Message

From: Nesci, Kimberly [Nesci.Kimberly@epa.gov]
Sent: 5/22/2016 1:28:54 PM
To: Wozniak, Chris [wozniak.chris@epa.gov]; Kough, John [Kough.John@epa.gov]
Subject: Fwd: Request for Meeting to Discuss Disparate Regulation of Zika Virus Vector Control Strategies

Heads up

Sent from my iPhone

Begin forwarded message:

> **From:** "McNally, Robert" <Mcnally.Robert@epa.gov>
> **Date:** May 21, 2016 at 10:59:51 AM EDT
> **To:** "Nesci, Kimberly" <Nesci.Kimberly@epa.gov>, "Keigwin, Richard" <Keigwin.Richard@epa.gov>, "Carlisle, Sharon" <Carlisle.Sharon@epa.gov>
> **Cc:** "Hartman, Mark" <Hartman.Mark@epa.gov>, "Leahy, John" <Leahy.John@epa.gov>
> **Subject: Fwd: Request for Meeting to Discuss Disparate Regulation of Zika Virus Vector Control Strategies**
>
> Sent from my iPhone
>
> Begin forwarded message:
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> > **From:** "Housenger, Jack" <Housenger.Jack@epa.gov>
> > **Date:** May 21, 2016 at 10:05:09 AM EDT
> > **To:** "Monell, Marty" <Monell.Marty@epa.gov>, "McNally, Robert" <Mcnally.Robert@epa.gov>, "Hartman, Mark" <Hartman.Mark@epa.gov>, "Leahy, John" <Leahy.John@epa.gov>
> > **Subject: Fwd: Request for Meeting to Discuss Disparate Regulation of Zika Virus Vector Control Strategies**
> >
> > Sent from my iPhone
> >
> > Begin forwarded message:
> >
> > > **From:** "Jones, Jim" <Jones.Jim@epa.gov>
> > > **Date:** May 21, 2016 at 9:08:45 AM EDT
> > > **To:** "Matthews, Keith" <keith.matthews@sidley.com>
> > > **Cc:** "Mojica, Andrea" <Mojica.andrea@epa.gov>, "Housenger, Jack" <Housenger.Jack@epa.gov>, "Keigwin, Richard" <Keigwin.Richard@epa.gov>
> > > **Subject: Re: Request for Meeting to Discuss Disparate Regulation of Zika Virus Vector Control Strategies**
> > >
> > > Keith, unfortunately, I am on official travel next week from Monday until Thursday morning. I'd be happy to help arrange a meeting with the appropriate EPA officials in the near future. Jim

Sent from my iPhone

On May 20, 2016, at 4:36 PM, Matthews, Keith <keith.matthews@sidley.com> wrote:

Dear Jim,

I am writing on behalf of Oxitec Ltd. to request a joint meeting between Mr. Hadyn Parry, CEO of Oxitec, you, and appropriate officials of FDA to discuss the significantly different regulatory approaches of EPA and FDA to engineered mosquitoes designed to combat the *Aedes aegypti* mosquito, which is the species vector of Zika virus and numerous other serious human health threats, including Dengue Fever and Chikungunya.

As you may know, the Oxitec mosquito is a self-limiting strain of *Aedes aegypti* that has been engineered to effectuate substantial reductions in *Aedes aegypti* populations, utilising what is known as RIDL (Release of Insects Carrying a Dominant Lethal) technology, which prevents the offspring of RIDL-carrying adults to mature to reproductive stage. Because of the inexplicable quirks of U.S. regulatory policy regarding engineered macroorganisms, the Oxitec RIDL mosquitoes are currently being regulated by FDA as a *new animal drug*. Meanwhile, a competing technology, *Aedes aegypti* infected with a strain of *Wolbachia pipientis*, engineered by the University of Kentucky Department of Entomology, is being regulated by EPA BPPD as a microbial biopesticide.

