

10/25/2022
Julie Miller
Executive Vice President, Philanthropic Partnerships and Board Relations
World Wildlife Fund
1250 24th Street, N.W.
Washington, DC 20037

Dear Ms. Miller,

Harmony for Horseshoe Carbs would like to present a grant proposal for your review. We are a 501(c)3 organization that is devoted to the advocacy of the horseshoe crab. Since the 1970s, horseshoe crabs have been maltreated by the biotech industry. Their blood contains properties that are useful for endotoxin testing. Though the horseshoe crabs are not killed for their blood, approximately 130,000 crabs die each year after their bloodletting procedure. The loss of crab has put a strain on the environment since they are considered a keystone species and other animals depend on them for their survival.

As it now stands, there is no reason that the biotech industry would require horseshoe crab blood since a synthetic version has been around since 1997 and is approved by the FDA. Biotech companies have been hesitant to use the synthetic since there were no set guidelines from the US Pharmacopeia until this year.

From November 1st to January 31, 2024, the guidelines will be reviewed by the scientific community and once they are approved, we want to get the word out to pharmaceutical companies that the synthetic is safe to use. Therefore, we request a grant in the amount of \$100,000 that will be used over the span of five years. The funds would be used to lobby pharmaceutical companies to switch to the synthetic and to create an ad campaign to advocate for the horseshoe crab.

Thank you for your time and consideration. We look forward to speaking with you more about our grant proposal.

Sincerely,

Pat Aoki

Founder and Executive Director

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# HORSESHOE CRAB RECOVERY GRANT PROPOSAL

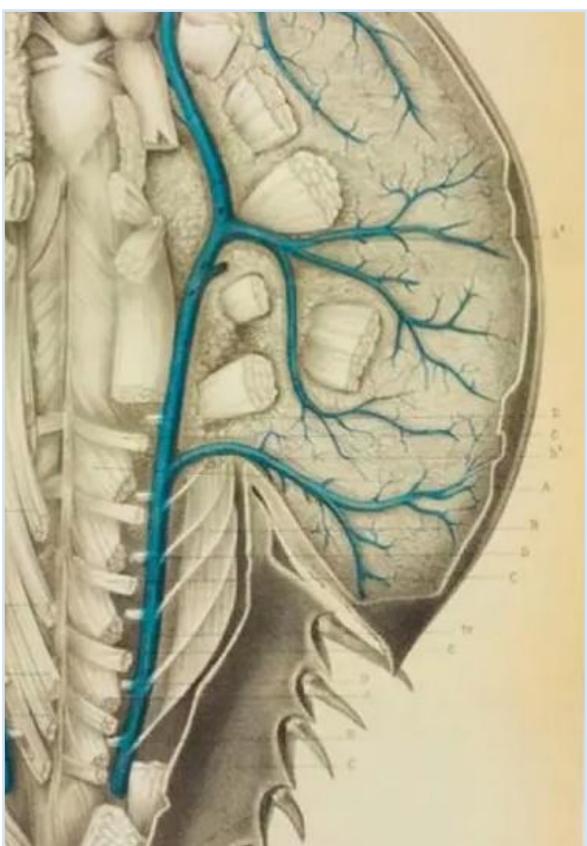


HHC Grant Proposal



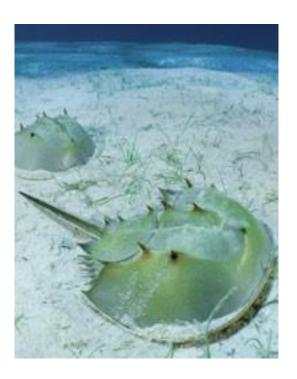
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# **Executive Summary**

To acquire horseshoe crab blood, pharmaceutical companies engage in less than ethical means that affect both the animal and the environment. Currently, there are five biotech companies along the Atlantic coast of the United States that retrieve horseshoe crabs for bloodletting, and each company is permitted to collect and 'harvest' a certain number of crabs per year. Both collection and 'harvesting' cause harm to horseshoe crabs and their habitats. Harmony for Horseshoe Crabs will drive an effort to sunset the extraction of blood and promote the adaptation of the synthetic alternative rFC through financial incentives. HHC will also push for new laws to protect horseshoe crabs and ban medical uses of wildlife.



