

Center for Strategic and International Studies (CSIS)

CSIS Conference on the Strategic Power of Vaccines

Moderator:

**J. Stephen Morrison,
Director, Global Health Center
CSIS**

Keynote Speakers:

**Dr. Anthony Fauci,
Director, National Institute of Allergy and Infectious Diseases,
National Institutes of Health (NIH)**

**Rajiv Shah,
Administrator,
U.S. Agency for International Development**

Panelists:

**Amanda Glassman,
Director, Global Health Policy,
Center for Global Development**

**Dr. Julie Gerberding,
President,
Merck Vaccines**

**Margaret McGlynn,
President and CEO,
International AIDS Vaccine Initiatives (IAVI)**

**Dr. Regina Rabinovich,
Director, Infectious Diseases, Global Health Program,
Bill & Melinda Gates Foundation**

**Helen Evans,
Deputy CEO,
Global Alliance for Vaccines and Immunization (GAVI)**

**Orin Levine,
Professor, Bloomberg School of Public Health,
Johns Hopkins University**

**Dr. Anne Schuchat,
Director, National Center for Immunization and Respiratory Diseases,
Centers for Disease Control (CDC)**

**Dr. Stephen Cochi,
Senior Adviser to the Director,
CDC Center for Global Health**

**Markus Geisser,
Sub-Delegation Head,
International Committee of the Red Cross**

**Eric Schwartz,
Dean,
Humphrey School of Public Affairs, University of Minnesota**

Admiral William Fallon

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J. STEPHEN MORRISON: Good morning and welcome to the CSIS conference today on the strategic power of vaccines. I'm Steve Morrison, senior vice president and director of the CSIS Global Health Policy Center. It's very heartening to see so many friends here this morning, and I want to offer a welcome to the 150 or so people who are joining us online. My boss, Dr. John Hamre, sends his regrets. An unforeseen circumstance has pulled him away, so I'll be doing the opening remarks here.

Special thanks are due to several people. Among my CSIS colleagues, I want to single out Seth Gannon, who has worked assiduously and indefatigably for the last several months in pulling all this together and done a masterful job. Matt Fisher and Julia Nagel, Margo Reeves (sp), Carolyn Schrote, Hannah Danji (sp), have all contributed very much to today's events. And many other friends have helped us. I want to single out, particularly, Amie Batson from USAID, Patricia Conrad from NIAID, Margaret Lidstone from IAVI, Alex Palacios from the GAVI alliance, Deb Derrick from the Bill & Melinda Gates Foundation and Chris Elias from PATH Decade of Vaccines. And many others have helped us.

The day's program today features the very best – the very best in terms of experts and leaders and people of astonishing personal commitment, and drawn from a variety of places – from the U.S. government, from international alliances, the business sector, the foundation and university worlds. We're greatly indebted to each of our speakers for taking their valuable time to share their thoughts with us today, and we're very reliant on all of you for your expertise, your generosity and your continued friendship.

This is the second high-level forum on U.S. leadership in global health that we're holding this year. The first, in March, was really looking at the value of global health investments. Today, we've chosen – and I'll explain why in a moment – we've chosen to examine immunization as an essential component of U.S. leadership and as a critical tool to advance U.S. national security and economic interests and to advance the broader human security of the world's populations.

We chose this date for a couple of reasons, and we chose the subject – first of all, this has been a very good year for immunizations and vaccines. We've seen the surprising and very heartening success of the GAVI Pledging Conference in June of this past year. We've seen the continued march forward of the Decade of Vaccines efforts. There's increased attention. There's increased momentum and hope.

And related to that, we've had, with respect to HIV/AIDS, Secretary of State Clinton's speech, followed by President Obama's speech – December 1 – on HIV/AIDS, on an AIDS-free generation, on beginning the end of the HIV epidemic. This has had a very profound – these series of events – a very profound, positive impact in renewing people's enthusiasm and focus.

Vaccines, we all know, need to have a better face, a better brand, a better understanding among policymakers and among the public. Our basic premise today, as we move forward, is the same as in March, which is that strong, continuing U.S. leadership in close, enduring

partnerships with others remains essential to global progress. Another core premise is that the vaccines are fundamental to human security.

And we mean that in respect to conflicted areas, to areas that are more stable, and in times of austerity they remain, across those settings, indispensable, cost-effective, best buys. We believe that we're in an era that's exciting – an era of continued innovation and discovery – and that as part of that process, the private sector remains fundamental to generating vaccines that do more, cost less, are more easily delivered and address diseases that have never been, before, able to prevent.

We'll hear much today about the complex and delicate scientific, business and policy partnerships that are essential to spur innovation in our global economy. We'll hear more about the competing priorities of balancing profit and deep, long-term, strategic investment with the need for addressing inequities and producing high volume and low cost.

This is not easy work. It's not for the faint-hearted. Public trust and confidence are often very fragile. Finances are not always secure. Supply chains and skilled personnel can be scarce. Trying to create a truly coordinated global strategic plan, we've seen, can be daunting. And as I said earlier, the broad, public understanding, the branding, the face of vaccines still is something that needs considerable work.

This brings me, really, to the defining message, I believe, for this day's conference, which is we're in an era of great forward movement, in which vaccines figure ever more significantly in U.S. leadership, in our national interests and in the discussion of how to advance global human security. There's much to be proud of, much excitement as we look to the future, and expectations are high.

As we move through our program today, we'll be covering these issues through individual speeches by Dr. Anthony Fauci, whom I'll introduce in a moment, three distinguished, high-level panels and a closing speech by USAID Administrator Raj Shah. We've also issued two papers today that I hope you will enjoy reading. We have hard copies that are available online. Dr. Phil Nieberg, a very close friend and ally of ours, and Nancy McLaren authored "Role of Vaccines and Immunization Programs in Global Disease Control." And Dr. Stephen Cochi of CDC authored "The Future of Global Immunization: Will the Promise of Vaccines be Fulfilled?"

We're going to open today with a very brief, four-minute video. It's a trailer from a broader project on Zambia. This is a fresh video that was put together by a CSIS team last month that visited Zambia, and the reason we're opening with this is to remind ourselves of the ground-level, human reality of immunizations.

We wanted to begin the day with voices of Zambian mothers, doctors and leaders and their partners in this trailer and to hear their compelling testimony as to the power and impact of vaccines, particularly for maternal and child health, and speak to the importance of achieving broader development goals and addressing the enduring challenges. Janet Fleischman expertly

guided the filming of this, joined by Emma Curran, Julia Nagel, and Seth Gannon. We're very grateful to them.

We're also very indebted, in putting this together, to the cooperation of the Zambian minister of health, Joseph Kasonde, to U.S. Ambassador Joseph Storella (sic) and his deputy, Stephen Schwartz, and public affairs officer, Priscilla Hernandez. We've also received extensive support, for which we're very grateful, from the Zambian embassy here in Washington. And we're joined here today – I just want to offer an special welcome to the Zambian deputy chief of mission, Alfred Chioza, and Ben Kangwa, the press attaché. So thank you very much. This product will be issued next month in a final version as a 10-to-12-minute video. If we could begin the video, please.

(Begin video clip, music.)

MR. : It is very important that we see development as a human development. It's not that we should have tall buildings. It's not that we should have only nice roads on which we can travel. It is about that we develop the human beings. And if we are going to develop human beings, it is logical that we see development as starting with what we do with the children as they are born. It is through vaccines that we have been able to protect the health of the child.

MR. : What you see in immunization is, very simply, prevention. When children are immunized, they don't get sick. When they don't get sick, they don't spread the disease to others. These investments in immunization, which sometimes can cost as little as under \$20 a year, can protect a child and a population for years.

MS. : (In foreign language.)

MS. : Immunizing children and protecting them from preventable diseases, you know, is incredibly important. And there's a lot of children and women out there that aren't getting the benefits of these services. We've got a huge geographical area with very few people in it. The topography is difficult to navigate. The road infrastructure is lacking. And often, people really don't have very regular or frequent contact with health facilities.

MS. : People have to walk long distances to go to the health facility, and it's not easy. So when the mother is bringing both children for health services, she might not be able to carry two or three children because she has to walk long distances.

MR. : Zambia is a huge, huge, expansive country, such that in certain places, you may not actually have – (inaudible) – electricity. So the sort of – (inaudible) – equipment you use has to be tailored to that local context.

MR. : When we are going to conduct these outreach activities, we make sure that we carry enough ice packs so that we maintain the – (inaudible). Most of the health centers are run by just, maybe, one nurse only. But for a center to run, you need about three trained staff.

MR. : You may actually appreciate that it's quite a challenge to ensure that vaccines are delivered in the remotest parts of Zambia to these women and children.

MR. : In our program on vaccination, it is becoming very, very apparent that it is the one area we would never have succeeded without partner support. So here, we have a situation where we accept responsibility for the core support of the programs but also appreciate very much the support that we are getting from our partners.

MS. : Immunizations are important for the development of Zambia. I will give an example of myself. I had a big scar here, which was given to me when I was in primary school for smallpox. Now, it's history. My children, my grandchildren will not know of smallpox because it has been eradicated.