The regulatory approaches of the two agencies, FDA with respect to the Oxitec mosquitoes, and EPA with respect to the *Wolbachia pipientis* engineered mosquitoes, could not be more different. For its application to release RIDL mosquitoes in a limited release trial in the Florida Keys, Oxitec produced numerous health and safety studies as part of its voluminous environmental assessment, which was reviewed by EPA and CDC, prior to a two month public comment period. Meanwhile, the University of Kentucky Department of Entomology has previously obtained Experimental Use Permits (EUP) for release of the *Wolbachia* carrying *Aedes polynesienis* mosquito in America Samoa and Fresno, California, and EPA currently has before it an EUP application for extensive releases of *Aedes aegypti* containing

Wolbachia pipientis in a number of locations in the United States, including the Florida Keys, i.e., in the same geographic area in Florida that Oxitec has requested permission to release the RIDL *Aedes aegypti* controlling mosquito in a limited trial. EPA is closing a comment period on the *Wolbachia pipientis Aedes aegypti* EUP application next Thursday, May 26, 2016. The stark contrast in regulatory approach is apparent from an examination of the publicly available documents that have been reviewed by the two agencies. Oxitec has submitted hundreds of pages of supporting studies and assessments to demonstrate the safety of release of the RIDL mosquitoes. Meanwhile, EPA's *Wolbachia pipientis Aedes aegypti* mosquito EUP docket contains substantially less supporting information and documentation. A more stark demonstration of the arbitrary and capricious differential regulation that can result from application of the current Coordinated Framework could not be found. There is no basis whatsoever from the standpoint of risk for the two engineered mosquitoes to be assessed and regulated in such a inexplicably disparate manner. This point bears repeating, there is no risk-based rationale for the wholly inconsistent approach that the Oxitec mosquito is subjected to by FDA, and that the *Wolbachia pipientis Aedes aegypti* mosquito enjoys with EPA. In point of fact, one must conclude that, if EPA's regulatory approach to the *Wolbachia pipientis Aedes aegypti* is adequate, then FDA's approach to Oxitec's RIDL technology constitutes significant overregulation.

Mr. Parry has been invited to testify before the Committee on Science, Space, and Technology at a hearing on Wednesday, May 25, 2016, titled "Science of Zika: The DNA of an Epidemic." Specifically, Mr. Parry has been requested to address (1) " the bioengineering technology Oxitec has developed for controlling the Aedes aegypti mosquito population and the current research and testing Oxitec is conducting on the method"; (2) "how the Oxitec approach compares to other methods of vector control"; and (3) "any economic, technological or regulatory challenges to bringing the product to market, particularly in the United States." Quite frankly, the question of the regulatory challenges that Oxitec faces in gaining regulatory approval is the issue that is of enormous importance to Oxitec – particularly in light of the significantly lesser regulatory burden faced by the

University of Kentucky Department of Entomology *Wolbachia pipientis Aedes aegypti* mosquito.

Oxitec would greatly appreciate the opportunity to meet with you and the appropriate counterpart at FDA to discuss this issue prior to Mr. Parry's testimony before the House Committee on Science, Space, and Technology on Wednesday, March 25. Oxitec feels that, given the Committee's specific request for his testimony on the regulatory challenges facing the Oxitec mosquito, that Mr. Parry has no alternative other than to highlight the extraordinary disparate regulatory approaches of FDA and EPA to similar risk scenarios. On the other hand, Oxitec would prefer to report to the Committee that it is engaged with FDA and EPA in a constructive dialogue to attempt to address this issue of non-risk-based regulatory disparity.

Please advise us if it might be possible for you to meet with Mr. Parry in advance of Wednesday's hearing. In the alternative, if a meeting in advance of the hearing is not possible, Oxitec would appreciate the opportunity for a joint meeting as soon as possible thereafter.

Best regards,

Keith

KEITH A. MATTHEWS
Counsel

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