After horseshoe crabs are returned to the ocean after the bloodletting, it is noted that 10% to 30% of drained crabs do not survive the collection and "harvesting" process. This amounts to an extinction of up to 130,000 horseshoe crabs per year.

## **HHC Problem Statement**

#### **BACKGROUND**

In the early days of drug manufacturing, it was commonplace for patients to develop a reaction from their injectable medication called 'injection fever'. This was induced by pyrogens, or germs, which had contaminated the drug product. From the 1940s to the 1970s, live rabbits were used to test for this kind of contamination, called endotoxin testing, but due to false positives and various factors due to the rabbits themselves, the rabbit model was not consistently reliable. Another method for endotoxin testing was required in drug manufacturing to ensure drug safety for human use.

During this time, in 1956, Johns Hopkins medical researcher, Dr. Frederik Bang, found that when horseshoe crab blood was exposed to gram negative bacteria, it coagulated around the endotoxin and essentially trapped it. This was because horseshoe crab blood is composed of cells and enzymes called Limulus Amebocyte Lysate (LAL). This was a significant breakthrough for endotoxin testing, but a mutually significant threat to horseshoe crabs, as, since 1977, when LAL was first approved by the Food and Drug Administration (FDA), the LAL harvested from horseshoe crab blood has been the gold standard for endotoxin testing.

#### THE PROBLEM

#### ANIMAL CRUELTY

To acquire horseshoe crab blood, pharmaceutical companies engage in less than ethical means that affect both the animal and the environment. Currently, there are five biotech companies along the Atlantic coast of the United States that retrieve horseshoe crabs for bloodletting, and each company is permitted to collect and 'harvest' a certain number of crabs per year. Both collection and 'harvesting' cause harm to horseshoe crabs and their habitats.

### **HHC Problem Statement**

- 1. Horseshoe crabs are collected during their crucial spawning season, harming their ability to reproduce. The crabs come to shore to mate, which makes them easily accessible for collection. When they are returned to the ocean after their blood is harvested, the crabs are lethargic and dazed, with these symptoms lasting for weeks, meaning that their original objective to leave the water to reproduce is hindered and continues to dissipate over time.
- 2. Horseshoe crabs are ruthlessly drained of up to 30% of their blood supply in the assembly line process of 'harvesting'. Once the horseshoe crabs are collected from the shores, they are washed, strapped to a table, and punctured in the heart with a trocar needle that drains them of the maximum amount of blood they can lose at one time. This is ruthless and rigorous bloodletting known in the biotech industry as 'harvesting'.
- 3. 10% to 30% of horseshoe crabs die following bloodletting. Even after the horseshoe crabs are returned to the ocean after their bloodletting, it is noted that 10% to 30% of drained crabs do not survive the collection and 'harvesting' process. This amounts to an extinction of up to 130,000 horseshoe crabs per year.
- 4. Horseshoe crab collection has steadily increased since their approved use for endotoxin testing. Since the FDA approved the use of LAL from horseshoe crabs for endotoxin testing in 1977, the retrieval of horseshoe crabs for bloodletting has steadily increased. There was an 86% increase in horseshoe crab collection since 2004, going up to 545,973 in 2013 to almost 720,000 in 2021.

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Pharmaceutical companies permitted to harvest horseshoe crab blood.

30%

Of a horseshoe crab's blood is drained during a single bloodletting.

720K

Horseshoe crabs were harvested for bloodletting in 2021.

## **HHC Problem Statement**

#### THE PROBLEM

#### **ENVIRONMENTAL HARM**

The increasing mortality of horseshoe crabs under the hands of biotech companies causes environmental harm. Horseshoe crabs are a keystone species, meaning that they are a species on which the environment and many other animals depend. When horseshoe crabs reduce spawning and/or disproportionately die, this dramatically affects the existence of other animals and organic matter sharing their habitat. Some of the affected species include:

- 1. Standard barnacles, Slipper Shell Marine Snails and anemones that live on horseshoe crabs shells.
- 2. Multiple migratory birds such as the threatened Red Knot which depend on the eggs of female horseshoe crabs released during the spawning season as a large staple of their diet. In fact, so symbiotic is their relationship, that the Red Knot time their migratory period with the horseshoe crab spawn so that they can refuel for their trip to the Artic tundra.
- 3. Loggerhead Sea Turtles also rely on horseshoe crab meat as a fundamental component to their diet.
- 4. Silt along the shoreline that is greatly improved when interspersed with horseshoe crab eggs.