MR. : It's not going to happen overnight. But by having a strong partnership with a country like Zambia – a country that's on a strong democratic path – we really can reach that point, eventually, where we're beyond assistance. And that's what we're looking forward to.

MR. : As the motto says, children are our responsibility. All of us, we are very much responsible for the children. So as you may be aware, these children are the future leaders. These are the future presidents, the future pastors. So we make sure that these children, they grow very healthy and they provide positively to the running of Zambia, as a country.

(End video clip, applause.)

MR. MORRISON: Thank you, and congratulations to Janet, Emma, Julia and Seth. Last month, in early November, I was in Fukushima City, in Tokyo, and there was a lot of discussion around how to resolve very controversial, outstanding issues around safety and science related to low-dose, long-term radiation and how to rebuild public trust and confidence.

And there was a frequent lament in Japan that I heard that there was no revered public health and science personality who could transcend the divisions there and speak authoritatively and command broad public trust. And the lament often concluded with the comment, "You wouldn't understand our problem. You have Tony Fauci." (Laughter.) So I just wanted to mention that, Tony, because it actually did happen.

And as a way of introduction, we have asked Tony to come and kick off this conference with a keynote address, offering his reflections on the state of vaccinology, looking backward and forward. And I don't think there's anyone better and more authoritative and respected in this field to fill this role. He serves as director of the National Institute of Allergy and Infectious Diseases at the National Institutes of Health. He's been in that role since 1984.

He has been a key advisor to presidents and Cabinet secretaries on a full range of issues around preparedness, clinical research. He's made many seminal research contributions across a very diverse portfolio. He's widely published. He's the winner of the Presidential Medal of Freedom, 36 honorary degrees, published over 1100 articles. This is one single man. I'm not

sure quite how that happens, Tony, but we're thrilled to have you here today. If you would please come up, and please join me in welcoming Tony Fauci. (Applause.)

ANTHONY FAUCI: Thank you very much, Steve, for that kind introduction. It's really a great pleasure to be here with you this morning to discuss the subject, which Steve has so nicely introduced, namely vaccinology. I chose as the title of my talk, "Considerations for the 21st Century," but before I do that, I'd like to just put it into some perspective about where we've been and where we are now and what we have to look forward to in the future.

And for the sake of some order and clarity, I decided to break up my relatively brief presentation into four major components: addressing vaccinology and global health, the economic impact of vaccines, the scientific issues that we face today and the future of the scientific approach to vaccinology and then finally, some future considerations for the field of vaccinology in general.

So let's start off with the issue of global health. I don't think I need to convince anyone in this room about the importance of infectious diseases, worldwide, as a global health issue. As you know, about 25 percent of all the deaths in the world are due to infectious diseases. It is the second-leading cause of death, worldwide; the leading cause of death in people from birth until early adulthood. And also, it is the leading cause of DALYs. So to say that we don't have a global problem is to not understand the issue.

Importantly, if you look at infectious diseases and their impact, it is really quite discordant, in that if you look at the number of deaths in high-income countries due to infectious diseases – about 6 percent. In contrast, in a region such as sub-Saharan Africa, greater than 60 percent of the deaths are due to infectious diseases. The important point that we're all familiar with is that many, many of these, if not all of them, theoretically, are actually preventable – preventable because we already have vaccines for them or preventable because we can have vaccines for them.

If one looks at this somewhat historical slide here, which really hasn't changed over many years except for the addition of some of the diseases – such as H. influenzae-b, which I'll get into in a moment – the impact of vaccines in the United States, which is a reflection of the developed world, is truly stunning in the history of the translation of biomedical research to practical countermeasures. The numbers speak for themselves.

If you look at the right-hand side of the slide, the percent decrease in these diseases, globally, is something truly of historic importance. If you take those numbers and look at them a different way, you can come up with the following important data: that of each U.S. birth cohort within the current childhood immunization schedule, it can prevent – vaccines – about 42,000 deaths and about 20 million cases of diseases.

And the pneumo-vaccine impact, such as pneumococcal vaccines and rotavirus, are really comparable to that, with over 200,000 serious infections and 13,000 deaths prevented over an eight-year period, from 2000 to 2008, and the most recent routine rotavirus vaccination

preventing up to 60,000 hospitalizations per year in the United States with an even greater impact, globally.

Speaking of the global impact of vaccines, immunization prevents about 2.5 million child deaths in the developing world, and about 20 million lives saved over the past 20 years, including from the following: measles, polio, neonatal tetanus and reduction about 35 percent since the institution of the pneumococcal vaccines. So from a global standpoint, not only is the impact extraordinary, but the potential is even greater.

I just want to point out three recently developed vaccines and their lifesaving potential in children. I know you're familiar with these: the pneumococcal conjugate, the haemophilus influenzae-b and rotavirus. Right now, the impact of these three infections – if you look 10 years from now, if I were giving this talk, I think these would be then relegated to the diseases that had a 99-to-100 percent decrease. Let me give you an example of that, and this has to do with the implementation of programs. Take the middle one on the slide, haemophilus influenzae-b.

In the United States, as, again, I'm sure all of you know that H. influenzae-b is the leading cause of microbial-related mental retardation and deafness in children. We are at the point, now, that we can really look at the potential elimination of this disease. If you look on the left-hand side of the slide with the United States, that the incidence of Hib cases has gone down dramatically. If you look at the right-hand slide, in Uruguay, we're seeing the same thing. There's no reason to believe that in the developing world, we're not going to see the same results that we're seeing here in the United States, which leads to the potential for another potentially eradicable disease.

So let's move on to a second item that I'm discussing – the economic impact. You can look at economic impact from two standpoints: the economic impact of not having to take care of sick people and the economic impact of people who might have been sick who are now well, who are going to have a positive impact on the economy.

So if you look in the United States, the vaccination, again, of each birth cohort is going to save over \$14 billion in direct costs, as well as close to \$70 billion in total societal costs. If you look at the global impact – take an example, the classic, historic example that was mentioned on the slide, on the video – eradicating smallpox cost the United States about \$100 million over a 10-year period, leading up to the 1977 eradication. And that investment alone has saved us, already, over \$1 billion per year in treatment and prevention costs.

And globally, the savings of vaccines were estimated in the tens of billions of U.S. dollars in direct savings. The other side of the coin that I alluded to a moment ago is that there are other economic benefits as to do, for example, with labor productivity. So if you immunize 90 percent of the children in the 72 most-poor countries, you could prevent 6.5 million deaths, 420 million cases of illness and save billions and billions of dollars, not only in treatment costs, but as I mentioned, in productivity losses. So again, the economic impact speaks for itself.

Now, scientific issues. This is really critical because we are now, in the 21st century, entering an era where we can take an already successful program and make it even more

successful. A recent, this past summer, publication in the journal OMICS was talking about the top five what they called game-changers in vaccinology, which are directed towards a rational vaccine development, as opposed to more of an empiric approach.

And we're using, now, technologies that are just starting to be applied to the field of vaccinology, such as immuno-genomics, next-generation, high-throughput sequencing. We can do things, now, with the sequencing of microbes that were unimaginable just a few years ago. Other cutting-edge OMIC technologies – bioinformatics, as well as the systems biology approach to a new profiling in vaccine responses. And I just want to take a moment to just flesh that out a bit.

When you talk about systems biology, you're talking about multiple (facets?) of the host, which you can learn from to help direct the vaccine development. I mentioned, just a moment ago, the issue of sequencing. It is really astounding that things that took months to a year to do, we can now actually do in a day. I can't even figure out the percentage of the cost of the first microbe, the first bacteria that we sequenced by Craig Venter years ago – haemophilus influenzae-b.

It took about a year-and-a-half to do for about \$25 million. We can do an E. coli, now, in about seven hours for about 25 cents. So it just boggles the imagination, what you can do now with our sequencing capability. With that as a background, the gene expression, profiling, the multiplex analysis we have in our systems biology approach with cytokines and chemokines, multiparameter flow cytometry and computational modeling – these are not things that are really confined to a few people. We have people in many laboratories throughout the country who do this routinely.

Another issue to bring up – again, I know that you're familiar with – but it is really extraordinary if you look at what we can do now, in the 21st century, compared to what we did. When we first had recombinant DNA technology, you would take a protein that you knew was an immunogen, you would clone the gene for that protein and, in an expression vector, you could make that protein. So that's using genome-based vaccinology.

A very important paper a few years ago by Rino Rappuoli introduced the concept of reverse vaccinology because you have the capability of essentially sequencing and expressing every gene in a microbe, getting the proteins that are coded for and then figuring out what the best immunogens are. And that's what he did with the meningococcal vaccine that he so successfully worked with.

I want to use HIV vaccinology, which is frustrating because we don't have a vaccine – I'll get to that in a moment – for HIV, to just mention the prototype of the challenges that we now face with vaccines or diseases that are not going to be low-hanging fruit. One of the beauties of vaccinology is that you learn from nature. In classic vaccinology, the response to natural infection directs you with its own, natural proof of concept as to where you want to go with the vaccine.

