GEORGETOWN LAW

Lawrence O. Gostin

University Professor &
Professor of Global Health Law
Faculty Director, O'Neill Institute
for National and Global Health Law
Gostin@law.georgetown.edu

Attn: Giulia Giannangeli
Legislative Clerk, Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, D.C. 20515
Giulia.Giannangeli@mail.house.gov

By post and email.

April 11th, 2016

Dear Ms Giannangeli,

Please find enclosed my responses to the additional questions for the record in relation to my oral testimony before the Subcommittee on Oversight and Investigations on Wednesday March 2nd, 2016 for the hearing "Examining the U.S. Public Health Response to the Zika Virus".

If you have any queries, please do not hesitate to contact me. On Wednesday, *JAMA* will publish on line a short article on United States Preparedness for Zika.[1] I will send you the PDF of that article on Wednesday to supplement my testimony and these answers to additional questions. The JAMA article can go on the record and be made public, as it is open access.

Sincerely

Lawrence O. Gostin

[1] Lawrence O. Gostin & James G. Hodge, Jr., Is the United States Prepared for a Major Zika Virus Outbreak? *Journal of the American Medical Association*, published on line April 13, 2016.

RESPONSES TO ADDITIONAL QUESTIONS FOR THE RECORD RELATING TO TESTIMONY: "ZIKA VIRUS: THE GLOBAL AND UNITED STATES DOMESTIC RESPONSE" (MARCH 2ND, 2016)

Prepared for the
Subcommittee on Oversight and Investigations
U.S. House of Representatives

Representative Tim Murphy, Pennsylvania
Chairman

April 11th, 2016

Lawrence O. Gostin, JD, LL.D (Hon.), Witness
University Professor and Faculty Director,
O'Neill Institute for National and Global Health Law

Alexandra L. Phelan, BBiomedSc/LL.B, LL.M
Adjunct Professor
O'Neill Institute for National and Global Health Law

The Honorable Tim Murphy

1. **Now that the Zika Action Plan Summit on April 1, 2016 in Atlanta, GA has passed, do you have any additional concerns or issues that you would like to raise – and that you believe have not been adequately covered thus far – to improve the federal response to Zika?**

There are worrying signs that the United States is unprepared to face the Zika response as a result of insufficient resourcing and variable legal authorities.[1] Scientific authorities now confirm a scientific consensus that the Zika virus causes neurological deficits including microcephaly and Guillain-Barré Syndrome. There is also a scientific consensus that it is highly likely that Zika outbreaks will occur this summer in the continental United States. Pregnant women, particularly those in lower socioeconomic status groups in the southern US are at heightened risk. Given that we know that Zika will affect the US population and that it has the potential to do harm to individuals and newborns, it would seem unacceptable not to fully fund preparedness efforts.

Insufficient Resourcing

The delay in approving President Obama's supplemental $1.86 billion funding request is a serious public health and political mistake. Without this funding, United States health agencies will not have sufficient capacity for the necessary surveillance, vector abatement, and healthcare services needed immediately to prepare for the start of warmer weather and greater mosquito activity in the continental United States. Vaccine development may also be delayed, as the failure to pass the supplemental request may have economic implications with funding uncertainties threatening industry confidence in the viability of public-private partnerships vital to the development of Zika vaccines and diagnostic tests.

Congress' hesitancy to act will have political repercussions if clusters of Zika infections this Summer are followed by avoidable cases of microcephaly nine months later. These delays have significant ethical, moral, political, and economic implications that Congress must not ignore.

The seriousness and immediacy of the situation was highlighted in the White House's temporary redirection of $589 million from already allocated Ebola funds. These funds will

[1] Lawrence O. Gostin & James G. Hodge, Jr., Is the United States Prepared for a Major Zika Virus Outbreak? *Journal of the American Medical Association*, published online April 13, 2016.

go to critical Zika prevention measures including mosquito control, building lab capacity, and developing vaccines and diagnostic tests. However, this money is insufficient to adequately protect the United States from the Zika virus. Large funding gaps exist, with the CDC unable to fully fund state emergency preparedness grants, impeding the capacity of states' health officials to fully implement Zika preparedness and response plans. Without the supplementary Zika funding, the CDC has reportedly been forced to reprogram $44.25 million for Zika preparedness and response that was previously allocated under the Public Health Emergency Preparedness Cooperative Agreement for states, territories and directly funded cities. This amounts to a 1-10% cut in the amount annually given to states under the preparedness agreement from July 1, 2016. These redirected funds are necessary to provide the direct technical and financial assistance to Puerto Rico and US Associated Pacific Islands now experiencing locally acquired Zika virus, as well as for the increased CDC internal operations necessary for a full United States response.