### **HHC Problem Statement**

#### THE SOLUTION

#### rFC - Synthetic LAL

What is so disheartening about the plight of the horseshoe crab is how unnecessary their continued collection and 'harvesting' all is. In 1997, researchers at Singapore University created recombinant Factor C, rFC, which is a synthetic of LAL. It has been proven that, when tested against horseshoe crab blood derived LAL, rFC is just as effective as the bio-organic, if not better.

If an effective LAL synthetic exists, why do biotech companies continue to harm horseshoe crabs?

Although rFC was approved by the FDA for commercial use in 2003, pharmaceutical companies have been hesitant to use it. This is because companies require guidelines from the US Pharmacopeia (USP), a non-profit organization that tests and provides regulatory information on the quality of a drug, supplement, or ingredient. Only just recently, in mid-2023, the USP have finally established guidelines for use of rFC. These guidelines will be under review from November 1, 2023, to January 31, 2024. Once approved, expected to be in February 2024, there will be no reason for the continued harm of horseshoe crabs for the ex- traction of biological LAL.

#### HARMONY FOR HORSESHOE CRABS

It is vital that we pursue harmony for horseshoe crabs! We must act to get the word out to replace LAL with rFC so that we can begin to restore lost horseshoe crab populations and the populations of other animals that depend on them.

Our advocacy and campaigning organization, Harmony for Horseshoe Crabs, is dedicated to EDUCATING & LOBBYING for the RESTORATION and CONSERVATION of the horseshoe crab population of the US Atlantic coast.

With funding from the World Wildlife Fund, Harmony for Horseshoe Crabs can help stop the harm and *END THE HARVEST!* 

## About Harmony for Horseshoe Crabs



Harmony for Horseshoe Crabs (HHC) was established in 2001 in the Delaware Bay area of the Northeastern Seaboard to protect this keystone species from overfishing, habitat loss, and other challenges. One particularly devastating threat to horseshoe crabs is the medical use of their blood, such as the accelerated development of the COVID-19 vaccine.

Protecting horseshoe crabs requires a multi-pronged effort. HHC focuses on three main areas: conservation science, education and awareness, and legal protections. Our staff collectively bring 40+ years of conservation research, 15+ years in communications and community building, and over a decade of environmental conservation law.

We welcome collaboration at any scale, from Audubon societies and biomedical companies to local tourism organizations and passionate citizen scientists. With all of our partners, we're committed to ensuring that horseshoe crabs have a future.

# The HHC Team

#### Pat Aoki

#### **Executive Director**

As founder of HHC, Pat Aoki is best situated to contact World Wildlife Fund executives to arrange for a proposal presentation meeting. They will leverage their extensive knowledge of horseshoe crabs to convince WWF staff of our expertise on this subject. With over 30 years of research logged, Pat can also use his net- work to secure subject matter experts to either contribute quotes or join us in the pitch meeting.

### Emily Rodriguez

#### **Community Organizer**

As an educator, Emily Rodriguez understands how to help people learn. When Hugo grabs reader attention with his media campaigns, he will also link them to informative videos, infographics, and articles that Emily has prepared in support of our efforts. In addition, she is going to create simple handouts for K-12 science classes that will be provided to schools at no charge. She believes it is important to help developing minds understand the impact humans have on the wildlife all around us.

### Hugo Simms

#### **Communications Coordinator**

Hugo Simms is a public campaign expert. He plans to use our social media presence to inform readers about the plight of these crabs. While somewhat disturbing, images of the crabs being bled out are highly effective and persuasive, so Hugo will use these to elicit engagement. These social media efforts will be highlighted in Hugo's part of the pitch presentation to have this same impact on WWF executives. It will also have the effect of putting preemptive pressure on the targeted pharmaceutical companies to enact our



## Goals



It is vital that we pursue harmony for Horseshoe Crabs! We must act to get the word out to replace LAL with rFC so that we can begin to restore lost Horseshoe Crab populations and the populations of other animals that depend on them.