So if you take smallpox, if you take measles, if you take polio, we know, as a proof of concept, that the body, even though you get sick and can die from that, really will ultimately make an immune response that will clear the infection and will protect you, usually lifelong, from subsequent challenge. So nature has already done a lot of the biomedical research work for us – not the case with HIV vaccinology because we don't have a proof of concept. In fact, the body doesn't handle, from an immunological standpoint, HIV very well at all.

So what we need to do is a combination of empiric and design of a vaccine to do better than nature. Recently, there was a trial, a couple of years ago, referred to as RV 144, which actually was the first signal of efficacy – modest though it was, 31 percent; not ready for wide distribution at all, but a proof of concept. So that's the typical example of doing something that isn't all empiric but has a large empiric component, and then go back and try and figure out what the correlate of immunity is.

And we have some very nice clues of that from Nelson Michael and Jerome Kim and Bart Haynes and others who are really studying this intensively, that there may be now some clues how you can identify one of the correlates of immunity – at least, of that vaccine. However, we need to even do better than that – not that, that's not going to be an important part of it, but we know now that there are some correlates there.

What about prospectively looking at inducing immunity that we would predict would be protective – namely, improving our natural immunity? Peggy Johnson, my colleague at the NIH, and I wrote a commentary about that in the New England Journal just a couple of months ago on that, and what we were really referring to was structure-based vaccine design. And for those who are not used to looking at this slide, I apologize if it looks a little confusing.

What it really is, is a molecular designation of the envelope of HIV, and those bars that are going – like CD4 binding site and quaternary epitopes, et cetera – are the sites in which we know the body has made neutralizing antibodies against. They do it poorly. They don't do it frequently enough. And they do it too late. But the body can make antibodies that can neutralize against those epitopes.

So what scientists are doing now is, by doing a variety of structure-based, high-sequencing, high-throughput cloning, are able now to identify a large number of neutralizing antibodies – specifically identify the (confirmation ?) of the epitope to which that antibody binds. And the big challenge now – and you're going to be reading about this, I'm sure, over the next few years – is to take those neutralizing epitopes and make them immunogens, namely something that will induce a response that, for reasons we still don't appreciate, the natural response to the virus doesn't do. Bottom line is we have to do better than nature.

Let me move on quickly in the scientific arena to the importance of employing existing and exploring novel adjuvants. We have not – certainly not in this country – used adjuvants to the extent that most of us feel needs to be used. Now, from a very simple standpoint, we know that what adjuvants do is they reduce the amount of antigen needed. That's good from a production standpoint. It promotes earlier, stronger and more – (inaudible) – immune response. That's good from a host-defense standpoint.

And importantly, it may increase cross-protective immune responses, which we've actually seen glimmers of in the influenza vaccines that have been given together with adjuvants. (Inaudible) – to think adjuvant kind of is a boost, in a very simplistic way – not really sure how that happened.

We now know, in the science of the 21st century, that in fact, what adjuvants do is they call upon molecules that literally, evolutionarily, forever have been used as part of the innate immune system and trigger that, which is a bridge to the adaptive immune system. So adjuvants have a very specific, molecular mechanism of why they work. And there's an extraordinary amount of information that is being accumulated right now by the study of the innate immune system and its relationship to adjuvants.

So let's now go to future considerations, and I will close on some considerations in this category. These are four important diseases in which we lack a vaccine. I already mentioned HIV/AIDS. In some respects, the same holds true for tuberculosis. As ancient a disease as it is, we still are somewhat in the dark about the immuno-pathogenesis of tuberculosis. We don't have a vaccine that's effective against pulmonary tuberculosis.

Malaria – there have been some very exciting findings over the last months to a year, and we look forward to that. And then there's the whole arena of neglected tropical diseases. So we have important challenges for us in the 21st century. To give you one example of this issue that I alluded to just a few minutes ago about inducing something that isn't natural to the immune response, I refer to it as unnatural immunity. It sounds a little ominous, but really what it is, is to get the immune response to do better than what it does against a natural infection.

A typical example of why we need to do that and I believe we will be doing it – and I'll give you some examples of why we're there – is the whole issue with seasonal influenza and the need to, every year, update the influenza vaccine because of mild drifts in the antigenicity, particularly of the hemagglutinin molecule. And then every once in a while, we get a crisis like we had with the H5 – and still do – with the H5N1 and that we had with the 2009 H1N1, where we have the emergence of an influenza virus that is different enough that we don't really have a lot of background immunity, and we don't really have a vaccine readily available.

What this screams out for is what we are doing now – when I say we, I mean the scientific community, the Department of Health and Human Services, particularly the CDC and the NIH and others and our international colleagues – are really diminishing, if not getting rid of, the barriers between seasonal influenza and pandemic influenza. How do you do that? You do that by getting a vaccine that actually has the induction of a response that's good against any influenza.

So again, it's a little bit complicated slide, but I just can't help myself from showing it to you because it's such exciting science – is that the immune response against a typical influenza virus, an influenza vaccine, is against the hemagglutinin. The good news is that it's immunogenic and it makes a protective response. The bad news is that most antibodies bind to epitopes that are highly variable. However, in the stem of this head-stem molecule, as you see in

the lower part of the slide, are epitopes that really don't change very much. They don't change in a drifted strain, and they don't really change, if at all, in a shifted strain – namely, a strain that would be a pandemic.

So antibodies that neutralize these areas, there, and bind to a (concerned ?) region are antibodies that would practically, in the real sense, be able to protect against any particular influenza. And in that regard, my colleague and I, Gary Nabel, did a commentary really summarizing the work of many people, including Gary himself, that we can actually, again, induce unnatural immunity.

And why do I call it unnatural? Because when you get exposed to influenza, the (confirmation ?) and typical physical association of molecules makes it very difficult for the immune system to see that part of the molecule that is conserved. And now, by using techniques like DNA prime and standard boost, you can actually induce the body to make a response that it doesn't see in natural infection. Hence, we use the terminology unnatural immunity.

Now, also, as we know, Rino Rappuoli and his colleagues – and he gives a great talk on this – talks about a new way of looking at vaccines. What he calls it is vaccines for the 21st century, and he's saying that vaccines now can address the new needs of the 21st-century society, which is not only the classic protect children from childhood diseases and occasionally adults – for example, with the pneumococcal vaccine – but take a look at society, look at the increase life expectancy, emerging infections, the diseases of poverty and have a whole new paradigm about how you look at vaccines.

And again, these are busy slides, and I certainly am not going to go through each and every microbe on the slide. But what we talk about is a vaccine for every age – (inaudible) – vaccines that we classically have done for infants and children; vaccines for adolescents, such as things like the human papillomavirus and the impact that it will have on cervical carcinoma; adults; elderly; travelers; patients with chronic diseases; obviously people with HIV who are susceptible to other infections; and then the whole host of emerging infectious diseases; and then, finally, vaccines which we would say should be given in the setting of poverty, particularly for many of the neglected tropical diseases, which we know so profoundly affects the bottom billion of people in this country.

There's also vaccines for cancer. I am an infectious-disease person, and I've thought about vaccines always in the context of microbes. But in the past couple of decades, we now have a very strong push, with appropriate scientific backing, to look for vaccines for cancer. Some of the examples of these are on this slide.

The ones with the asterisks are ones in which we already have a vaccine. Most recently, there's been a considerable amount of justifiable excitement over the human papillomavirus and the impact that would have on cervical cancer, particularly in the developing world. The history of hepatitis B and its important impact, ultimately, not only on the disease but on the development of a hepatocellular carcinoma.

And then most recently, we at the NIH, in a nice collaboration between the Infectious Disease Institute and the National Cancer Institute – is that Harold Varmus and Gary Nabel and I and Jeff Cohen and some of our colleagues held a conference about the importance of getting a vaccine against Epstein Barr virus, not only for the protection against infectious mononucleosis but also because of the multiple neoplasms that are associated with Epstein Barr virus.

So what we now have – and essentially, in closing – all of those four issues, but we can achieve this and the global immunization goals. Obviously, you need the science for that, but there are a number of vaccine initiatives. And these are just a few of them. Steve alluded to some of them before – the Decade of Vaccines collaboration, the Millennium Development Goals, the U.S. Institute of Medicine consensus study, in which they identified and prioritized new prevention vaccines for developing.

The Decade of Vaccines, I've had the privilege of being on the leadership council, which involves WHO, which involves UNICEF, which involves GAVI and a number of other important organizations. So I'm very optimistic that this is going to provide the incentive to move forward. The Pacific Health Summit that I went to last year was really a very, I think, exciting experience. I show this because I want to close with this slide.

You know, we have been working with the Bill & Melinda Gates Foundation and with other organizations for a considerable period of time, now. But the reason I liked what was said at that conference – and I'll just give a quote from one of the things that I took out of it and read it to you in closing – that the successes of vaccines really do, as I've tried to allude to in the few minutes that I've had with you this morning, stand alone in the enormity of the impact they have on global health.

Anytime you talk about a scientifically based intervention on global health, vaccines is always in the top two or three. In fact, it's always number one. I don't want to be too provincial about it, but it is essentially number one. However, we really can't rest on our laurels. Many important challenges remain. We have at our disposal the scientific toolkit, some of which I've mentioned just a bit ago, to meet the challenges and to elevate the field of vaccinology to unprecedented heights.

