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**Web Briefing for Media – The Zika Virus: What’s Next in the  
U.S. and Abroad?  
Kaiser Family Foundation  
February 17, 2016**

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**JEN KATES:** Thank you and welcome everyone to our reporter call on Zika virus. This is Jen Kates of the Kaiser Family Foundation and with me today, we are very pleased to have Dr. Tom Frieden, the Director of the Centers for Disease Control and Prevention, and Dr. Tony Fauci, the Director of the National Institute of Allergy and Infectious Diseases at NIH. In addition, I have my colleague, Dr. Josh Michaud here who will be on hand during our Q and A.

Just as a reminder, this is a call for media only. It is similar to other calls we have done on urgent or timely global health topics, particularly ones that are fast moving where information is changing readily, so we hope that this will be of use. As you just heard, this is being recorded and we will have the recording and the slides posted after the event and we will let you know when that is available. It is a listen-only format, but we encourage you to chat or type in your questions for us at any time during the briefing and we will get to them at the Q and A.

Just to get us started, I am going to show just a couple of slides. Again, these will be available, they are more scene setting, and the first one just lays out some key facts. The one I wanted to call your attention to as most of you, I assume, know that the WHO has declared the cluster of

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Zika-associated cases of microcephaly a public health emergency of international concern. This was done on February 1st and actually yesterday, the WHO released its strategic response plan. I encourage you to look at that if you have not had a chance.

Twenty-six countries in the Americas have had local transmission thus far and six have reported an increase in microcephaly or other complications in conjunction with Zika, an association that is not yet proven. I am going to the next slide just to show you visually which countries have local transmission. Again, next slide.

Importantly the White House has asked for an emergency funding request of 1.8 billion to address Zika domestically and internationally. We lay out here the components of that request. I will just highlight that one component at USAID does include the ability or the quest of the ability to reprogram some unspent Ebola funding, but this request has not yet been acted on by Congress. The last slide that I am going to show is just based on an analysis that we did at Kaiser. I did this with Josh Michaud and Allison Valentine to look at the challenge that this poses through women given the association with microcephaly and other negative outcomes and the call by some health authorities that women should delay pregnancy in countries where women have limited access to reproductive

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health services and what challenges that actually means. We lay out some of the data here, contraceptive prevalence rates being relatively low in some of these countries and that these countries tend to have some pretty restrictive abortion laws. This is just of concern and something that we have more information about on our site.

With that, I am going to quickly turn this over to Dr. Frieden who will provide some remarks and then we will move on to Dr. Fauci. Dr. Frieden.

**TOM FRIEDEN, MD:** Thank you very much and I will just be very brief. First, the bottom line for people in the continental US remains the same, that their recommendation is that pregnant women not travel to areas where Zika is spreading and that women who have traveled there and are pregnant see their doctors about being evaluated for possible Zika infection. We have also provided guidance for pregnant women whose sexual partners have traveled to Zika-affected areas, because we do know that Zika can be transmitted sexually at least with a short period of time when someone is ill and we will learn more about that going forward.

First point I wanted to make is the bottom line pretty much stays the same. The second point I wanted to make is that we are learning more literally every day. We have about 500 staff at CDC working in the field in Brazil, Columbia, Puerto

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Rico, Atlanta, and elsewhere and this is a rapidly changing situation. It is really unprecedented to have a mosquito-borne disease causing a birth defect. Each of the cases that we have seen can be heartbreaking and devastating. What we are doing now is making sure that we learn as much as we can as rapidly as we can, that we share that information promptly, and that we take whatever actions we can to reduce the risk to pregnant women in particular.

Both epidemiology and laboratory data does strongly suggest a link between microcephaly and Zika infection in pregnancy. We do not yet consider that to be a definitive causal link and there may well be co-factors either other infections or other factors that could account for why this is occurring. In terms of Guillain-Barre syndrome, we would not be at all surprised if this was related. Guillain-Barre follows many different infections, including infections that are with viruses similar to Zika, and the pattern of illness following infection is characteristic in the case of Guillain-Barre.

