe crab blood when readily available alternatives are recognized as equivalent."

Media Contacts:

John Bloomfield
Communications Lead
Horseshoe Crab Recovery Coalition
john.bloomfield@hscrabrecovery.org

Agatha Szczepaniak
Media Relations Specialist
American Bird Conservancy
media@abcbirds.org