

## FDA could set millions of genetically modified mosquitoes loose in Florida Keys

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Millions of genetically modified mosquitoes could be released in the Florida Keys if British researchers win approval to use the bugs against two extremely painful viral diseases.

Never before have insects with modified DNA come so close to being set loose in a residential U.S. neighborhood.

"This is essentially using a mosquito as a drug to cure disease," said Michael Doyle, executive director of the Florida Keys Mosquito Control District, which is waiting to hear if the Food and Drug Administration will allow the experiment.

Dengue and chikungunya are growing threats in the U.S., but some people are more frightened at the thought of being bitten by a genetically modified organism. More than 130,000 signed a Change.org petition against the experiment.

Even potential boosters say those responsible must do more to show that benefits outweigh the risks.

"I think the science is fine, they definitely can kill mosquitoes, but the GMO issue still sticks as something of a thorny issue for the general public," said Phil Lounibos, who studies mosquito control at the Florida Medical Entomology Laboratory. "It's not even so much about the science — you can't go ahead with something like this if public opinion is negative."

Mosquito controllers say they're running out of options that can kill *Aedes aegypti*, a tiger-striped invader whose biting females spread these viruses. Climate change and globalization are spreading tropical diseases farther from the equator, and Key West, the southernmost city in the continental U.S., is particularly vulnerable.

"An arriving person would be infectious for several days, and could infect many of the local mosquitoes," Doyle said. "Within a few weeks you'd likely end up with several infected mosquitoes for each infected visitor."

There are no vaccines or cures for dengue, known as "break-bone fever," or chikungunya, which causes painful contortions. U.S. cases remain rare for now, but dengue sickens 50 million people annually worldwide and kills 2.5 percent of the half-million who get severe cases, according to the World Health Organization. Chikungunya has already overwhelmed hospitals and harmed economies across the Caribbean after infecting a million people in the region last year.

Insecticides are sprayed year-round from helicopters and door-to-door in charming and crowded neighborhoods throughout the Keys. But because *Aedes aegypti* don't travel much and are repeatedly doused with the same chemicals, they have evolved to resist four of the six insecticides used to kill them.

Enter Oxitec, a British biotech firm launched by Oxford University researchers. They patented a method of breeding *Aedes aegypti* with fragments of proteins from the herpes simplex virus and *E. coli* bacteria as well as genes from coral and cabbage. This synthetic DNA has been used in thousands of experiments without harming lab animals, but it is fatal to the bugs, killing mosquito larvae before they can fly or bite.

Oxitec's lab workers manually remove modified females, aiming to release only males, which feed on nectar and don't bite for blood like females do. The modified males then mate with wild females whose offspring die, reducing the population.

Oxitec has built a breeding lab in Marathon and hopes to release its mosquitoes this spring in Key Haven, a neighborhood of 444 homes closely clustered on a relatively isolated peninsula at the north end of Key West.

FDA spokeswoman Theresa Eisenman said no field tests will be allowed until the agency has "thoroughly reviewed all the necessary information."

Company spokeswoman Chris Creese said the test will be similar in size to Oxitec's 2012 experiment in the Cayman Islands, where 3.3 million modified mosquitoes were released over six months, suppressing 96 percent of the targeted bugs. Oxitec says a later test in Brazil also was successful, and both countries now want larger-scale projects.

But critics accused Oxitec of failing to obtain informed consent in the Caymans, saying residents weren't told they could be bitten by a few stray females overlooked in the lab.

Instead, Oxitec said only non-biting males would be released, and that even if humans were somehow bitten, no genetically modified DNA would enter their bloodstream.

Neither claim is entirely true, outside observers say.

"What Oxitec is trying to spin is that it's highly improbable that there will be negative consequences of this foreign DNA entering someone that's bitten by an Oxitec mosquito," said Lounibos. "I'm on their side, in that consequences are highly unlikely. But to say that there's no genetically modified DNA that might get into a human, that's kind of a gray matter."

Asked about these points, Creese says Oxitec has now released 70 million of its mosquitoes in several countries and received no reports of human impacts caused by bites or from the synthetic DNA, despite regulatory oversight that encourages people to report any problems. "We

are confident of the safety of our mosquito, as there's no mechanism for any adverse effect on human health. The proteins are non-toxic and non-allergenic," she said.

Oxitec should still do more to show that the synthetic DNA causes no harm when transferred into humans by its mosquitoes, said Guy Reeves, a molecular geneticist at Germany's Max Planck Institute. To build trust in any cutting-edge science, a range of independent experts — not just the company that stands to gain or the regulatory agency involved — should have enough access to data published in peer-reviewed journals to be able to explain the specific benefits and risks, he said.

"Failing to do this almost inevitably means a potential for controversy to be sustained and amplified," said Reeves, adding that mosquito-borne diseases need more solutions. "We should not be closing down productive avenues, and genetically modified mosquitoes might be one of them."

With the FDA watching, Doyle and Oxitec's product development manager, Derric Nimmo, checked their frustration at public meetings in November and December, repeatedly fielding the same questions from the same critics.

Their selling points:

This experiment is self-limiting, using insects engineered to kill their progeny, not make them stronger. It is contained, since Oxitec's mosquitoes won't breed with other species. Killing off *Aedes aegypti* can protect human health while eliminating an invasive species. And most Key Haven residents responded positively to a district survey about the planned field test.

Using GMOs also could save money: The district spends 10 percent of its budget on *Aedes aegypti*, which represents less than 1 percent of the 45 mosquito species buzzing around the Keys.

Key Haven resident Marilyn Smith still wasn't persuaded. The Keys haven't experienced a dengue outbreak in years, and no chikungunya cases have been reported here, she said.

"If I knew that this was a real risk and lives could be saved, that would make sense," Smith said. "But there are no problems. Why are we trying to fix it? Why are we being used as the experiment, the guinea pigs, just to see what happens?"

If the FDA decides against the test, or the modified mosquitoes fail to work as promised, Doyle will still need to kill the bugs.

"I'm convinced the only way to fight this is using the mosquitoes to fight each other," he said.

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