In both cases, we do think a causal link is increasingly likely, but we do not yet have definitive proof on either. That is why we are doing rigorous studies now in Brazil and elsewhere to better understand. As you know, there has been no mosquito-borne transmission in the continental US

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yet. We do expect that there may be some limited local transmission with warmer weather in the mosquito season. That is based on the previous experience with dengue and chikungunya.

The difference in the US is the territories, Puerto Rico and the other territories. Puerto Rico has had very large outbreaks of chikungunya and dengue. Just to give you a sense, in less than 12 months, nearly one out of four adults in Puerto Rico became infected with the chikungunya virus, which is spread by the same mosquito. We think there is a potential for many cases, tens of thousands or even more of infection with Zika virus in Puerto Rico. With about 34,000 births per year, there is a risk of microcephaly there as well.

We currently have more than two dozen CDC employees deployed to Puerto Rico in addition to our dengue branch, which long-term is based in Puerto Rico and has about 50 staff. The challenge here is mosquito control, protection of pregnant women, diagnostic capacity, and establishing the systems to monitor both human health, Guillain Barre, microcephaly, to do laboratory testing, to do effective communication with the public, engagement of the communities, and better understanding of the health risks of Zika.

Just for a moment about the tests that are available, we have already developed and distributed a test that can

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accurately identify whether Zika is present in the blood. We have sent this out to more than a dozen countries around the hemisphere. With funding previously provided by Congress, we were able to move very quickly to provide those. The bigger challenge is prior infection with Zika. We do have a test that can identify that, but it is not fool proof. It can have false positives. We definitely need better testing to determine if someone was infected, better methods of mosquito control, and optimization of the method of mosquito control that we have now. There are some tools that are available, but mosquito control tends to be an area that has not been intensively supported in the past and is particularly important.

Our recommendations, again, are that all women in all trimesters of pregnancy postpone travel to areas where Zika is spreading widely and we will continue to provide information and guidance as we learn more. Obviously, a vaccine would be particularly important, and we are delighted that the NIH is the lead working on this. I will turn it over to Tony for a discussion of the vaccine.

**JEN KATES:** Thanks Tom. Just really quickly, Dr. Frieden is going to have to leave relatively soon, so any questions that come in for you, we will get to as soon as Dr. Fauci is done. Dr. Fauci.

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**ANTHONY FAUCI, MD:** Thank you very much. It is good to be here with you. I am just going to follow up and continue along the line of what Tom had just described. The role of the NIH, NIAID, and other institutes within NIH is obviously in the arena of doing the basic in clinical research not only to better understand both the natural history and the fundamental basics of the disease itself, particularly the relationship between infection of a pregnant woman and the potential, in reality, of congenital abnormalities in the child.

I want to just focus my remarks, because I want to be brief, about the major issue that we are addressing that Tom alluded to and that is the development as quickly and as expeditiously as possible of a safe and effective vaccine for Zika. To remind the listeners that a similar situation decades and decades ago in the United States when we had the vulnerable child-bearing aged women in the country with regard to the development of the congenital rubella syndrome in babies born of mothers who are infected during pregnancy with rubella. That situation was as many as 20,000 babies per year born with congenital rubella syndrome, which can be characterized by blindness, deafness, mental retardation, and heart abnormalities. That was essentially taken off the table by the successful development of a rubella vaccine, which was

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developed for everyone but really targeted women at childbearing age.

The situation with regard to a vaccine for Zika, which in fact the primary target would be women of child-bearing age, because as we know that as a disease, apart from the possible association which is likely with a low degree of Guillain-Barre, that this is generally a mild disease, self-limiting with virtually no mortality. The real issue that is driving all of us is the threat to pregnant women.

In that regard, we have moved quickly in the arena of developing a vaccine, multiple candidates. Very briefly, we have had experienced in the past which puts at somewhat of an advantage of successfully developing vaccines for other flaviviruses. The long history of a successful yellow fever vaccine, at least a couple of vaccines for dengue, one already approved by Sanofi in Mexico and in Brazil, and a Phase III trial, which we at NIAID are conducting currently in Brazil that was started in January of 2016.

