House Energy and Commerce Committee, Subcommittee on Oversight and Investigations
March 2, 2016 Hearing
Examining the U.S. Public Health Response to the Zika Virus
Questions for the Record

The Honorable Gus Bilirakis and The Honorable Morgan Griffith

1. **You have previously stated that genetically modified mosquitoes have been shown to successfully reduce the *Aedes aegypti* mosquito population by 90% in trials of up to 5,000 people. The technology has been tested in southern Brazil, Panama, the Cayman Islands, and Malaysia and has suppressed the *Aedes aegypti* mosquito population more than 90 percent.**

    a. **How is your agency assisting the company that developed this novel technology?**

NIAID Response:
Oxitec, the company developing this technology, has briefed NIAID on the use of its self-limiting mosquito technology and the status of the controlled release studies in Brazil. This is one of several approaches currently under investigation for control of *Aedes aegypti*—a species of mosquito known to transmit human diseases such as Zika and dengue. NIAID is in discussions with Oxitec and other investigators pursuing a variety of novel approaches to vector control.

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2. **In previous hearings, vector control has been described as "expensive and complicated." From what I understand, that is not the case with regard to genetically engineered mosquitoes. Releasing mosquitoes out the window of a van seems easier than spraying insecticides door to door throughout a city.**

    a. **Have you reviewed the details of both the implementation and cost of genetically engineered mosquitoes? What are you doing to make this technology more affordable and accessible in the way that you are working to make vaccines and diagnostics more affordable and accessible? I ask this question because you have stated that in addition to the creation of diagnostics, the U.S. Public Health response will include both vaccine development and vector control.**

NIAID Response:
NIAID is supporting the development of effective vector control strategies and has been in contact with a number of investigators pursuing this research. NIAID welcomes research applications related to vector control and will support meritorious projects as funding constraints allow. For information about implementation of vector control in State and local jurisdictions, you may wish to contact the Centers for Disease Control and Prevention. In addition, the Oxitec genetically engineered (GE) mosquito is subject to FDA regulation.

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3. **The President's emergency supplemental for the U.S. response to the Zika virus includes $8 million in funding to the International Atomic Energy Agency in order to "implement sterile insect projects that help suppress mosquito populations." Why wouldn't the U.S. government want to direct all or part of this funding or even additional funding to a technology that is available today and that has already**

proven capable of suppressing the mosquito that carries viruses such as Zika and dengue?

NIAID Response:
The U.S. Government (USG) is assisting States and local jurisdictions in implementing established vector control methods. In addition, the USG is pursuing the development of improved and/or novel vector control strategies. Supporting the development of multiple vector control strategies provides flexibility should an individual technology not prove as successful when moving from a small scale field study to wider application. As part of this effort, NIAID is in contact with investigators pursuing a variety of novel approaches to vector control and will support meritorious vector control research as funding constraints allow. Some of this research may be subject to FDA regulation.

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4. **In your testimony, you state that you and your staff are already talking to Oxitec, the company that produces genetically modified mosquitoes. That is good news. Please walk me through what are the next steps as far as those conversations are concerned.**

NIAID Response:
As noted in response to question number one, NIAID is discussing possible opportunities with Oxitec regarding their GE mosquitoes. Should Oxitec decide to submit a research application for NIAID funding, it would be considered through the NIH peer review process, which evaluates and rates the scientific and technical merit of applications. Peer review of applications submitted to the NIH takes place in multiple steps. The initial step of the peer review process takes place in Scientific Review Groups. The second level of peer review is carried out by the NIH National Advisory Councils, which are composed of scientists from the extramural research community and public representatives. More detailed information on the NIH peer review process can be found at http://grants.nih.gov/grants/peer_review_process.htm. In addition, NIAID is in contact with and welcomes research applications from other investigators pursuing novel vector control strategies. NIAID will support meritorious vector control research as funding constraints allow, subject to regulatory requirements of other agencies.

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5. **What type of follow up are you having with Oxitec to address your questions and concerns regarding the scalability of a project that would launch genetically modified mosquitoes? Why do you believe that scalability is going to be a "major problem?" You also said that "you don't want to scale up unless you know it works." Have you had discussions with Oxitec regarding its data on projects taking place outside of the US which indicate very positive outcomes in decreasing the *Aedes aegypti* mosquito population?**

NIAID Response:
Oxitec has briefed NIAID on the use of its self-limiting mosquito technology and the status of the controlled release studies in Brazil. It is important to note that to be effective, scale up of the

release of GE mosquitoes is essential to cover the large areas needed to control the current epidemic. Since each release of Oxitec's GE mosquitoes only covers small areas and lasts a limited period of time, scale up is an important consideration due to the requirement for repeated releases at multiple time points and in multiple geographic areas. Furthermore, the speed with which GE mosquitoes would result in mosquito control over large areas may not be fast enough to stop the current Zika virus epidemic. The FDA's Center for Veterinary Medicine is currently reviewing information in an investigational new animal drug (INAD) file from Oxitec, Ltd. The company is seeking to conduct an open release field trial of their GE mosquitoes in Key Haven, Florida.

Successful control of mosquitoes will require a multi-pronged approach suitable to the particulars of each geographic area. Moreover, GE mosquitoes, or any other novel vector intervention, should be used in concurrence with established vector control approaches (e.g., insecticides, repellents, and destruction of breeding sites). In addition to the discussions with Oxitec, NIAID has been in contact with other investigators pursuing a variety of novel approaches to vector control.