



# HORSESHOE CRAB RECOVERY COALITION

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## **Coalition Asks Congress to Protect Horseshoe Crabs**

**Washington, D.C., October 22, 2020:** Leaders of the Horseshoe Crab Recovery Coalition briefed congressional staffers Thursday on the plight of the American Horseshoe Crab, urging greater adoption of a synthetic alternative to the blood of this ancient species, widely used in testing vaccines and other biopharmaceutical products. The virtual briefing was titled: Conserving Wildlife While Maintaining Human Safety.

“More than 750,000 horseshoe crabs were captured in 2019 for biomedical bleeding, and up to 30 percent die in the process,” said Eric Stiles, President and CEO of New Jersey Audubon, which played a leading role in organizing the coalition. “In a technologically advanced society, there has to be a better way. Fortunately a synthetic alternative exists that would conserve this iconic species without compromising human health.”

All vaccines, injectable medications and medical devices must be tested to ensure they do not contain fever-causing materials before being administered to humans. A synthetic alternative to horseshoe crab blood, known as recombinant Factor C (rFC), now exists that would allow scientists to safely test for fever-inducing substances without using the blood of a living animal. The alternative has demonstrated equivalence to horseshoe crab lysate in more than 190 pharmaceutical products, such as active pharmaceutical ingredients and clinical trial supplies, and is now being used in the manufacture of two marketed medicines.

rFC has been recognized as equivalent to horseshoe crab lysate by the European Pharmacopeia. Pharmacopeias help to establish quality standards and provide overall guidance on manufacturing medicines and vaccines. The US Pharmacopeia has yet to follow its European counterpart and has instead proposed a lengthy and burdensome pathway to further evaluate rFC.

“The COVID-19 pandemic is likely to lead to major increases in the use of horseshoe crab blood, as the nearly 200 vaccines and over 60 injectable therapies in development for COVID-19 will all

need to be tested multiple times for fever-inducing contaminants,” said Elizabeth Baker, Pharmaceutical Policy Program Director, Physicians Committee for Responsible Medicine. “As is often the case, policy is lagging behind the science. We must act now to remove unnecessary barriers to industry use of rFC.”

Hon. Jim Greenwood, former Member of Congress and past Chief Executive Officer of the Biotechnology Innovation Organization, told the group: “As a lifelong birder and bird photographer and a member of the board of the National Audubon Society, and as a former leader of the world’s largest bio-pharmaceutical trade association, it is clear to me clearing the path for drug manufacturers to switch from LAL to rFC is the right thing to do for the environment and for patients.” Greenwood is current a Senior Policy Advisor for the law firm DLA Piper.

Recognizing the plight of the horseshoe crab and the species that depend on them, a group of 30 organizations, including the National Audubon Society and many state Audubon organizations, the National Wildlife Federation and the Physicians Committee for Responsible Medicine came together in June to launch the Horseshoe Crab Recovery Coalition. The coalition aims to fully restore horseshoe crab populations by 2030 through the following efforts:

- Reduce overharvest of crabs for bait where scientifically appropriate
- Reform the biomedical bleeding process with best practices to reduce mortality
- Encourage the pharmaceutical industry to adopt synthetic alternatives to horseshoe crab blood in endotoxin testing
- Build a network of volunteers to monitor and assess populations of horseshoe crabs.

“Congress has multiple roles to play in horseshoe crab recovery, and it starts with raising awareness,” concluded Stiles. “We’re asking members to join with us in urging that the US Pharmacopeia and the U.S. Food and Drug Administration remove barriers to adoption of rFC, ensuring patient safety while conserving our natural world.”

To learn more about the Horseshoe Crab Recovery Coalition, visit <https://hscrabrecovery.org>.