There are two prototypes, and there will be more, but at least two. One is a DNA vaccine, which was used successfully to develop a West Nile virus vaccine. We brought it in phase I, it was safe and induced a very good response. The reason we are able to move quickly, because as being a DNA construct, we had put the original insert of the West Nile

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viral gene in there. We are making it by just substituting the Zika gene in the plasmid, which would then be used ultimately in a Phase I trial which we hope to start somewhere by the end of the summer or early fall, I would say end of August, beginning of September, and hopefully get some results about safety and immunogenicity so that we could field, depending upon the extent of the outbreak, in the beginning of 2017 to move in to more advanced trial.

The progress of developing a vaccine, the encouraging news is that we have done this before with similar viruses. Obviously, no vaccine can be made immediately and it is going to take a considerable amount of time before we have a safe and effective fully approved vaccine, but we are moving rapidly into clinical trials and we would keep you updated as to the progress of those trials. I will stop there and be happy with Tom to answer any questions that you have.

**Jen Kates:** Thank you both so much. We do have several questions that have come in. One I will direct primarily to Dr. Frieden, but I think it is also for both of you. It is a question from Tom Howell with the *Washington Times* who asked, how significant is the fact that Zika is transmitting in Puerto Rico while it grapples with a fiscal crisis? Specifically, will the island be forced therefore to seek blood supplies from the mainland US given Zika-related restrictions on donors?

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**Tom Frieden, MD:** Thank you very much. Maybe I will start and if Tony wants to add. Clearly, Puerto Rico has many challenges and Zika is the most recent. Given the way the ecology of the island is, we do expect there could be a substantial number of Zika infections and therefore there is risk for Zika-associated microcephaly on the island. Of note is that the Center for Birth Defects at CDC estimates that a child with birth defect can have a lifetime incremental cost of care of between 1 and 10 million dollars. In addition to the tragedy that it can represent, the economic cost can be quite high. Puerto Rico has had 80 to 90-percent of adults infected with the dengue virus. As I mentioned earlier, about one in four adults infected with the chikungunya virus in the first year of its introduction into the island. We do have concern that there could be rapid and widespread transmission of Zika and that is why our focus is on reducing the risk to pregnant women.

In terms of the FDA recommendations for blood donations, first of all for the places where Zika is not spreading, we have already recommended that returning travelers defer donation for 28 days, FDA is releasing guidance on that, and yesterday actually released additional guidance on that. This does have implications for blood in Puerto Rico. We are currently actively working with Puerto Rico, with some of the

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blood banks there. They already do import a significant proportion of their blood, but not all of it. We were seeing whether we could rapidly implement screening tests that would allow blood to be screened and then used in Puerto Rico. That is a complex undertaking, because it requires both validation of the test and approval by FDA. FDA has been very forward leaning on this and very supportive. Tony, anything you want to add?

**ANTHONY FAUCI, MD:** No, very well said. Just to underscore what Tom said that the general plan of the FDA, and I just got off the phone with him just a little while ago, obviously working very closely with the CDC to develop a screening test for the blood. Prior to the availability of a widely available screening test is that in areas like Puerto Rico that really have a significant ongoing problem is that blood will be imported from areas of the country and regions in which there is no known Zika infection, so that you could at least have a safe supply of blood being brought into an afflicted area.

**JEN KATES:** I just will add one thing, this is Jen Kates, to that. As part of the White House's request for emergency funding for Zika there is a part of that that would be an increase in the federal matching percent that goes to Puerto Rico for Medicaid to provide for healthcare costs

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related to Zika for pregnant women and beyond that. Just to flag that.

Another question here is from Jeff Tyson who is from Devex who asks, beyond the White House request for funding, what is the overall state of funding for Zika? I assume this means US specific, but other comments on funding beyond that are welcome.

**Tom Frieden, MD:** I will start and I am sure Tony will want to add. First off, the Zika emergency supplemental request is intended to address three broad areas. One, urgent action in Puerto Rico and the other territories that face the prospect of widespread transmission. Second, support in the US where mosquito control is generally underinvested in and not done in as systematic and rigorous a way throughout the at-risk areas as we would hope. Third, support for international partners to better understand and support the activities in Zika prevention and control.

