ZIKA VIRUS: THE GLOBAL AND UNITED STATES DOMESTIC RESPONSE

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Executive Summary

Following the 2014/15 Ebola epidemic, the World Health Organization (WHO) was widely criticized for its delay in taking decisive action and leadership to protect global health. Four international panels found that the WHO unreasonably delayed declaring Ebola a Public Health Emergency of International Concern (PHEIC) to call the international community to action in providing financial and technical resources for the global health humanitarian and security threat posed by Ebola.

The WHO appeared to learn from the Ebola experience. On February 1st, 2016, the Director-General, Margaret Chan, declared the clusters of microcephaly and neurological syndromes (including Guillain-Barré Syndrome) associated with Zika virus infection a PHEIC. The link

between Zika virus infection and microcephaly and Guillain-Barré Syndrome is not yet proven, although suspected. Now the international community, including the United States, must answer the call to action to ensure global health security and equity against the risk posed by the spread of Zika virus.

As the only developed country in the Americas with the *Aedes aegypti* mosquito, the United States bears not only a unique responsibility to take leadership for global health in our region, but also to protect the health of United States residents. The Zika virus is already embedded in Puerto Rico, and it is likely that by the summer time there will be local transmissions in Florida and the Gulf Coast. During the summer, the *Aedes aegpyti* mosquito has been observed as far north as Washington, DC,[1] and the *Aedes albopictus* mosquito, believed to also transmit the Zika virus, is found in at least 32 states in the United States.[2]

As Ebola demonstrated, the health security of the United States is intrinsically tied to ensuring strong health systems and a coordinated international response at the source of the outbreak. Furthermore, as a global leader for humanitarian action, the United States can provide the financial and technical resources necessary to address the Zika epidemic and protect global health. The work of the United States military and the Centers for Disease Control and Prevention (CDC) during Ebola proved to be transformative. The Ebola response was made possible by a special appropriation during the height of the epidemic, as requested by the President and allocated by Congress.

[1] Andrew Lima et al., "Evidence for an Overwintering Population of Aedes Aegypti in Capitol Hill Neighborhood, Washington, DC," *The American Journal of Tropical Medicine and Hygiene* 94, no. 1 (January 6, 2016): 231–35, doi:10.4269/ajtmh.15-0351.

[2] Anthony S. Fauci and David M. Morens, "Zika Virus in the Americas — Yet Another Arbovirus Threat," *New England Journal of Medicine* 374, no. 7 (February 18, 2016): 601–4, doi:10.1056/NEJMp1600297.

I fully support President Obama's FY2016 emergency supplemental appropriations request of $1.86 billion to respond to the Zika virus domestically and internationally. This must be in addition to existing global health security funding – including unobligated Ebola funding – to ensure flexibility to respond to the United States' needs as we progress towards Summer and the threat of domestic mosquito-borne transmission.

The Global Response to the Zika Epidemic

I have served on several high-level panels reviewing the WHO and international community's response to the 2014/15 Ebola outbreak including on the Harvard-London Hygiene and Tropical Medicine Independent Panel on the Global Response to Ebola and the National Academy of Sciences Global Health Risk Framework Commission. I also closely advised the United Nations Secretary General's High Level Panel on Global Health Crises. The WHO's failure to act quickly and decisively cost thousands of lives.[3] Of particular concern was the unreasonable delay in the convening of an Emergency Committee to advise to the WHO Director-General whether she should declare the Ebola outbreak a Public Health Emergency of International Concern (PHEIC) under the International Health Regulations (2005). The Director-General was also late in mobilizing the international financing needed to prevent international spread of the Ebola Virus.

Despite these critiques from numerous independent panels as well as implementing internal reforms, the WHO delayed taking its leadership role in response to Zika. The CDC and Pan American Health Organization had been working actively on Zika, in collaboration with the Brazilian government for months prior to the WHO's active engagement. Given the broad,

[3] Suerie Moon et al., "Will Ebola Change the Game? Ten Essential Reforms before the next Pandemic. The Report of the Harvard-LSHTM Independent Panel on the Global Response to Ebola," *The Lancet* 386, no. 10009 (November 2015): 2204–21, doi:10.1016/S0140-6736(15)00946-0.