As outlined in my written testimony, while it may seem appealing to use money previously allocated to the Ebola outbreak, such a move risks making the United States more vulnerable to infectious disease threats. Failure to develop and secure health systems in developing countries – whether in West Africa or South America – risks the health, safety, and security of the United States. This is especially so with Ebola cases continuing to be reported in both Guinea and Liberia.[2]

Variable legal authorities

Mosquito vector control in the United States is primarily the legal authority of states and local governments, resulting in a considerable degree of variability in the resourcing, expertise, and power for vector control. While the federal government is not in a position to

[2] WHO, "New positive case of Ebola virus disease confirmed in Liberia" (April 1, 2016). Available at: http://apps.who.int/ebola/current-situation/ebola-situation-report-30-march-2016, Accessed: April 11, 2016. The latest Ebola Situation Reports can be accessed at: http://apps.who.int/ebola/ebola-situation-reports.

assert legal authority over states or local governments to conduct the necessary vector control programs, equipping federal health authorities with the funding necessary to offer financial and technical support to states is essential to promote the consistency needed for United States health security.

The Honorable Marsha Blackburn

1. **In previous hearings, vector control has been described as "expensive and complicated." Is vector control more complicated and more expensive than vaccine development?**

   Preventing and responding to the Zika outbreak will require a multifaceted approach: one that includes strong vector control measures, as well as research and development into a vaccine. With sufficient funding, vector control measures can be implemented immediately, and while complexities exist, it is one of our primary methods of preventing the spread of Zika within the United States. It is true that the *Aedes* mosquito species most linked to Zika virus transmission is exceedingly difficult to control, however successful control efforts have been accomplished in the past, and we could significantly reduce the mosquito population today given sufficient resources and legal authorities. The development of a vaccine must be done in parallel however the outcomes are much less certain. Existing research into other vaccines may be able to be modified, reducing the time and cost for development of a Zika vaccine. However, none of the current candidate vaccines have reached the stage of testing in human subjects. As a result, vaccine development is a longer term – but also critical – measure, that may vary greatly in cost depending on how research proceeds and the involvement of industry partners.

2. **In your opinion, if a vaccine were tested on 5,000 people and proved to be safe and 90 percent effective would that warrant further development? The genetically engineered mosquito has achieved such success in suppressing the *Aedes aegypti* mosquito.**

   If demonstrated to be effective and safe to humans in the clinical environment, I would support the watchful use of genetically engineered mosquitoes through a carefully controlled release that monitors the *in situ* effects on mosquito-borne diseases such as Zika, as well as any potential ecological or unanticipated harms. Thus far, the Food and Drug Administration and other scientific authorities have not found ecological or other harms from the release of transgenic mosquitos.

3. **How high of a priority should vector control in Puerto Rico be for the federal government? Should the federal government focus more resources on the development and deployment of innovative vector control solutions?**

   Puerto Rico is already experiencing local transmission of the Zika virus.[3] In the absence of a vaccine, vector control – especially in impoverished areas of Puerto Rico – is critical. Vector control and other preparedness measures are vital in Puerto Rico to safeguard the island's population and also to safeguard the US mainland. Given the high travel between Puerto Rico and mainland US (and given the right of free travel), there is every reason to stem the spread in Puerto Rico for all of our national interests. Innovative vector control solutions that are safe and effective should form part of a multifaceted strategy – including existing vector control measures, personal insect repellants, and vaccine development – to stop the spread of the Zika virus.

[3] CDC, "Zika Virus in Puerto Rico", Available at: http://wwwnc.cdc.gov/travel/notices/alert/zika-virus-puerto-rico Accessed: April 10, 2016.

The current delay in Congressional approval the President's supplemental Zika funding request means that health agencies are unlikely to have the capacity to focus on the development of innovative solutions, with funding for existing safe and proven strategies already disastrously insufficient.

4. **In light of the Olympics later this summer, should Brazil be more aggressively deploying innovative solutions, such as genetically modified mosquitoes, to slow the spread of Zika virus?**

   The World Health Organization has noted that Brazil faces many challenges with traditional insecticide control measures for Dengue, which may be similar for stopping the spread of Zika virus. Innovative strategies for mosquito control – which may include genetically modified mosquitoes or mosquitoes infected with bacteria that inhibit virus development – may therefore be necessary to slow the domestic transmission of Zika virus in Brazil. However, these innovative strategies will require carefully monitored pilot program deployments or further initial research.[4] It will also require significant funding and technical support to Brazilian authorities. This should be well in advance of the Rio Olympics, which will have an amplifying impact on the spread of Zika virus.

[4] WHO, "Zika virus: mosquito control works if implemented well; new control tools in the pipeline" (March 18, 2016), Available at: http://www.who.int/emergencies/zika-virus/articles/mosquito-control-tools/en/ Accessed: April 10, 2016.