From a scientific standpoint, it's interesting – we've been so successful that in some respects – not all, but in some respects – we've let the science of vaccinology lag because we did so well with it. What we really need to do now is bring the science of vaccinology squarely into the 21st century, and then I think the results that we have will far outstrip the historical results that we've seen over the last many decades. Thank you. (Applause.) I don't see Steve, but I think I'm supposed to take – there he is.

MR. MORRISON: We have a question back there.

Q: Yes, Allen Moore with the Stimson Center and George Washington University. Thank you for that. I didn't quite get all of the science, but I'm hopefully not the only one here who didn't. Next summer, Washington will be full of thousands of people here for the international AIDS conference.

You talked about AIDS, and I guess I'm wondering if you can say a little bit more about the outlook as you see it on the hope for a vaccine for both the international community and the domestic community. The president made some very positive comments for World AIDS Day. Can you expand a little bit on the message of hope or realism for the international AIDS community?

DR. FAUCI: Yes, well, I will be delighted to do that. Interestingly enough, we're at a vaccine conference now, and vaccine is not going to play heavily into the theme and spirit of what we're going to be talking about in July. And let me explain what I mean. It isn't that vaccines are not important. It remains the holy grail of scientific accomplishments for HIV/AIDS.

But right now, what Secretary Clinton said at her visit to the NIH on November the 8th, when she spoke of an AIDS-free generation, and what the president, himself, said on World AIDS Day here in Washington about increasing the benchmark and the goal for number of people on therapy is that we already have within our grasp right now, if we implement it properly, the wherewithal, with treatment and prevention together – there was a tension between treatment and prevention.

What should you do for prevention? What should you do for treatment? Now we know that if you take treatment as a prevention tool because you can actually treat people and know very clearly from a very, very good study that you could remarkably, by over 95 percent, decrease the likelihood of transmitting infection from an infected person to their uninfected partner by getting the viral load low, and you scale up things like circumcision, mother-to-child transmission prevention, proper use of condoms, that if you mathematically model it, you can actually see the decrease in the trajectory of the pandemic to the point of going down to elimination. That's the great news.

So you say to yourself, what has that got to do with vaccine? What it has to do with vaccine is that you could change the trajectory, but given human behavior of prevention and adhering to treatment, that, as the malariologists say, you can control malaria. You can even eliminate malaria, and hopefully, we can eradicate malaria, as Bill & Melinda Gates have said. I think what we're talking about with a vaccine for HIV, if you really want to eliminate and hopefully eradicate HIV, you're going to need a vaccine.

That's not going to come for several years because we still are in the discovery phase, as opposed to the implementation phase. So what I'm really trying to say is that the July meeting is – hopefully will articulate well that we can implement things that we've already scientifically proven and have a major impact, but we've got to do the science to get a vaccine to really put an end to the pandemic. So that's the way I look at it. One is implementation of what we already have, and the other is the scientific discovery to give us a vaccine.

Q: Matt Lawlor from – (inaudible, background noise) – HHS. Thanks for that great overview. I was curious about one thing in the Zambia video that you didn't touch on in your talk, which is the ease of use of vaccines. There are a lot of technologies that are nascent and

available now for eliminating cold chain or easier delivery devices, but they're really not being implemented where they need to be in a lot of these products. Is that an issue of providing enough incentive to manufacturers, or are there other ways for getting better implementation?

DR. FAUCI: Yeah, actually, you bring up a very good point. I didn't include that, not because I didn't think it was important – because Steve told me I had 23 minutes and 41 seconds, and that was it. (Laughter.) So I'm pretty compulsive about staying within my time. But you're bringing up a really very good point.

There are many, many – in fact, we at NIAID have a research program that is, in fact, directed – I say program, I mean a research initiative – at not just getting a new vaccine or improving on vaccines that we have from an effectiveness standpoint but for adding a degree of practicality to vaccines that we already have, including cold-chain issues and others.

So we think it's important enough that we're actually making it a research initiative. And people were surprised at that, saying, well, why would you be interested in that because – be interested in it because if you have a vaccine that you can't implement because of technical constraints, then you've really got to get a vaccine that you can get to the people. So your point is very well-taken. Yes?

Q: I'm Georgia Sambunaris with USAID. My question deals with cost-effectiveness. Given the high cost of vaccine development and the limited budget resources we will have in the future in the foreign aid programs, as well as host-country counterparts, I'm wondering if you recommend a model such as the U.K.'s National Institute for Health and Clinical Excellence for assessing cost-effectiveness analysis related to vaccine development. Or institutionally, how do you recommend dealing with the cost issues, given limited budget resources?

DR. FAUCI: Well, from the standpoint of how I look at it, since we do the research development, that's an interesting tension that we have because vaccine development, particularly vaccine trials, are very costly. And right now, particularly when you have a flat budget, like we've had for the last several years and are even looking, if you read the paper, at the possibility of even a cut in our budget, the tension is between doing fundamental, basic research – the typical R01 grant approach – and every time you do an initiative that's a programmatic initiative – vaccine trials cost, as you well know, tens and tens and tens of millions of dollars.

People look at that and say, my god, you're talking, now, about hundreds and hundreds of grants that won't get funded. So what we try to do is do a delicate balance between maintaining the investigator-initiated approach and actually continuing to make vaccine a high priority. And that's what we've done. Again, I can't speak for implementation because we do that vaccine. We have vaccine programs, now, in tuberculosis and malaria and in HIV, that are really quite expensive.

And we're struggling right now – just, if you just take HIV as a prototypic example, so we have a successful-albeit-modest vaccine that I alluded to – the RV 144. We need to follow up on that, not only in Thailand but also in a different risk region, like in Southern Africa. That's

very costly, and we made a decision that we are going to pursue that, despite the fact that it's going to cost a lot of money.

So you know, we have partners in that. We have the Bill & Melinda Gates Foundation. We have the Department of Defense. We have a bunch of others. So it's a very difficult decision to make, but the bottom line of what I'm saying is that, ultimately, vaccines are so cost-effective that the logic tells you that the investment now is going to pay off.

Q: I found it interesting that you really never once mentioned vaccine manufacturers during this talk. What should be the relationship between those of you in NIH and the other governmental organizations and the people who are going to produce these vaccines? What would be the most productive relationship?

DR. FAUCI: You know, it's interesting that you say that. I sort of, like – (inaudible) – when you say that. It's sort of – I'm so wedded to our collaborations with industry that, you know, I didn't mention my daughter in the talk, either, but you know – (laughter) – she's a really important part of my life. So I sort of put it in the same category. I apologize for not doing it, but you're absolutely right.

Everything we do in vaccine is in a public-private partnership with industry. I mean, I mentioned the RV 144 vaccine. That is a very close collaboration not only with NGOs like the Bill & Melinda Gates Foundation, but with Sanofi Pasteur, with Novartis and others. Every vaccine that I mentioned that we're involved with is involved with a pharmaceutical company. So you're absolutely right. I didn't mention it, and I'm not being facetious when I say because I take it for granted that I didn't mention it. So thank you for bringing that up. (Pause.) OK, thank you. (Applause.)

MR. MORRISON: Thank you very much. We're going to move right into the next panel. I'd like to invite our three panelists to come forward: Dr. Julie Gerberding, president of Merck Vaccines, former head of CDC from 2002 to 2009, member of the Institute of Medicine, undergraduate and M.D. degrees from Case Western, clinical pharmacological training at UCSF. Welcome, Julie.

Margie McGlynn, president and chief executive officer of the International AIDS Vaccine Initiative, former president of vaccines and anti-infectives at Merck. And Dr. Regina Rabinovich, director of global health, infectious diseases at the Bill & Melinda Gates Foundation. So thank you all.

This is really meant to be a conversation among these three experts around some of the questions and issues that Dr. Fauci touched on towards the end of his presentation, which is how do we think in a strategic and long-term way about guaranteeing that there is a robust engagement by the private sector over the long term in bringing forward new discoveries and developing new vaccines and also being present in the production and distribution side of things?

And these are complicated and difficult issues. And we'll hear about many of the competing tensions around guaranteeing that there are finances at the front and back end,

guaranteeing that there are sufficient incentives, guaranteeing that there's enough of a mix between the profit considerations and the considerations around equity, high-volume, low-cost access.

We know that partnerships is the broad frame in which these relationships, over the long term, are sorted out. And we know there are many other issues that surface, with respect to defining what your goals are, looking to the future with some specificity as to what the products should look like, preserving public investment at the early phase and the back phase, talking about quality and the like.

We want to bring this discussion back to the question of U.S. leadership and policy because, ultimately, we're trying, today, to think about the role in the policy environment here in Washington in trying to guarantee the stability and robustness and vitality of private-sector engagement in this area as we look forward. Margie, I'd like to ask you to kick things off with a few minutes. We'll go Margie, Julie, and Gina with opening remarks, and then we'll carry forward a conversation and we'll ask you to join us. So welcome, and thank you.

MARGARET MCGLYNN: Great, thanks, Steve – a great introduction. I think you covered everything I was going to say, so maybe I'll turn to Julie. Just kidding. (Laughter.) You know, when I thought about what perspective do I answer the question that Steve posed – how do we assure a robust market for vaccines and really have the incentives that the private sector needs to participate in that market – I thought, you know, what perspective do I come at this from, given my history?

