The first malaria vaccine? RTS,S enters the final stage of testing

Remarks of
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November 18, 2009

Thank you for this opportunity to speak here today. I greatly appreciate that for the United States, tackling the problem of malaria has bipartisan support. I would like to thank in particular Senators Brownback, Durbin, and Murray, and Representative Smith. Thank you!

I am here speak to you today:

- First as an African, and a citizen of Kenya. I live and work in the coastal town of Kilifi, about 40 miles north of Mombasa;
- Second, I come here as a pediatrician. Every day I see firsthand the human face of malaria beyond the statistics and that the disease continues a serious killer.
- Third, I come here as a research scientist, to inform you that I and my colleagues across Africa are working diligently on the health problems that afflict us.
- And fourth, I come as the mother of a three year old daughter, who I care for very much.

In all of my roles, I am concerned about malaria—which is why I am so excited to be here today to talk about the most advanced malaria vaccine candidate on the horizon, called RTS,S.

I will provide you with an overview of:
- The malaria situation in Kenya and Kilifi
- The place of this vaccine in the fight against malaria
- The status of the trial and how we got this far
- And finally steps we need to take for the future.

Malaria in Kenya and Kilifi
- In Kenya, I regularly see the tragedy of young children dying of the disease and the grief of their parents who couldn't protect them. I too share the concern of those parents. It makes me determined to search for better and more effective solutions.
- So I am pleased to be here today to tell you about what MAY be the first malaria vaccine to become available for use.
- RTS,S, the world's most advanced malaria vaccine candidate, has this year entered the final stage of testing in Africa. If all goes well, it could be the first-ever malaria vaccine and could save hundreds of thousands of lives.

- As a doctor and a medical researcher, I've taken the lead in studying this vaccine for the hope it offers the Kilifi community, the nation of Kenya, and indeed children across sub-Saharan Africa.

- . Every year, malaria kills approximately 34,000 Kenyans, mostly under the age of five.
- The Kenyan government has made efforts, with the support of donors such as the United States, to roll out national programmes to control and treat malaria including increased use of bed nets, as well as access to effective anti-malarials.
- But reports of increasing drug resistance and the persistence of malaria cases in areas of high transmission show that other tools are needed.
- Malaria persists as one of the most lethal diseases in Kenya.

So, how will a vaccine fit into the fight against malaria?

- Every day I see the impact of malaria and how the situation is improving with tools such as bednets and indoor spraying of insecticides—but not enough despite these measures.
- History has shown vaccines to be the most cost effective public health intervention against infectious diseases.
- For malaria we see RTSS as complementary to the other interventions
- RTS,S protects infants and children when they are most vulnerable and allows them to build up their own immunity.
- **Importantly,** earlier trials in infants have shown that the vaccine can be administered safely together with standard childhood vaccinations. So on the practical side there are existing national African health systems equipped to deliver this malaria vaccine to vulnerable children.

***Now to the crux of the matter, where is this vaccine today and how did we get* here?**

- This Phase 3 trial builds on more than 20 years of testing in Europe, the United States, and Africa as we started testing with adults and carefully moved our way down to young children and infants. A Phase 3 trial is typically the last stage of testing before approval by regulatory authorities.
- The Phase 3 for RTSS is being conducted at 11 sites in seven African countries, and will enroll up to 16,000 infants and children.
- **So where are we today?**
- We are at a very exciting point in this trial. Phase 3 trial began first in Bagamoyo, Tanzania, in late May. Sites in Kenya began vaccinating children in July and August.
- More than 6,000 children have been enrolled and the research is progressing well.

Next steps:

- In the case of RTS,S—if the results of the trial are positive—the vaccine will be submitted for approval to regulatory bodies. This will also involve the

World Health Organization, which we hope will recommend the vaccine for use, as well as regulatory authorities in African countries.

- This recommendation for use would pave the way for UNICEF and funding agencies to actually buy and supply the vaccine.
- This trial is important for other reasons, however. District hospitals and dispensaries working with the trial centers have already benefited from upgraded facilities and equipment; staff have been trained.
- **A key point here is these investments mean better healthcare for children—whether involved in the trial or not.**

I only have about a minute left, so want to remind you of three things:

- First, the pathway from discovery to delivery for a vaccine is complex, but we are well on our way with the launch of the phase 3 trial
- Second, a vaccine together with other tools such as bed nets, IRS and effective anti-malarials, brings us closer than ever before to significant control and even elimination of malaria in some regions
- Finally, experience teaches us that even if a vaccine is years away from widespread use, preparation should start now.

My hope is that the global community will be ready to support the availability of this vaccine, if approved, so that the children in Kenya and other African countries will have access to it as soon as possible. **There are lives to be saved**.

On behalf of the families of Kilifi and my African research colleagues, I thank you for your time and attention today.