I think a broader issue within the US is funding for mosquito control activities at the state and local level. This is an area that often falls between counties. There are mosquito control districts and they vary quite widely in their level of expertise and the resources. This is an area that needs further investment, but the emergency supplemental request would provide us with resources we need to mount a

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robust response over the next one to two years. It does not address some of the longer term issues on investment in newer tools in the long-term for mosquito control and some of the other very basic issues where this type of infection, mosquito-borne illness, arboviral illnesses are increasingly problematic. We need to invest in systems to find them through detection, better diagnostic systems to control them through mosquito control and other rapid response capacity and to prevent them through better research on both the vaccines as well as vector control issues, which Dr. Fauci can speak about.

**ANTHONY FAUCI, MD:** Just to add a bit about the question that was asked about the supplemental funding and what are we doing until the time we get the funding? We certainly, like the CDC, are very much in need of the request that the President made for supplemental funding. Most of what NIH will be getting in that particular request will be related to the development of vaccines not only for Zika, but also for chikungunya as part of the broad problem that afflicts both South America, particularly Puerto Rico.

Right now, we have already started on that. There is a limited amount that we can do with existing resources, which is the reason why we are looking forward to the rapid implementation of that resource that was asked for by the President. We have started on our vaccine work by moving

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resources originally designated for Flavivirus. We have a substantial Flavivirus portfolio and we have a number of investigators in the United States and in South America, particularly in Brazil, who for a very long time measured in decades have been working on Flaviviruses with us. We have switched those resources to address the immediate problem of getting the vaccine off the ground. Hopefully when we do get our allocation of the request from the President we will be able to accelerate that even more.

**JEN KATES:** This is perhaps a followup to your answer, which I think you answered this. Melanie Zanona from *CQ Roll Call* says, how quickly the Congress need to act on this emergency funding package before you run out of money, essentially, in terms of what you are doing and using other allocations to try to respond quickly? What is your timeline for each of you do you think on this?

**Tom Frieden, MD:** The sooner Congress acts, the better. We are currently in discussions now to figure out what might be able to be done as a bridge, but we are not slowing down any of our activity. As I mentioned, we have now about 500 people working on this response. We are activated at level 1, which is the highest level of activation of our emergency operation center. This is only the fourth time we have been activated at that level. This is a big effort. It is an all hands on deck

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effort for us, but in order to begin really strengthening states and arranging for some of the larger activities that are needed, it will be very important that Congress acts promptly.

**ANTHONY FAUCI, MD:** Totally agree the sooner the better.

**JEN KATES:** We have a question here from Serena Marshall from ABC News, and she wants to know when microcephaly is most likely to show up in an ultrasound. Related, when it comes to vaccines, how will you handle or deal with vaccinating pregnant women? What is the risk to them with a vaccination at that point and at what point in pregnancy?

**TOM FRIEDEN, MD:** We are still learning more about this virus. If it acts as other viruses act, the greatest risk will be in the first trimester and early second trimester. We have already seen case reports of women who had a normal ultrasound at 18 to 20 weeks, but then later gave birth to an affected child. This is an area where we are continuing to learn more and understand more so that we can provide information to women, their families, and their clinicians so that they can make the most informed decision possible and be ready for a birth if a child with microcephaly is possibly or likely to be born.

**ANTHONY FAUCI, MD:** With regard to the vaccine question, as in any vaccine that you use, you always prove safety in nonpregnant people before you introduce into a pregnant person. That has been

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the protocol that we have used for virtually every vaccine that we have developed.

With regard to the specific candidate vaccines, the one that I mentioned, as the one of the two candidates is a DNA vaccine with a Zika insert that when you inject it virus-like inert particles are made, we don't anticipate any safety issues in a pregnant woman with that. We will obviously do a Phase I with nonpregnant individuals, men and women, and then move on to pregnant women.

The situation that you have concern with is a vaccine that's a live attenuated vaccine, particularly if it's live attenuated Zika, which we suspect is having some neurotropic issues with the fetus. You want to be very, very careful about ever using a live attenuated vaccine in a pregnant woman, particularly when the microbe in question might have some deleterious effects on the nervous system. We will go with the non-live-attenuated one first and that I think would not be a problem in pregnant woman.

