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
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Slides presented by
Dr. Zach Adelman
Associate Professor of Entomology
Texas A&M University
Regulatory Landscape for Gene Drive in Laboratory Containment

- Generating microorganisms resistant to molecules used for treatment
- Cloning of potent biological toxins
- Gene drive in insects/animals (except rodents) and invasive weeds
- Gene drive in yeast
- Human Gene Therapy
- Gene drive in some plants and rodents
- IBC, RAC, NIH Director
- IBC, IRB, (RAC)
- Exempt
- IBC (notification at initiation, eventual approval)
- IBC (approval prior to initiation)
- IBC, OBA

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

**U.S.**

- **EPA**
  - Environmental impact: effect on other species, biodiversity.

- **USDA**
  - Impact on animals or crops as new pest.

- **FDA**
  - Impact on human health as new type of drug.

**WHO**

Guidance framework for testing of genetically modified mosquitoes

**FDA Guidance issued Oct 2017 (#236)**

**Examples of New Animal Drugs (FDA would review)**

a. 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.

b. Products intended to prevent mosquito-borne disease in humans or animals.

**Examples of Pesticide Products (EPA would review)**

a. 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).

**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/