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BULLETIN:

FDA MOVES TO KEEP ZIKA OUT OF U.S. BLOOD SUPPLY

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by Lynne Peterson

The FDA recommended (*translation*: mandated) that all donated blood in the U.S. and its territories be tested for the Zika virus, citing a need to keep the nation's blood supply safe. Eleven southern states must begin testing within four weeks, and the other states within 12 weeks. The requirement is that individual units of donated whole blood and blood components be tested.

In a teleconference with reporters, Peter Marks, MD, PhD, director of the FDA's Center for Biologics Evaluation and Research (CBER), admitted there is "tremendous uncertainty" about the impact of Zika on the blood supply, so this measure "needs to be implemented to keep our blood supply safe."

He added, "The current incidence and prevalence is at a point that [Zika] does affect potential blood donor populations... There is Zika infection going on in Puerto Rico and multiple areas in Florida... and there is still plenty of mosquito season to go... [There are] >8,000 people infected in Florida and Puerto Rico and >2,000 travel-associated cases in the U.S., and the additional possibility of sexual transmission over the course of months."

The recommendation comes a day after the FDA said that a case of Zika transmitted by mosquitoes was detected in Pinellas County, about 265 miles from Miami, where the first locally-acquired cases of Zika in the U.S. were reported. Last month the FDA ordered blood banks in Miami-Dade and Broward counties to stop collecting blood altogether.

Dr. Marks said Zika was found in one blood bag, but he emphasized that this case proved that the system worked, "The blood was interdicted before it could be transfused to anyone."

The FDA authorized the emergency use of two investigational Zika screening tests. Dr. Marks said the companies have sufficient product to meet demand, and the FDA "has confidence the tests perform appropriately for use in this setting."

■ Hologic and Grifols' Procleix Zika

■ Roche Molecular Systems cobas Zika

Dr. Marks said that these tests are not being used as diagnostic tests for people who might be diagnosed by a physician.

Asked how long a potential donor who tests positive for the Zika virus must wait to donate, Dr. Marks said, "If a donor has a recent history of Zika infection, blood should not be collected for 120 days or until it tests negative."

Asked if men, who can carry the virus in their semen for >6 months, will be able to transmit the virus through blood donations and if blood is safe in men with Zika-positive semen, Dr. Marks said, "The infections that seem to go on for six months are generally not in the bloodstream; they are in other tissues, like semen... We are reasonably confident these tests will take care of testing for the infection [in blood]... It

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is an investigational test...It is complicated...but from the standpoint of infectivity, if it is not in the blood, it will not be transmitted by blood.”

The tests for Zika will be done by the blood collection establishment – whether it is the American Red Cross, a smaller blood bank, or an academic center – and the FDA will work with them “to ensure orderly testing,” but he admitted it will require resources, and there are likely to be logistical issues with implementation. He could not answer how much it will cost to implement the testing, but that cost will be “passed on through the system” at least initially.

Asked whether antibody-based tests for RNA-based tests are better for detecting Zika, Dr. Marks said, “It is not which is preferable...They each have their own use in different settings.” He said the antibody tests are good for diagnosing individuals, but the RNA tests are better for picking up very early infection in blood. So, the ones being used to ensure the safety of the blood supply are the RNA tests.

Asked how long the virus can survive in semen and if it is only contagious when in the blood and when it is acceptable to donate blood, Dr. Marks answered, “This gets a little complicated. It can be transmitted from individuals by blood when RNA is present in the blood and that may be for up to 30 days...We are uncertain how long it could be transmitted by semen and vaginal fluids. It could be a number of weeks or a number of months. If you are a male and you receive a blood transfusion and you don’t know it is contaminated, you could potentially have sexual relations for a number of months and transmit Zika. It is not just a matter of the positive donation being a problem for pregnant women...It is a problem for a man who has a partner who might be pregnant or become pregnant while he is able to transmit sexually.”