**TOM FRIEDEN, MD:** If I can just add, I 100-percent agree with what Dr. Fauci says. In addition, some people are wondering well if this effect in infant is a result of the reaction to the Zika virus rather than the virus itself, and then could a vaccine have the same problem? I think given the studies that we and others have found that have actually

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identified the Zika virus in the brain tissue of affected infants, it looks like it's a direct effect rather than an immunologically mediated effect.

**JEN KATES:** Another question we have here is from Robert King from the *Washington Examiner* who asks how many cases are in the US now? Will there be heightened restrictions on travel or trade if more cases in the US emerge?

**TOM FRIEDEN, MD:** We'll be reporting the cases on a weekly basis. They'll continue to increase. We already have more than a dozen states involved and we expect, based on experience from chikungunya and dengue, that there will be hundreds if not thousands of returning travelers with Zika infection. There are an estimated more than 40 million people who travel to and from Zika-affected areas from the US each year.

Our emphasis is first that pregnant women should strongly consider not traveling. Second, that everyone who travels should carefully protect themselves against mosquito bites. There are things that you can do with DEET, long sleeves, and permethrin treated clothing and staying indoors to the extent possible and air-conditioned or at least screened space for returning travelers, if symptoms develop it's important to seek care so we can see if an infection is present. For returning travelers with an infection, living in

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parts of the US where there are mosquitoes that can carry this, protecting yourself against mosquito bites is very important to protect your family from being infected via a mosquito.

**JEN KATES:** One quick followup on that from Samantha Caiola from *The Sacramento Bee*, which I think is related, is how far do mosquitos themselves migrate? If they were to be in the US, would there be movement from state to state is what she is looking at.

**TOM FRIEDEN, MD:** The data we have on where these mosquitoes occur, where they are present, is somewhat incomplete and somewhat out of date. From what we know there are maps on our websites of where the primary vector, which is *Aedes aegypti*, is present in the US and where a mosquito that can spread it less efficiently, the tiger mosquito *albopictus* is present as well. What we've seen generally for diseases spread in the same way is that the mosquitoes that spread it well, *aegypti*, can spread as explosively with lots of cases in parts of the world where you do not have a lot of screens and air conditioning. Even in areas of the US with these mosquitoes, what we have seen so far with dengue are isolated cases, not large outbreaks. That is related to the density of population, the density of mosquito populations as well as human populations, and the presence of air conditioning and screens.

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The primary way this virus is spreading around the world is hitchhiking in people who are sick with it or infected with it. Given the amount of travel there is around the world, that is not something that is likely to change.

**JEN KATES:** Thank you. Here is a question from Tom Murphy at Humanosphere. I am going to ask Dr. Fauci first. How does the experience with the West African Ebola outbreak influence the current US and global response to Zika? Is there a risk of an over-reaction?

**ANTHONY FAUCI, MD:** I don't think there is or will be an over-reaction to Zika. I think the lesson that the world, if you look at it from a global perspective, learned is that you don't ever want to get behind the problem. You really want to get ahead of the problem. That's the reason why you're seeing such attention being paid and why you have activity that goes from the level of the President himself through our Congress, through the agencies, CDC and NIH that are involved. We don't have local transmission in the United States yet. We wouldn't be surprised if we did. We feel we have a responsibility not only to protect our country, but also our neighbors to the south as being part of the global community. We are very much involved in working to help what's going on in South America and the Caribbean.

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The lesson of Ebola is don't let something get away from you and get ahead of you, because in some respects that did happen in West Africa and we certainly don't want that to happen here in the Western hemisphere or even anywhere in the world.

**TOM FRIEDEN, MD:** I think, and I'll have to go after these comments, that both Ebola and Zika remind us of how important it is to strengthen the systems around the world to find threats when they first emerge, stop them as rapidly as possible, and prevent them wherever possible. It is certainly possible that Zika was causing similar problems before, but nobody noticed because we didn't have the monitoring systems in place.

The fact is we have to invest in the systems that can find, stop, and prevent health threats in our country and around the world and that includes for mosquito-borne diseases as well as for other health threats both emerging and re-emerging health threats. We will only be safe in this country when we have a safer system, a more robust system around the world to find and stop health threats. In the case of Zika, we have a very different set of challenges than we had with the Ebola. With the Ebola, we had a very clear sense of what was needed. It was incredibly difficult to do. It required

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enormous effort. Exactly as Dr. Fauci says, if we had started a lot sooner, it would have been a lot easier with Ebola.