Sunset the extraction of horseshoe crab blood which currently supplies the pharmaceutical industry with LAL.



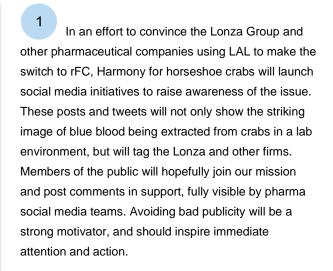
Promote the adaptation of the synthetic alternative rFC through financial incentives.



Advocate for new laws to protect horseshoe crabs and ban medical uses of wildlife.

# How HHC Will Help

Harmony for
Horseshoe Crabs
is campaigning
to end the
harvest.





Once we have their attention, HHC will take the conversations off social media and privately engage with the companies. This is when we will inform them of our ability to award grant money to any firm willing to make the switch to rFC. Our contracts will include a reasonable timeline and an expectation of confirmation. We will also promise social media updates to turn the bad publicity into good.

While our main goal is to pressure a full switch to the rFC synthetic alternative, we also seek protections for horseshoe crabs to avoid future exploitation. HHC is planning a signature gathering campaign to support our proposed initiatives in Delaware and New Jersey. We will be lobbying state legislators, and providing the background and legislation content to persuade state representatives to turn these protections into law.

# **Success Metrics**

HHC will measure our success from the communities most connected to horseshoe crab protection and the pharmaceuticals adopting the use of the synthetic.

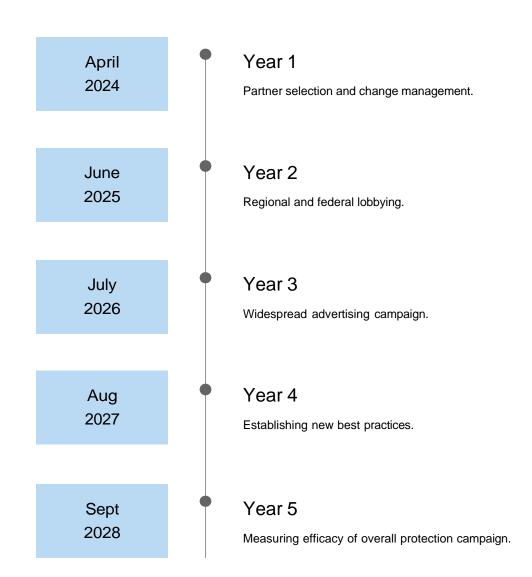
Information Needs	Indicators of Success	Timeline	Internal vs External evaluation
Volume of horseshoe blood used in pharmaceutical research.	<ul> <li>Horseshoe crab population off spawning season</li> <li>Volume of horseshoe crab eggs during spawning season</li> <li>Demand for horseshoe crab blood in volume and price.</li> </ul>	Annually	External (partner with local organizations close to horseshoe breeding grounds)
Adoption rates of synthetic alternative	<ul> <li>Educational materials regarding synthetic are accessible to pharmaceutical companies and are integrated with local tourism repertoire.</li> <li>Demand for synthetic alternative increases.</li> </ul>	Years 1-5	External
Behavior of fishing and harvesting organizations.	<ul> <li>Increase % of calendar year that horseshoe crab protections are in effect.</li> <li>Comprehensive adoption of laws to protect crabs.</li> </ul>	Years 1-5	Internal (by Hugo Simms)

# The Timeline



HHC is devoted to reaching our goals within a reasonable and predefined time frame.

Adequate funding is crucial to this process.



# Budget Breakdown

Component	Budget
Component 1 Proof of concept changing to synthetic	\$30,000
First 6 months: Select partner company to support change to synthetic and vet source of synthetic.	\$10,000
Month 7-24: Change management: update to supply chain logistics from horseshoe blood and update protocols.	\$20,000
Component 2 Awareness	\$20,000
Year 1: Lobbying efforts to regional and federal governments to implement conservation strategies and legal protections for horseshoe crabs.	\$10,000
Year 3: Ad campaign promoting success of partner company transition	\$10.000
Component 3 Research & Innovation	\$50,000
Year 1-2: Conservation strategy research to establish new best practices for protective methods.	\$30,000
Year 3-5: Measure efficacy of protection methods.	\$20,000
Total Budget	\$100,000



# Thank You



## Contact Us

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## Our Office

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