global distribution of the mosquitoes that transmit Zika virus, and in the absence of rapid diagnostic tests or a vaccine, on January 27, 2016, my colleague Daniel Lucey MD and I called for the WHO to not repeat its mistakes from Ebola, and for the WHO Director-General to immediately convene an Emergency Committee on Zika virus to assess whether a PHEIC should be declared.[4] On January 28, 2016, the WHO announced that the Director-General would convene an Emergency Committee on Zika virus and the observed increase in neurological disorders and neonatal malformations.[5]

Following this announcement, the WHO acted decisively and with leadership. On February 1st, 2016, the WHO Director-General Margaret Chan declared the clusters of microcephaly and neurological syndromes including Guillain-Barré Syndrome a PHEIC.[6] This was the fourth PHEIC the WHO Director-General has declared since the International Health Regulations (2005) came into effect in June 2007, including for Influenza A (H1N1), polio, and Ebola.[7] While a causal relationship between these clusters and Zika virus is strongly suspected, it is not yet scientifically proven. Nonetheless, the declaration of a PHEIC reflects the pressing need for the coordination and resourcing of international efforts to address the Zika epidemic.

Accompanying the PHEIC, the Director-General issued temporary recommendations to countries on handling the Zika epidemic. While not legally binding, these temporary recommendations

[4] Lucey DR and Gostin LO, "The Emerging Zika Pandemic: Enhancing Preparedness," *JAMA*, January 27, 2016, doi:10.1001/jama.2016.0904.

[5] WHO, "Emergency Committee on Zika virus and observed increase in neurological disorders and neonatal malformation" (January 28, 2016), available at: http://www.who.int/mediacentre/news/statements/2016/emergency-committee-zika/en/ (accessed: February 24, 2016).

[6] WHO, "WHO statement on the first meeting of the International Health Regulations (2005) (IHR 2005) Emergency Committee on Zika virus and observed increase in neurological disorders and neonatal malformations" (February 1, 2016) available at: http://www.who.int/mediacentre/news/statements/2016/1st-emergency-committee-zika/en/ (accessed: February 24, 2016).

[7] The previous declarations were the Influenza A H1N1 pandemic in April 2009, Polio resurgence in May 2014, and the Ebola outbreak in West Africa in August 2014.

have significant normative weight and are issued in accordance with the legally binding International Health Regulations (2005). The recommendations advise countries to enhance surveillance for Zika virus infections, develop diagnostic tools, communicate the risks of Zika virus infection, aggressively implement vector control and personal protective measures, and ensure reproductive health services, including access to contraception (including emergency contraception) and maternal health care.

On February 16th, 2016, the WHO released its "Zika Strategic Response Framework & Joint Operations Plan".[8] This plan is a critically important step towards an effective response to the Zika epidemic. It is also a critical step towards re-establishing the WHO's global health credibility which was significantly undermined during Ebola. The plan estimates that $56 million will be required for the Zika epidemic response.[9] The majority of the funding is for risk communication and community engagement ($15.5 million) and care for those affected ($14.2 million). Given the vital role that the Pan American Health Organization (PAHO) plays in leading the global health response in the Americas, a large amount of the funding under this plan is appropriately earmarked for PAHO ($8.1m), including $1.5 million for surveillance and $2.25 million for vector control measures. Yet, despite this estimate of the needs, the WHO has yet to mobilize the required funding. That is still another reason to support the President's proposed emergency Zika appropriation.

While the WHO's commitment to raising funds needed for the global response is positive, the estimate of $56 million is far less than that required to stem the Zika epidemic in the Americas.

[8] WHO, "Zika Strategic Response Framework & Joint Operations Plan" (February 16, 2016), available at: http://who.int/emergencies/zika-virus/strategic-response-framework.pdf?ua=1

[9] Specifically, $55,743,651: See, WHO, "Zika Strategic Response Framework & Joint Operations Plan" (February 16, 2016), available at: http://who.int/emergencies/zika-virus/strategic-response-framework.pdf?ua=1, Part III: Annexes.