Zika is very different. The threat appears currently to be primarily to pregnant women and their pregnancies as opposed to the threat in Ebola, which was of a very widespread effect not just through Ebola, but through the healthcare system stresses that Ebola created in Africa.

In Zika, we have a challenge of dealing with this particular mosquito, which really is the cockroach of mosquitoes. It lives indoors in the dark, it's hard to kill, it's sneaky, and it can bite multiple people at one blood meal. We need better tools to stop mosquito-borne illness. Of course, both of these diseases, Zika and Ebola, are examples of diseases that started in the animal world and then affected the human community and shows how important it is that we continue to work to get a better handle on the prevention of zoonotic disease and its spread among people.

Again, thank you very much for joining. I am sorry I have to jump off the webinar now.

**JEN KATES:** Thank you so much Dr. Frieden. Dr. Fauci you have a little bit more time to answer a couple more questions?

**ANTHONY FAUCI, MD:** Sure, I am fine.

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**JEN KATES:** Great, we have a few questions that have come in about microcephaly specifically, so I am going to read those. The first is from Sandee LaMotte with CNN and she wants to know about the new numbers of microcephaly out of Brazil, which are beginning to narrow the number of babies with Zika associated microcephaly. Does that mean that the Zika connection is growing weaker since the virus is not found in all those cases? That is a question. Her followup is, some local scientists, and I know you are aware of this study that came out linking microcephaly to larvicide placed in drinking water. If that is not proven, what role might it play? Related Tulip Mazumdar from BBC News says how soon will we be able to confirm whether there is a causative link between Zika and microcephaly?

**ANTHONY FAUCI, MD:** Those are the three questions that are a little different. They are really related by one common thread and the common thread is that we will know the direct cause-effect relationship or not with Zika infection of a pregnant woman and microcephaly by doing careful case control studies which are already being initiated right now in Brazil. That will tell us a number of things. It will tell us whether or not there is a connection and what the magnitude of the connection is. I think if you go down and talk to our colleagues in Brazil there may be some overestimation to some degree of the numbers of cases, but that does not necessarily

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mean that there is not still a strong association and a major uptick in microcephaly.

The other part of the question is what about these theories of larvicides being the causal relationship and not Zika? That is a theory that is difficult to disprove at the time. However, you still have to explain the mounting evidence of the association, as Tom mentioned, of demonstrable virus in the brains of stillborns, of miscarried fetuses, demonstration in amniotic fluid, and in placenta. I never rule out anything, I take all theories seriously, but there is no evidence that strongly suggests that theory about larvicide is in fact a theory that is based on reality. As I mentioned, we will find out the answer to all of the questions that the questioner asks by doing the case controlled studies. The third question was how long would it take? It probably would wind up taking several months to do a good case control study, at least several months.

**JEN KATES:** Very helpful. Thank you. We have a question as well from Donna Young from Scrip Intelligence. The question is how many pharmaceutical companies are now engaged with you at NIH on discussions about the Zika vaccine and R&D related to it?

**ANTHONY FAUCI, MD:** Literally, as the days and weeks go by, we get more and more companies expressing to us an interest in partnering with us particularly into development of vaccines

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in the advanced development stage. I cannot give you exactly the number, but I can tell you that I have been dealing with directly at least three major companies and there likely will be more.

**JEN KATES:** Great, thank you. Just to let all of you who are in listen mode and sending in questions, we have one more question that I am going to ask. If you have any others, send them in now. Here is another question from Jeff Tyson of Devex. I think Dr. Fauci you started to talk about this earlier. What lessons, funding or otherwise, can global health professionals take from other mosquito-borne tropical diseases and apply them to Zika?

**ANTHONY FAUCI, MD:** I think there are some important lessons, because we have a situation here with Zika in which you have a flavivirus, which is the same class of virus of other infections that have been in the western hemisphere, namely dengue, the history of yellow fever, and West Nile throughout the United States. The mosquito that transmits Zika, dengue, and yellow fever are all the same mosquito, the *Aedes aegypti*, so you can generally get a good idea of how this particular virus likely will act.