And I thought of the Joni Mitchell song, "I've looked at life from both sides now," spending 26 years with a pharmaceutical company and running a global vaccine business and now being a CEO of a product-development partnership focused on coming up with an HIV vaccine. Fortunately, I come to the same answer looking through both of those lenses: The only way, as Tony clearly stated in the Q&A session, to address this is public-private partnerships.

And each sector has an absolutely critical role. And I'll focus more on what the private sector needs, but clearly, the public sector provides the funding – provides the funding, upfront research and development to remove that risk, which is so critically important when you're talking about diseases for the developing world because to ask a private company to invest R&D dollars, especially with the tough economic times and financial situation that most participants in the industry have found themselves in – to ask them to take on that risk, especially before you have proof of concept, is a very difficult value proposition.

So the public funding that's available to support that research – the NIH funding, the funding that comes to organizations like IAVI and other product-development partnerships addressing these diseases of the developing world – we're able to channel that to various researchers, including pharma vaccine biotech companies, to help support that early research and remove that risk.

Also, critically important, then, is a market being available because to make the subsequent investment decisions, private industry needs to know, when they get to the back end

– should they get to the back end of that development cycle and introduce a vaccine – that somebody is actually going to fund it. And certainly, there's no guarantees. There will be competition. And that's all expected.

The industry knows how to deal with that. But to not know that when you get to the end of a development cycle where you may have invested hundreds of millions or well over a billion dollars that funding will be available for that vaccine, it's just not something that's going to cut it. And so knowing, through organizations like GAVI, knowing through the funding that comes from governments like the U.S., as well as foundations like Gates Foundation – knowing that funding is available overcomes the second critical hurdle.

Clearly, then, private industry is absolutely essential, as Tony said. I loved the analogy to his daughter. I don't know why he didn't say his wife. I know he's happily married. (Laughter.) But anyway, that was a great answer, and I was pleased to hear it. And when you think about why is that true, there really is no broad-based vaccine that's come from anywhere other than an industry source, and in many cases, a public-private partnership.

When you think about all the tools needed to get through that R&D process, whether you're talking about some of the game-changing technologies like sequencing, high-throughput screening, whether you're talking about the bio-process development to actually come up with a way to make that vaccine, and then to be able to scale it up to produce hundreds of millions of doses a year, clearly, you need industry to do that.

Also to introduce vaccines, to be able to figure out what is the right product profile, and working through partners, organizations like GAVI, WHO, SAGE, what's the right presentation of that product? Do we need a multi-dose vial, or will this not be utilized in a campaign, such that you could end up with a lot of wastage with multi-dose vials? So all of that clarity is needed up front, but there are a couple of additional things that are needed.

One is accurate demand forecasting. How big a plant, or multiple plants, do you need? Will this be widely adopted? Will this have a universal recommendation for everyone at a certain age, or will this be targeted to more high-risk populations? And from a funding perspective, will the funding be there for all countries or more endemic, high-risk regions? You need clarity on that in order to be able to move forward with that investment decision.

You also need to know that IP protection will be there, and we know there's a few examples around the world where that's been an issue. You need to know that if you are developing this vaccine and expect there to be a high- and middle-income market, but you're going to have tiered pricing and be able to provide a very affordable price in the world's poorest markets, you need to know that, that IP protection will be there to justify your investment.

You also need to know that, from a regulatory perspective, there's going to be support for efficient trials and you're going to be able to have low-cost manufacturing and perhaps tech transfer to organizations that may be able to take advantage of a lower-cost labor base, particularly in the south.

So there are a lot of characteristics that are needed, but fortunately, we have a lot of very positive examples of things that have happened. And that's why we have many vaccines in development, even for the big three – AIDS, TB and malaria – where, across those three, we have 4 million deaths per year, most of which occur in the developing world. So we now have pipelines of seven candidates in the pipeline for TB, over 20 for malaria, plus, as you heard Tony talk, very promising results have come out over the past year.

And for HIV, he talked about the RV 144 results. While modest, we can build upon that. We have some clues as to why that may have worked. And then very importantly, over 25 other candidates in the clinic, some taking advantage of the technology that Tony talked about, broadly neutralizing antibodies. So I'll just end with what Tony said: This can only happen through effective public-private partnerships.

MR. MORRISON: Thank you. Julie?

JULIE GERBERDING: So thank you for allowing me to be on the panel, and I agree with everything that Margie said. In fact, she taught me most of what I know, so I'm very happy –

MS. MCGLYNN: Not true.

DR. GERBERDING: – to condone – I mean, to support and agree with what she said. However, I also just came from Zambia, and so this video was really remarkable to me. And I came from Zambia, where Zambia announced that it's the first African country to make a commitment – a national commitment – to reducing cervical cancer among women and girls in that country. And many of you know that cervical cancer is essentially an opportunistic infection associated with HIV infection.

So in our world, where cervical cancer, fortunately, is rare because we have screening and we have tools to detect and treat it, in the developing world, cervical cancer is common. About 25 percent of the women in Zambia with HIV infection have cervical disease. And it is a killer. It's the number-one killer of girls and women in those age groups. So it was a remarkable experience for the president and the first lady of a country that just had a peaceful change of government to stand up and make a commitment to this disease program in their nation. So why did that happen in Zambia?

Well, it happened, first and foremost, because of the national leadership. The first lady is an ob-gyn doctor, so that certainly was a big help. But it also happened because of the leadership of the health ministry that you met, the leadership of the ambassador, who was also on this video, the leadership of the missions from other countries who are there supporting this effort.

It happened because of the leadership of the CDC in the country. Our CDC leader, Larry, has been out experimenting with inexpensive ways to diagnose and treat cervical cancer in the HIV clinics there. It happens because of the USAID investment in logistics and supplies. It happens because of the medical leadership of the teaching hospital there and the Zambians who are out.

But it will happen, most importantly, because of a woman named Mildred. Now, what Mildred is doing is bringing women into her clinic – HIV-infected women into her clinic. She's examining them. She's applying vinegar to their cervix and then taking a picture of it with a camera that has a magnifying lens. And when she sees lesions that are white, that's a sign that they're probably cervical disease and early stages of cancer. If she has a doubt about that, she flashes that picture by email to the doctor in the teaching hospital, who is on call to run to the computer, check out the lesion.

And if he agrees that it looks suspicious, she immediately takes a canister of carbon dioxide, freezes off the lesion on the cervix. The woman goes home and does not have to worry about cervical cancer in her near future. Mildred is teaching women all over Zambia to be able to do this. So we're now in a situation where we have an inexpensive screen; we have an inexpensive treatment; we have trained personnel; and we have a vaccine that can essentially eliminate the hazard for a whole generation of women in Zambia.

Now, that happened because of leadership. It happened because of ingenuity. It happened because there's a CDC that knows that there is a problem with cervical disease in the nation and can track the epidemiology and the unmet health need. But it also happens because there is a vaccine. And when we sit in the United States and think about cervical cancer prevention with the vaccines that we have, they're expensive. They're not easy to have distributed properly in our society because we don't have school-based programs.

But we have the capacity, here, to protect our girls and women very easily from a disease that really should go away. But in the rest of the world, that vaccine is a lifesaver, and we wouldn't be able to think about a cancer-free world for women if we didn't have those vaccines. The challenge is, how do we make it cheap enough so that we can afford to use it in those nations?

And one of the things that I've learned is that – when Margie was talking about the market commitment – there's no better way to get the cost down than to increase the volume because once you've covered all that R&D cost, all the costs of the things that you try that fail, all the costs of building the plant, all the costs of the regulatory environment, all of the money that you have to put into it, at the end of the day, once you have covered those costs, any additional dose of vaccine you make, you can make, essentially, for the raw-material price that pulls it together.

And that's how we get the costs down so that we can afford to bring vaccines into the areas of the world where people need them the most. But in order to do this, we have to know that there's procurement. So we need GAVI. We need the United States government committing to GAVI. We need UNICEF. We need the mechanisms that many of the developed-world nations are contributing to assure that we can purchase the vaccines and that there's a future commitment to do that not just this year but five years from now or 10 years from now.

We also need one other thing that was really remarkable in Zambia, and that was the mobilization of the partnerships. The Susan G. Komen for the cure is now working globally to

mobilize women, build advocacy and start at the grassroots to engage people in the awareness that cervical cancer is a preventable disease and that women need that protection in order to thrive and to be able to raise healthy children who are benefiting from all the other vaccines that get distributed in the world.

So you've got leadership; you've got the vaccine; you've got these incredible partnerships; and now you have social mobilization so that awareness and demand for these lifesaving interventions can come through. I believe if we can do this in Zambia, we can do it anywhere.

MR. MORRISON: Thank you, Julie. Gina?

REGINA RABINOVICH: Thank you. I guess I'm here from the perspective of non-governmental organization, I guess we were called – the Bill & Melinda Gates Foundation. And our focus really is on the global health aspects and the global health impact of vaccines. Tony showed a very long list of potential candidates for the (live course ?). And out of those, we don't focus on all of them, not only because of budgets but because we have to set priorities to be able to deal not only with R&D but our commitments to GAVI and on the implementation side.