Major global funding is needed for aggressive mosquito control, surveillance, and research. Under the WHO's plan, the overall estimates for these strategies are $6.4 million, $7.1 million, and $6.4 million respectively. The Zika epidemic is likely to spread to many regions of the world beyond the Americas, which will require considerably greater funding. During the Ebola outbreak, the WHO released financing estimates that were far from adequate, requiring repeated increased cost estimates as the Ebola outbreak unfolded. Overly conservative estimates for the Zika epidemic response could result in the same mistakes seen with Ebola: waiting until a global emergency to mobilize funding will always be too little, too late. The WHO must have access to a much larger emergency contingency fund. The trigger for use of this fund would be the declaration of a PHEIC.

The Global Health Risk Framework Commission (on which I served) estimated that it would cost $4.5 billion annually to truly reduce pandemic risks.[10] While this may appear to be a great deal of money, it pales in comparison to the global costs of a pandemic. Previous epidemics have demonstrated that states with major emerging disease outbreaks experience a loss in GDP of up to 10%. Brazil is may experience a similar economic impact with the upcoming 2016 Olympics and Paralympics in Rio de Janeiro. The World Bank has advised that while initial estimates of the short-term economic impact of the Zika epidemic in the Latin American and Caribbean region is 0.06% of GDP, such estimates are based on a swift, coordinated international response. The World Bank however advises such estimates could be significantly larger given the high dependence on tourism in the region if the virus is not promptly contained, if a causal association

[10] Commission on a Global Health Risk Framework for the Future and National Academy of Medicine, Secretariat, *The Neglected Dimension of Global Security: A Framework to Counter Infectious Disease Crises* (Washington, D.C.: National Academies Press, 2016), http://www.nap.edu/catalog/21891.

between Zika virus and clusters of microcephaly and Guillain-Barré Syndrome is established, and if public perceptions of the risks of Zika change.[11]

In addition to the financial and technical resources dedicated by the WHO, it is vital that the WHO use its normative power for global public health. The WHO was criticized for prioritizing politics over public health during the Ebola outbreak. It must not let the same happen with the Zika epidemic, which disproportionately burdens women and the poor. In particular, calls by governments that women avoid getting pregnant – including Brazil, Honduras, Colombia, and El Salvador – without providing access to reproductive health and rights services, are not only ineffective but also unfair to women. In Central and South America, there is limited access to contraception – especially in poorer communities most at risk of Zika virus infection and cultural and religious norms still restrict the availability and use of contraception. Nearly all countries in the Americas currently experiencing or likely to experience Zika virus cases have laws preventing women from accessing reproductive health services such as emergency contraception and abortion. In addition, the quality, accessibility, and affordability of maternal health care systems vary greatly between and within countries, with varying degrees of post-partum support services for children born with disabilities. Pope Francis recently supported the expanded use of contraception in the face of potential harms to pregnant women from Zika virus infection.

Both the WHO and the international community's response to the Zika epidemic must therefore be comprehensive, equitable, and substantial.

The United States' Domestic Response

[11] World Bank, "The short-term economic costs of Zika in Latin America and the Caribbean (LCR)", (February 18, 2016), available at: http://pubdocs.worldbank.org/pubdocs/publicdoc/2016/2/410321455758564708/The-short-term-economic-costs-of-Zika-in-LCR-final-doc-autores-feb-18.pdf (accessed February 24, 2016).

The Risk to the United States

The mosquitoes that transmits Zika virus – *Aedes aegypti* (primary vector) and *Aedes albopictus* – is present in the United States and its territories.[12] One recent study modeling possible Zika spread estimates that more than 60% of the US population lives in areas conducive to seasonal Zika virus transmission,[13] with Florida and Southern Texas at risk of year round transmission. The United States is the only high-income country in the Americas at risk of local Zika virus transmission.[14] As a result, the United States domestic response must cover not only returning travelers who may be infected and local transmission of Zika virus from sexual intercourse, but also local transmission of Zika virus due to infected mosquitoes.

On February 3, 2016, the CDC's Emergency Operations Center (EOC) moved into Level 1 activation to accelerate domestic preparedness in anticipation of local Zika virus transmission by mosquitoes in the Continental United States.[15] Level 1 is the EOC's highest level of activation, reserved for critical emergencies. This involves assignment of the largest number of staff possible to work on a response. There have been three previous EOC Level 1 responses: the Ebola outbreak, Influenza A H1N1 outbreak, and Hurricane Katrina. Moving to this level of response demonstrates the importance of preparedness for the Zika outbreak and supports the

[12] CDC, "Surveillance and Control of *Aedes aegypti* and *Aedes albopictus* in the United States", available at: http://www.cdc.gov/chikungunya/resources/vector-control.html (accessed: February 24, 2016).