Explosion in Brazil was probably due to a couple of confluent factors. One is the relative immunological naivety of the population never having been exposed to Zika before, but

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also the extraordinary burden of mosquitoes that we are seeing in Brazil, particularly in the northeast region where that's the hardest hit section. The lessons learned are we have dealt with this class of viruses before and we have had some success in the development of vaccine, so I think that is going to be the roadmap of hopefully a successful countermeasure approach to Zika.

**JEN KATES:** Thank you. I think I have our last question from Jon Greenberg at PolitiFact. I am going to read what he says. Not to drag down the discussion, but is there any evidence that the TDAP vaccine used in Brazil was any different from the version used in US and Europe? He says that this is a question they have been getting. He will welcome your input on that.

**ANTHONY FAUCI, MD:** I am sorry. I did not get it, which vaccine?

**JEN KATES:** TDAP. The TDAP vaccine used in Brazil was any different from the version we have here in the US or Europe.

**ANTHONY FAUCI, MD:** I do not have any specific knowledge of any differences in those vaccines that is used here and used in Brazil.

**JEN KATES:** I thought it was actually our last question. Two more just came in. See, when you are always

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about to cut people off, you get questions. We will take a couple more and then we are going to end the call. I am just waiting for those to come to me. Here is one. This is from Alicia Ault from Medscape. Yesterday at an IOM forum, an NIH staffer said it would take four years to bring the vaccine to market. Could you comment on that?

**ANTHONY FAUCI, MD:** Yes, I do not know why he said that. I think that has to be put into context and that is why people get confused. A vaccine that comes to market that has the full approval with safety and efficacy, all the I's dotted and the T's crossed from the FDA or a related regulatory authorities, it is true it likely will take a few years. That could be three to five or more years before it is in a vial in a pharmacy ready to be dispensed.

That is different from the development of a vaccine under an emergency situation, which I described in answer to a previous question. Let me very briefly go over that. There is no doubt that unless something happens that we don't predict that we'll be able to have a vaccine in a Phase I study by the end of the summer or early fall, let's say September. It takes about three months or four months to do a Phase I trial. That means by the end of 2016 or early 2017 we will know if the candidate is safe and induces a good immune response.

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If there are no more infections, if the epidemic dies down, you may take several years to prove that it works, because you need a certain number of infections that you prevent to determine if it works. However, and I hope this isn't the case, but if in the beginning of 2017 we still have a raging epidemic in South America and the Caribbean, you may be able to prove within a six to eight months period, let's say eight months, that the vaccine actually does work. You are getting towards the end of 2017. If you're then showing that it's effective, you may not get official approval with all the I's dotted and the T's crossed, but it is conceivable that you can get an emergency accelerated approval of the vaccine within far less time than five years.

That is the reason why the statement that was made at the IOM is true, but I don't think it took into account what could happen if you are in an emergency situation.

**JEN KATES:** Great, thank you. This is the last question. After this, we are going to end the webinar. The last question is from Tulip Mazumdar from BBC News. Do you think the most likely outcome here is that people will develop their own immunity before a vaccine becomes available?

**ANTHONY FAUCI, MD:** The people who are infected would certainly develop their own immunity, but what about the people who didn't get infected? That's the reason why you want a

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vaccine. If the question is, do you think that people will continue to be developing immunity because of getting infected, of course. There have been estimated only 1.5 to 2 million infections of Zika in Brazil right now, which means that there are millions and millions and millions of people who've not been affected and have not been infected and those are the people that you want to protect with a vaccine.

**JEN KATES:** Thank you so much. I would like to actually bring this to a close. I think we had a couple more questions come in, I will just encourage anyone who did not have a question answered to communicate with our associate, Katie Smith. We will make sure to get some answers to you and you can find additional resources at our site, [kff.org](http://kff.org). A lot of information that you heard today will be shared.

I really wanted to first thank Dr. Fauci and Dr. Frieden for taking the time to be here with us and answer these questions. We know how important it is to reporters who are also trying to follow this information. We really appreciate your time and thanks to everyone who joined today. Again, we appreciate you sending in questions and if we didn't get to you, we are happy to follow up. Thanks again. This is Jen Kates and have a great rest of your day.

[END RECORDING]

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