And those priorities are set according to disease impact, the potential for preventing disability, life-years lost. And so there are a group of diseases that we do prioritize. And of course, it includes HIV, TB, malaria, but a number of others, including pneumococcus and rotavirus. The challenge is, in terms of answering your first question, which is how do we ensure engagement of the private sector – and I will define that very broadly: not only pharma, but biotech and the developing-country manufacturers – so I include private sector outside the United States – is that we have sort of a triple challenge.

For many diseases – not all of them – we're talking about first – (inaudible) – vaccines that don't exist, yet. So we are engaged with U.S. and European innovators because, really, this requires innovation. And we've made some of those investments, but largely, that depends on the number-one funder in the world, which is really NIH. And the second is that when we do have a vaccine, we need it at really large scale. It's either the world's birth cohort or catch-up campaigns that go beyond one birth cohort.

And you take any competent, mature company that's used to dealing with markets in the U.S. and Europe, and you're really talking about a much larger commitment in terms of the facility that's required. And therefore, you have the potential for efficiencies of scale, but boy, do you have to make investments to get those potentials in efficiencies of scale.

And I think the third challenge is that, realistically, the problem in terms of cost-effectiveness analysis is not one in which you would limit that analysis to R&D costs, but you have to look at what the potential cost-effectiveness would be of vaccines at the end. And those vaccines have to compete not only with each other for attention on the global stage but with the other potential mechanisms for ensuring impact. And on malaria, it's bed nets. Do you buy a vaccine? Do you buy a bed net? Do you use spray, personal protection prophylaxis? And how do you pull together the story of how you would maximize impact?

So we give industry a very large challenge, indeed, and I think larger than if they remained focused on northern, higher-profit markets. Now, under the framework of the Decade of Vaccines – and Tony alluded to it – which is really a collaboration to bring together all of the parties that are working on the various aspects of vaccine R&D on one side to delivery and financing on the other side, as I thought about the various work streams – and we're funders of the secretariat on this – the concept, it came out of a speech that Bill Gates gave at Davos in 2010, saying there is so much potential for impact with rota and pneumo that could be introduced this decade, but for the R&D base to really generate the next generation of vaccines, it really has to be the decade of vaccines.

And so it's both. It's both about delivery and maximizing impact, but it's also about the R&D base. As I think back to the challenges we faced when we had Jim Grant the last time that vaccines were really beginning to be scaled up, is that the challenge on the global stage has changed. It's not a single entity that drives or owns the entire agenda. Countries have to make decisions. There's GAVI, as a financing vehicle. But then for vaccines, every single district has to meet certain performance characteristics and make decisions about where they put their resources.

So the Decade of Vaccines is really about bringing leadership to bear across the value chain. And I think an example of that is the work that has been done on a malaria vaccine. And you asked me to address one vaccine, so let's talk a little bit about malaria because it's easier than HIV, right? We have some things. We've got years of research. HIV has a lot more money. But we have a human challenge model. The most advanced vaccine was just recognized by Time magazine as the number two invention or medical breakthrough of the year, which was rather cool, you know.

But let's look at where that vaccine came from. The collaboration included pharma, so it actually was born out of a collaboration with Walter Reed and the Department of Defense laboratories, which is something we haven't talked about. There really has been so much support for R&D, particularly in neglected and emergent diseases, coming out of those laboratories and their engagement with GlaxoSmithKline.

And if I were to show you what is now a 30-year picture of that vaccine in its first iteration, in its second iteration, in its third – the trial in Gambia – there was a whole lot of work that got done. And then, here, the Gates Foundation got involved – really from the trial that had been done in the Gambian adults – then to supporting – to prove that it worked or didn't work. And it was actually quite risky that it wouldn't. I actually thought that was the likelihood when we made that decision to prove that it would work or not work in children.

It has a couple things going for it: the partnership structure, the challenge model, which demonstrated the concept that it worked in humans, which is – you know, think about the enormous investment that industry had to make in HPV vaccine, not knowing till the very end they were going to have something that not only was immunogenic, but it actually worked. That's pretty scary. And then what it has had is the ability to do – it has an adjuvant.

And I want to focus on the adjuvant because adjuvants, per se, are very expensive products to develop. They have to be developed with a vaccine. And the reason this worked for GSK, I think – I'm not speaking for them; this is my assessment – is that because of the human challenge model, they were able to test adjuvants and optimize. Malaria occurs so frequently, you can do a trial in 2,000 toddlers and figure out if it works or not, and you don't need to spend five or 10 years and do it in 90,000 people.

So really, they were able to optimize the vaccine and then take it down into infants for the results that just got announced in the New England Journal just out of the first year of the study. So the industry is important. Having a good scientific base with a human challenge model, having the product components like an adjuvant program to enhance the immunogenicity, which is challenging for a parasitic disease – I think those are all critical elements that allow a company to engage in something which really will not be a product for the north but really be limited to a product for the south. So maybe I should just stop there and let you take it further.

MR. MORRISON: Great, thank you very much. This has been very rich. I'm very pleased to hear the reference to the DOD overseas medical research labs, which are terribly important and under-recognized in the contributions that they've made historically and continue to make. And also, congratulations on the Pink Ribbon Red Ribbon initiative, which is really quite innovative and exciting.

And when it was first rolled out in mid-September here in Washington, it was amazing to see the excitement and the presence of Secretary Clinton, along with President Bush and Mrs. Bush and the many other partners from the corporate side that had come forward, like yourselves, to join into this effort and to make use, very systematically, of those 250 PEPFAR clinics that are now becoming the access point.

I want to bring it back to questions around U.S. policy. You made a strong case for strong, upfront public-sector investment as part of setting the incentives for the discovery and development. We're in a tough budgetary situation right now. We're in a very austere and uncertain climate. You could make a case that we're in an exceptionally austere and uncertain sort of climate.

So the question, I guess, for all of you is how do you best make the case? Because this is a long-run investment. These are not necessarily well-understood among the broad public. But they're so fundamental to guaranteeing that those partnerships take place, that the development and discovery of new products proceeds along a course and that you can build towards that. That's one big question I was hoping you could speak to.

And related to that is, do we need – in this time that we are in – do we need a renewed focus on some of the innovative financing alternatives to both build into that thinking about how we get through this difficult period? Because this difficult period could stretch for a while, and what you're saying is you need the very long-range thinking. That's what the Decade of Vaccines is about. That's what the private sector is looking for. So maybe if you could jump in, Margie, do you want to –

MS. MCGLYNN: Sure, in terms of how do you make the case, especially with these tough economic times, I think you have to focus on three aspects, especially you know, if you're within the U.S. thinking about the leadership role that we play in global health. Look first at the human aspect. Clearly, that's what drives our global health agenda, is doing something to help those more vulnerable, less fortunate.

And so with all of these diseases, unless you've got the vaccines that can prevent the illness, you can only get so far. We should absolutely make the best use of all prevention and treatment technologies that we have available today. As Tony said, we'll bend the trajectory. But the holy grail, getting to the end, will require a vaccine. So you can model that many different ways. Sure, you can model it that if we could really control human behavior, you could get to zero.

And I wish we could, but we all know we can't control human behavior so we'll get to something less than zero. So let's let the experts who understand what you can achieve with human behavior – and many groups have put forward projections. I know Bill & Melinda Gates Foundation had a project where they put forward projections. But you clearly can't get to the end game without the vaccines. And how does that impact human beings? How many millions of lives will still be lost?

Second is the economic impact, and when you think about, you know – I'll take HIV since I know the figures much better there – if we're spending, globally, \$15, \$16 billion a year right now to get I think it's between 6.5 and 7 million people on treatment over the next couple of years, and the projections have been, if we go out to 2030, that will be over \$30 billion a year to continue that treatment. I can't tell you exactly what a vaccine would cost when you get through that catch-up cohort and get to immunizing a full cohort, but it's in the low-single-digit billions if you look at any other model that's out there.

And so thinking about it from the cost-effectiveness, the total impact on budgets globally, that's a clear argument. And then the third aspect to look at is just the leadership role of the United States – the United States government, the United States research institutions. We have been the leader in innovations like this, and just imagine the pride we will have as a government and as a company if we reach that holy grail and we bring out the ultimate solution to these devastating illnesses.

DR. GERBERDING: So you know, from a 40,000-foot level, for the United States government and the policymakers here, I would say it's about the three Ds. It's about development. It's about defense. When you think about the threat that infectious diseases bring, it's not just for those people over here. As we learned over and over again, we're one traveler away from an infectious disease problem in the United States. So we have every reason to be thinking about diplomacy, development and defense in the realm of vaccination.

Development, in particular – it's not just health, which is what motivates me to get up in the morning, but it's about development from a global standpoint of economic security for the countries where people will have lower birthrates because they have more confidence that their children can grow to become adults. It's about development of the systems to deliver and

produce vaccines and what an incredible force of economic growth this could really be and has been in nations that have taken this on. It's about development of capacity and infrastructure and rising into the global economy.

