

GENE DRIVES

Media Briefing



April 25, 2018

Sciline Gene Drives Media Briefing

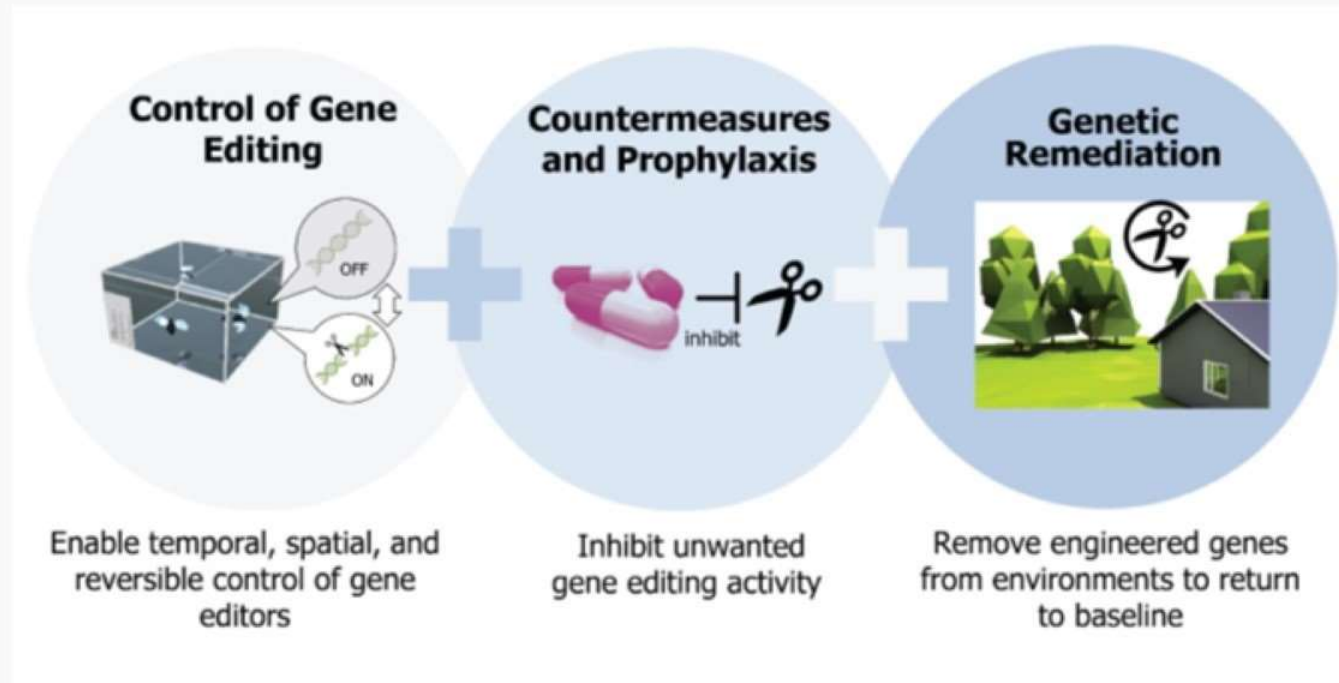
Slide presented by
Dr. Renee Wegrzyn
Program Manager

Defense Advanced Research Projects Agency (DARPA)



DARPA Safe Genes Program:
A toolkit for innovation, biosafety, and biosecurity

Vision: Create biological capabilities that enable the safe pursuit of advanced gene editing applications and protect against potential engineered genetic threats



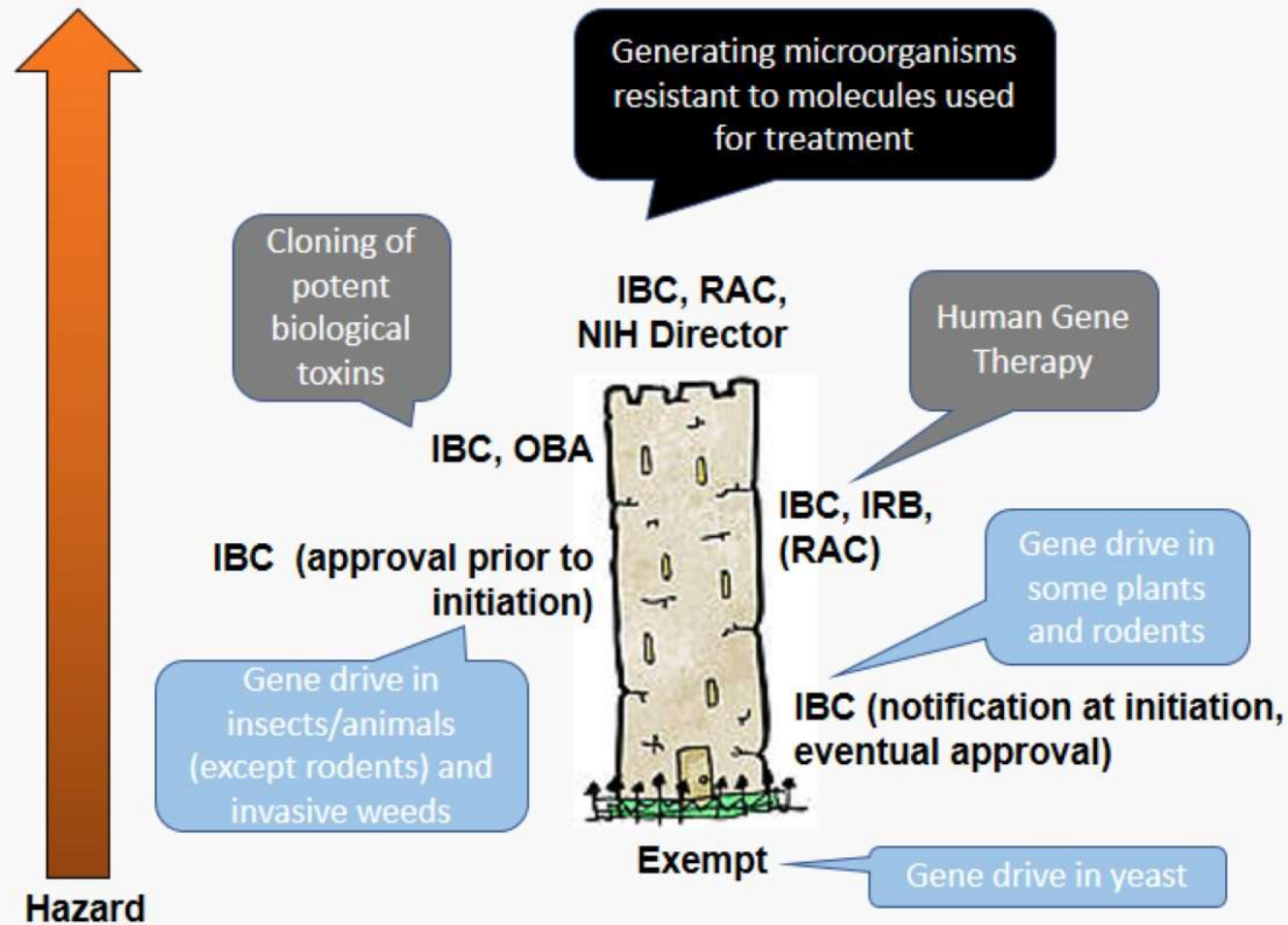
Goals:

- **build-in biosafety** for new biotechnologies at their inception
- provide a **toolkit** to enable previously unattainable applications in synthetic biology
- create an **understanding of what is possible, probable, and vulnerable** with regard to emergent gene editing biotechnologies

Sciline Gene Drives Media Briefing

Slides presented by
Dr. Zach Adelman
Associate Professor of Entomology
Texas A&M University

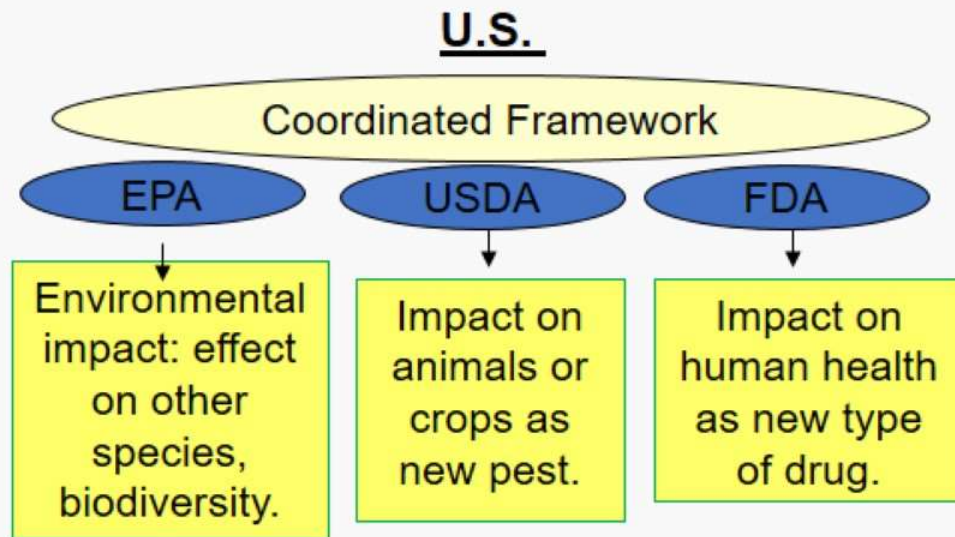
Regulatory Landscape for Gene Drive in Laboratory Containment



Individual Entities may require additional review

Entities receiving no NIH money may not require any review

Regulatory Landscape for Gene Drive in Open Field Trials



FDA Guidance issued Oct 2017 (#236)

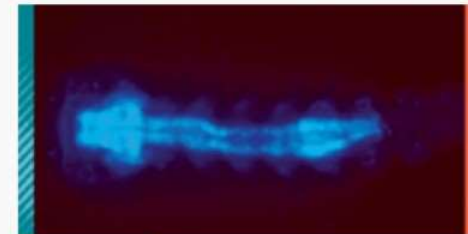
Examples of New Animal Drugs (FDA would review)

- Products intended to **reduce the virus/pathogen load** within a mosquito, including reduction in virus/pathogen replication and spread within the mosquito and/or reduction in virus/pathogen transmissibility from mosquitoes to humans.
- Products intended to **prevent mosquito-borne disease** in humans or animals.

Example of Pesticide Products (EPA would review)

- Products intended to **reduce the population** of mosquitoes (for example, by killing them at some point in their life cycle, or by interfering with their reproduction or development).

WHO



FOUNDATION National Institutes of Health World Health Organization TDR For research on diseases of poverty

Guidance framework for testing of genetically modified mosquitoes

No CFR or agency document references gene drive, so in practice the regulatory pathway is still to be determined

For more information about this Media Briefing:

<https://www.sciline.org/media-briefings/>