[13] Moritz U. G. Kraemer et al., "The Global Distribution of the Arbovirus Vectors Aedes Aegypti and Ae. Albopictus," *eLife* 4 (2015): e08347, doi:10.7554/eLife.08347 as cited in: Isaac I Bogoch et al., "Anticipating the International Spread of Zika Virus from Brazil," *The Lancet* 387, no. 10016 (January 29, 2016): 335–36, doi:10.1016/S0140-6736(16)00080-5.

[14] Canada does not have the *Aedes aegypti* mosquito. Developmental status taken from: UN, *World Economic Situation and Prospects Report 2014*, available at: http://www.un.org/en/development/desa/policy/wesp/wesp_current/2014wesp_country_classification.pdf (accessed February 24, 2016)

[15] CDC, "CDC Emergency Operations Center moves to highest level of activation for Zika response" (February 3, 2016), available at: http://www.cdc.gov/media/releases/2016/s0208-zika-eoca-activation.html (accessed February 24, 2016)

development of laboratory tests to diagnose Zika infection, studies to investigate the association between Zika virus and microcephaly and Guillain Barré syndrome, surveillance in the United States and its territories, and support of efforts in Puerto Rico, Brazil, and Colombia.

Travel advisories and restrictions

The CDC has issued Level 2 (Alert: Practice enhanced precautions) general travel advisories for Zika virus in areas with local transmission such as South America, Central America, Mexico, Pacific Islands, and the Caribbean.[16] In addition, these Level 2 travel alerts include specific interim recommendations that pregnant women should consider postponing any travel to affected regions. The CDC has not issued any Level 3 (Warning: Avoid all non-essential travel) travel advisories which would indicate danger to all travelers, not only travelers with specific risk factors, such as pregnancy.

Travel advisories are important for ensuring that individuals traveling to Zika virus affected countries have adequate information to decide whether to travel and what steps they should take to prevent Zika infection while in affected countries and upon return to the United States. Given the typically mild symptoms of Zika virus in healthy, non-pregnant individuals, Level 3 travel warnings are not currently warranted. Priority should be given to continuing the current information sharing process to travelers on how to prevent mosquito bites, such as through the use of EPA-registered insect repellents, the covering of exposed skin, and sleeping in screened or air-conditioned rooms, and how to prevent possible infection of pregnant partners through sexual intercourse upon return to the United States.

[16] CDC, "Zika Travel Information", available at: http://wwwnc.cdc.gov/travel/page/zika-information (accessed February 23, 2016).

Notably, the CDC and WHO have different advice to pregnant women traveling to Zika affected countries. The CDC's response is more proactive and one that I strongly support.

Travel bans are not warranted, including specific bans for pregnant women at any stage during pregnancy, which would be unnecessarily discriminatory and intrusive. It is important that the CDC is supported in its efforts to set, continually review, and update travel advisories as the public health circumstances change. The WHO Director-General's temporary recommendations issued with the PHEIC declaration specifically advise against travel or trade restrictions to prevent the spread of Zika virus.

Quarantine & Isolation

As a vector-borne disease, Zika virus is predominately transmitted through the bite of an infected female *Aedes aegypti* mosquito. In addition, most individuals infected with Zika do not show symptoms, making identification of individuals for isolation very difficult. The quarantine of persons suspected of Zika virus infection, or isolation of persons with Zika virus infection, is therefore not an effective or warranted public health strategy. While there is evidence of sexual transmission of Zika, this mode of transmission would also not be favorable to quarantine or isolation measures. As a result, the use of quarantine and isolation in response to Zika is unfounded and therefore likely to be considered an unreasonable and unnecessary burden on individuals' liberty that does not have justification in public health. In the temporary recommendations issued with the PHEIC, the WHO Director-General has advised against restrictions such as quarantine and isolation to prevent the spread of Zika virus. Control efforts should therefore focus on mosquito eradication, education about the measures individuals can take to protect themselves from infection, and funding the development of a vaccine.