Vaccines are a very important tip of the spear in those areas, but they are also very important diplomatically. When we launch the Pink Ribbon, Red Ribbon campaign in a country – and I was just there last week – the outpouring of human emotion, their love for the United States, their appreciation for what we do as a generous nation, is really emotionally overwhelming. It is such a powerful statement that our country that has so much is willing to do this for the people who have so little. It's an absolutely – an epitome of the United States government at its best.

And it makes me, personally, very proud to be a part of it, but I think many people in our country don't realize that their tax dollars are doing such good in the world. And it's really important that we step up as policy leaders to continue to make those investments. Now, those investments need to go to the NIH. There's no question that, that's the powerhouse of basic research that fuels that kind of research all over the world.

But those investments also need to go to CDC because if we don't have a CDC, we not only don't understand where the disease threats are, but we don't have the laboratory and the programmatic support to get immunizations with the technical capability where they need to be. And we must continue to fund those DOD labs. They are the front line of defense, particularly for influenza, around the world.

If we did not have the DOD labs, we would not have the surveillance capability that we have for understanding which flu strains are emerging in which parts of the world and what do we need in our vaccine in the United States. So it isn't just about a platform to put money into the global fund or to put money into the GAVI fund. It's about supporting those agencies in the U.S. government that are globally relevant and really provide a front line of defense, of diplomacy and development for all of us.

MR. MORRISON: Gina, would you care to –

DR. RABINOVICH: So in the best of all worlds, I believe that global health compassion and understanding the impact on diplomacy would be drivers for U.S. investment. I think there are drivers for our investment. This is why we engage. This is what we see when we go out to countries. But I think what resonates when we're talking to decision-makers here who are trying to make the difficult tradeoffs in financing and investments in NIH, et cetera, are numbers. So the person who asked the question about – and vaccines do very well on that.

Prevention – highly cost-effective. Really, when you think about what you could invest in – and you can make projections. It's called modeling. There are people who are spending their careers doing this. What you could invest in that would have the biggest impact – U.S. and globally – and you test vaccines against other health interventions, they come out number one. And we have to be rigorous about bringing those numbers together, about utilizing them.

I loved Tony's figures – and I don't know what the sources of those data are, but he's rigorous, too, so I'm sure he's looked – in terms of not only impact on lives but impact on dollars. We have to make the case, and having made the case, then we need to bring the funders, the donors, around those kinds of investments. I think the numbers have to speak for us, and we have to be rigorous about developing those numbers and driving their use.

MR. MORRISON: Thank you. I'd like to open the floor for some comments and questions, and just stand up or raise your hand, and we'll bring a microphone to you. And please identify yourself and offer a quick comment or question, and we'll bring together two or three at a time and then come back to our panelists. There's a hand right here, and I think there's someone in the back row. So why don't we start with you, ma'am, please?

Q: Hi, good morning. My name is Ashley Weatherford. I'm from the Best Shot Foundation, a global child-health nonprofit. And first of all, I'd like to thank the panelists for coming out today and taking the time to speak to us all. And my question is, given the recent trends in economic and budgetary constraints, what is your overall sense of the future of public health programs in the next five, 10, 15 years, including vaccine R&D and other health interventions?

MR. MORRISON: Thank you. There's a gentleman right here. Please.

Q: Oh, sorry. I'm Matt Lawlor from HHS. I just wanted to ask about prioritization. So Dr. Fauci showed some slides with probably 75 worthwhile targets, but given diminishing resources and given what seems to be a broadening number of NGO, private-sector and government partners interested in this space, is there value in bringing people together and focusing on two or three or five, or some limited subset and really galvanizing more support around a limited list of threats?

MR. MORRISON: Thank you. We have a hand here, please.

Q: Thanks you. My name is Ann Thompson. I'm with World Vision and the CORE Group Polio Project, which is funded by USAID and the Gates Foundation to play a part in eradicating polio. I just was wondering if you all could comment on the drive to eradicate polio in relation to resources and priorities, those types of issues.

MR. MORRISON: There's a question right here, hand up. Then we'll come back to – we'll take the fourth – yes, sir?

Q: I'm David Curry, Center for Vaccine Ethics and Policy at the University of Pennsylvania. I'm interested, perhaps for Julie, the Decade of Vaccines collaboration has been mentioned a few times. And obviously, that longitude has interesting implications for industry. I was wondering how industry is participating, or will participate, in the refinement of that strategy.

MR. MORRISON: Thank you. Julie, do you want to lead off? I mean, we had a question specifically directed to you. Then we have a question around polio, around

prioritization. How might we prioritize? And then Ashley's very broad question around what does the future for the next five to 15 years look like, given the austerity. Julie?

DR. GERBERDING: So I'll start. First of all, with respect to the future, I'm very bullish about vaccines in the future. I think that we're slowly but surely making progress on the big three, as you said, but we're also, I think, really beginning to build the social mobilization, the political mobilization and the private-sector mobilization necessary to really pull forward and continue to use this very cost-effective intervention for protecting health.

With respect to polio, I – you know, the world's expert in polio eradication is sitting here – or was sitting here – in the room, Steve Cochi. And we just have to do it. There's no question about it. It needs to get done. We can do it. Look at India right now. I think this is the longest India has gone without a case. This disease can go away, and we have a responsibility to make sure it does. And yes, the last cases are very expensive on the relative scale, but once it's done, it's done. That's it – bing, bang, boom. And it's just hard to have any other talk about it. It just needs to happen.

The question about prioritization is really the toughest question. And one of the challenges that I think we are maturing into now is an appreciation that, ultimately, the decider about what the priority should be is, first and foremost, the person who's receiving the vaccines – mom, or woman, or child – but more importantly, the country. And it is tempting to sit in the United States and think we know best, but in actual fact, a country's agenda – to understand and make values about their own health priorities is really the most important aspect of making decisions about prioritization.

Many countries welcome the support and the input from technical experts and health-economic data from outside of the country, but ultimately, we need to be in a position where our vaccine agendas are, first and foremost, addressing the needs of the people in the countries who are making and paying for them. Having said that, I also think that prioritization is changing. We're seeing, now, multinational companies put enormous emphasis and investments in vaccines that will not be marketed in the United States. Merck is doing that. Glaxo is doing that. Companies are stepping up and saying that we have a responsibility here.

This isn't just about the developed world. This is also about using our excellent science and our capabilities to solve problems in new markets. And we're doing that through partnerships. We're doing that through creative funding mechanisms. Merck has a wonderful partnership with the Wellcome Trust called the Hilleman Laboratories. It's a nonprofit vaccine developer in India that is taking products that, right now, are not suited for developing-world use because of cold-chain requirements or various other characteristics and trying to repurpose those vaccines in ways that will make them easier to use or less expensive to use through the leverage that, that kind of partnership can build.

And there are many examples of this kind of innovative solution. So I think the prioritization process is beginning to have a better match with the true health needs in the world – not just those in the countries that can afford them but in the countries where people need them the most.

MR. MORRISON: Gina?

DR. RABINOVICH: On the topic of polio, it's our number-one priority. And I'm optimistic not only about polio, which has its challenges, but also about the whole arena of vaccines. And that's not only because I'm an optimist, but I also work for an impatient optimist – (laughter) – who wants to have results soon. And we all know about that. (Laughter.) On the issue of prioritization, I do want to support NIH and other likeminded organizations that must keep a warm research base and make investments across a number of diseases at the research level.

Where it gets really expensive, and where we need to understand who's going to use it, that it's really wanted, is at the phase III trials. And while some of them are less expensive and others are really expensive – so an order of magnitude – I think what makes the difference is that people are informed and there's been discussions on what it is they want. This week, one of the Decade of Vaccines teams is in Namibia as part of their consultative process to understand what it is they need at a country level – listening not just to Namibia but the nearby countries – in terms of being ready to introduce a vaccine. What is it that would actually help them?

And they're looking for some help in things that may be technical assistance, that may be preparing for launching into a campaign. It was very personally gratifying, I have to say, to be in Burkina Faso last year for the launch of the meninge (sp) vaccine – which I'd been involved with the CDC and WHO teams in writing that proposal to this Gates Foundation, prior to my joining the foundation – and watch it go from the concept of partnership, potentially, with pharma to one in which it became a very sort of complicated partnership engaging not only CDC, WHO, and PATH and NGO, but developing-country manufacturer.

And you can shrink 10 years of work – well, nine years of work on that – to a launch in which rather than hitting 99 percent of the population from age 1 through 29 in 10 days, Burkina Faso did it in eight. And they did it with massive mobilization of the national resources and health-care workers, but with 10,000 volunteers. It was done. And that is because that disease really matters to them because of the annual epidemics that they get.

And I think that, that prioritization needs to happen, particularly at the phase III level and with an eye towards not only what vaccines are needed where – have we done the right work to create the information base on what diseases are important – but also what Marc LaForce did for that project, which is say, the countries want it, but it has to cost less than 50 cents. And that forced a massive restructuring to actually be able to reach that goal for a single-component conjugate vaccine. So I remain extremely optimistic.

MR. MORRISON: And impatient.

DR. GERBERDING: And I am also impatient. (Laughter.)

MR. MORRISON: Margie?