Vector-Control

It is a public health priority that the main source of Zika virus transmission – principally the *Aedes aegypti* mosquito – is subject to aggressive vector control efforts. In addition to the physical removal of stagnant water that serves as mosquito breeding sites, the use of safe, effective and approved insecticides is necessary. However, insecticide resistance is growing and the WHO is investigating novel mosquito control strategies, such as the use of transgenic mosquitoes to reduce local mosquito populations.[17]

Given the public health impact of the *Aedes aegypti* mosquito, I support the watchful use of transgenic mosquitoes through a carefully controlled release that monitors the effects on mosquito-borne diseases – including Zika, Dengue, and Chikungunya viruses –as well as any potential ecological harms. Trials so far have demonstrated promising results in drastically reducing local mosquito populations that carry these diseases without causing other harms. There is also little evidence that transgenic mosquitos cause ecological harms, although potential harms need to be closely watched and controlled for.

Ensuring Equity and Justice in the United States' Health System

Given the disproportionate impact of the Zika epidemic on women, it is essential that women in the United States are guaranteed access to reproductive health services including contraception, emergency contraception, and maternal healthcare. Where it is lawful, pregnant women with a fetus known to have microcephaly should be offered the opportunity to abort the pregnancy.

[17] WHO, "Mosquito control: can it stop Zika at source?" (February 17, 2016) available at: http://www.who.int/emergencies/zika-virus/articles/mosquito-control/en/ (accessed: February 24, 2016).

Given the possible sexual transmission of Zika virus, condoms must be readily available and accessible to both men and women in the United States. In addition, concerns about fetal health cannot stop at birth: infant, child, and ongoing healthcare and support services for babies that may be affected by the Zika epidemic must be guaranteed. The Federal and States Governments must act to protect the health of US citizens, and meet their obligations under international health and human rights law.

Ensuring Financing for Response Efforts: President Obama's Supplementary Funding Request

On February 22nd, 2016, President Obama submitted a FY 2016 emergency supplemental appropriations request of $1.86 billion to respond to the Zika virus domestically and internationally.[18] The vast majority of this funding request is directed to the Department of Health and Human Services – $1.48 billion, $828 million of which is directed to the CDC. This funding includes $200 million to support the development of a vaccine through to commercialization with the National Institutes of Health and product development and approvals with the Food and Drug Administration. The United States Agency for International Development (USAID) would receive $335 million for targeted activities in South America, Central America, and the Caribbean. Finally, $41 million would be directed to the Department of State to *inter alia* support WHO, PAHO, and UNICEF public health efforts to address the Zika virus in affected countries while ensuring United States health security. Given the unknowns of the health humanitarian and security risk posed by Zika – especially as we transition to Summer – this funding is essential to ensure flexibility to respond to the United States' needs, including beyond that already identified.

[18] Letter from President Barack Obama to Speaker Paul Ryan (February 22, 2016), available at: https://www.whitehouse.gov/sites/default/files/omb/assets/budget_amendments/emergency_supplemental_2-22-16_zika.pdf (accessed February 24, 2016)

Use of unobligated Ebola emergency funds for the Zika response

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.

Ensuring global public health is not simply about a rapid response, but a sustainable response. Reallocating money from one infectious disease outbreak to another undermines efforts to ensure surveillance, detection, response, and control strategies are not only operational but sustainable in countries at risk of outbreaks. While infectious diseases may appear quickly, the efforts to prevent and respond to them cannot simply be about extinguishing fires, but rather preventing them from flaring up and occurring again in the future. Given the economic impact of outbreaks, sustainable and systems-wide technical and financial resources are essential to ensure taxpayers' money is utilized effectively. Furthermore, reallocating money from one infectious disease outbreak to another infectious disease outbreak risks the long-term health, safety, and security of the United States. It is important to note that the USAID funding request in President Obama's FY2016 emergency supplemental appropriations request would provide flexibility in the use of remaining USAID Ebola funds.[19]

Global health security and public health is grossly underfunded. I strongly advise that the Zika supplementary budget request is funded independently from unobligated past emergency funds.

[19] White House, Office of the Press Secretary, "Fact Sheet: Preparing for and Responding to the Zika Virus at Home and Abroad" (February 8, 2016), available at: https://www.whitehouse.gov/the-press-office/2016/02/08/fact-sheet-preparing-and-responding-zika-virus-home-and-abroad (accessed February 24, 2016).