MS. MCGLYNN: Yeah, I'll try to touch on maybe two aspects of the four or five questions that we didn't hear as much on. And the one is, you know, in the next five years, I'm also very optimistic, and I was thrilled to see the GAVI funding coming through with the meeting that, I believe, with donors was held in June, including the U.S. government being a strong supporter of GAVI. And I believe – and I know Helen will be up here soon – I believe GAVI has about \$7 billion in order to implement immunization programs over the coming years. And I am a big fan of what GAVI has accomplished and I've seen firsthand.

I sat on the board of GAVI representing the industry for a few years, and I saw firsthand how the efforts of GAVI were leading to tremendous uptake of vaccines. Whereas historically, it would have taken 15, 20 years to get an innovative, new vaccine into the developing world after it was launched in high-income markets like the U.S., GAVI has brought that down to a couple of years. And it's just great to see, and with pneumococcal – the new vaccines now coming out because of the advance market commitment – it will be even quicker.

And so I'm real bullish on the delivery side of what we can accomplish in the next five years. I'll admit I'm more nervous on the R&D side, and there are many government organizations that, you know, are subject to funding reductions because of the budget situation. You heard Tony mention it could happen to NIH. I know Nelson Michael is here – the MHRP, or military program which funds important vaccine-development work for HIV. You heard about the DOD labs. Certainly, CDC could be part of that.

We don't know what will come out of this. USAID, which is an important donor, certainly, to AIDS vaccine research in our organization, as well as capacity development in the developing world, which supports vaccine trials. And so you know, what we have to do is make sure that we're not shortsighted, that we keep the end game in mind and go after that holy grail. And I know it's difficult to fund both the delivery and the R&D for the ultimate solutions at the same time, but I think we just have to find a way to really do both.

And the last thing I'll mention is the question on industry involvement in the Decade of Vaccines initiative. The initiative has been going on, now, for several months. We have Orin Levine, who will be up here, who is leading one of the task teams. I've been involved, as have a few others who have had industry experience.

And the decision of the steering committee was to get through the initial phase, including people who had industry experience but weren't currently sitting in roles in the industry, and then to go to a broad, consultative phase, not only with the industry but with many other key stakeholders. And that is now where the initiative is over the coming months.

And I know many discussions are taking place to make sure there's industry input. Because I'm a big believer that to have solutions that will work, you need to get the industry engaged and make sure you're coming at it in a way which is going to align with their decision-making and incentive processes. And then I think we'll be able to accomplish what we're setting out to do.

DR. GERBERDING: And if I could just add to that, just a couple days ago, I sat with the five CEOs from the other R&D vaccine-manufacturing companies, and we signed a commitment to support the Decade of the Vaccines. And we'll be coming out with our own statement of what that support will look like and how we can do our part to step up and contribute to the success of the effort. So I don't have specifics to give you today, but we are certainly committed.

MR. MORRISON: Thank you. This has been a rich and wonderful discussion. Please join me in thanking our speakers. (Applause.) OK, knock 'em dead.

(Off-side conversation.)

AMANDA GLASSMAN: OK, well, I think we'll start right away, even though I'm sure there are many needs for coffee. Our panel is focused on overcoming strategic obstacles, I believe, to the delivery of immunization. And I really like that this panel is framed as a global issue because it's not a problem that's restricted to low- and middle-income countries because elimination of vaccine-preventable diseases is a shared enterprise that demands a coordinated response.

So there are two kinds of challenges or obstacles. On the supply side, we have challenges related to financing; we have challenges related to priority-setting; we have challenges related to supply and cold-chain quality, among others; and we have, ultimately, challenges associated with the quality provision of services to people in need. And then we have challenges on the so-called demand side – so families and households, themselves. There are economic barriers to access for the poor. There's this tendency to wait to vaccinate your children until they're already sick. And there's also a lot of issues around trust and misinformation.

So today, we have three very prominent panelists who will discuss a selection of these issues, these challenges to immunization. First, we'll start with Helen Evans of the GAVI alliance, who will talk about GAVI's approach to overcoming some of these challenges in their eligible countries. We have Orin Levine of Johns Hopkins University, who will talk about these challenges in the context of the decade of vaccines. And finally, Dr. Anne Schuchat from the Centers for Disease Control, who will talk about issues of public trust, both here and abroad, I think. So I'll start with Helen. Thank you, Helen.

HELEN EVANS: Thanks, Amanda. I'm just working out how I sit. What do I do? (Laughter.) All right, good. OK, yeah, thank you very much, Amanda, and thanks to CSIS and especially to you, Steve, and to Seth Gannon and others who have organized this fantastic conference. It's very good to see so many familiar faces, and I really wanted to convey GAVI's deep appreciation for CSIS's support over the years. And I also wanted to personally thank you, Amanda, because Amanda has shown enormous leadership in highlighting GAVI on her blogs on a regular basis. So thanks.

And I'm pleased to be here on the panel with Ann, who is a GAVI board member, and with Orin, who is really right at the heart of our effort in his work on the accelerated vaccine initiative. So as Amanda has said, I've been asked to speak about GAVI's strategic, long-term

thinking, and within that, about three very specific challenges to achieving success in immunization – and all in 10 minutes, so I'm going to talk fast.

The first is about delivery of vaccines to the poorest countries. The second is about financing and affordability of immunization. And the third is about public trust. I'm actually going to leave the public trust part largely to Ann, but I did want to say that public trust really has multiple dimensions.

For GAVI, I would say, specifically, it's trust amongst our donors that they are investing in the best buy in public health and that it's achieving results. Economic times are tough everywhere, and it's incredibly important to donors that they can trust that we're going to deliver with the taxpayers' money they're using. And there's trust around demand-based trust for the people in the poorest countries that when they immunize their children with a growing number of vaccines – and that, in itself, is a challenge – that this is the right thing to do. So let me start with the big, strategic picture with GAVI.

For those of you who don't know GAVI, I'll just briefly say it's a public-private partnership. There's been a bit of a discussion about public-private partnerships already. It's the Global Alliance for Vaccines and Immunization. And its mission is to save children's lives and protect people's health by increasing access to immunization in the poorest countries in the world.

We have an income cutoff for the countries that we fund. And in this country, the U.S. government, through USAID and Amie Batson – I'm not sure whether Amie is here, but Amie is the USAID board member on the GAVI board. Ann, from CDC, is there representing research and technology, as well as the Bill & Melinda Gates Foundation, who are enormously generous contributors. So this country is very well-represented on the GAVI board. And the board is actually a truly global board. It has membership from developing countries, from donors, from civil society, from vaccine companies, both north and south, and our multilateral partners: UNICEF, WHO and World Bank.

And we have a small secretariat in Geneva and here in CDC, which is responsible to the board for managing and coordinating the alliance business. So since its launch in 2000, GAVI's support to countries contributed, we estimate with solid data from WHO and UNICEF – not just GAVI – to averting more than 5.5 million future deaths and to contributing to immunization of 326 million children in the poorest countries. So that's a pretty impressive track record, I think, however great challenges still remain.

I'm not very technologically competent, as you can see, so I seem to have lost my slides. They're not coming up there. (Pause.) I'm going to keep talking. I actually have a beautiful slide, which may come up at a later stage – (laughter) – which shows the challenges. Because each year, 130 million children are born, but 19 million of those children go unimmunized and 1.7 million of them will die, each year, of vaccine-preventable diseases. So these are deaths that could be prevented. And over 80 percent of them are in the poorest countries in the world, which GAVI supports.

So the graph, if it was there, would show you that the majority of those children live, actually, in two countries. They live in India and in Nigeria. So to tackle this – because that’s our mission – we have what we think is a pretty clear – I’m going to hold up the document – a pretty clear five-year strategy, a comprehensive strategic plan with focused objectives and deliverables. And if you could also see the slide, you’d also see where the worldwide coverage is on the vaccines that GAVI funds, and you could see there clearly where the unfinished business is.

Pentavalent vaccine, which covers the five areas, is reasonably covered now. We are heading towards the homestretch on that. But with rotavirus and pneumococcal vaccines, we still have a long way to go. So in the next four years, we aim to immunize an additional quarter of a million children and to contribute to preventing what we think will be 4 million deaths and seeing not only a reduction in deaths but a reduction in morbidity. Because I think it’s much harder to measure morbidity, but as someone was talking earlier about the meningococcal vaccine, morbidity is a huge issue.

But to do this, it’s going to need an unprecedented increase in the number of vaccine introductions – unprecedented in a rollout we’ve never seen before. And I’m sure that Orin is going to comment on this. So this is where we get to challenges in country. To be able to do this, we need a strong immunization system sitting at the heart of a well-functioning health system providing robust and timely data so that programs – great, OK. So let me just quickly go back. That’s where the unimmunized children are.

This is how we’re progressing on the vaccine – current GAVI-approved vaccines. I’ll go back to that one. So we need a well-functioning health system with a strong immunization system sitting at the heart of it. And this requires clarity around roles and responsibilities for country ministries of health and finance – and I stress and finance – GAVI alliance members and partners and the secretariat. So we need to get this all working together. And country capacity to deliver is very variable, I would have to say.

We’ve had comments this morning about issues around stock management and cold chain, and that’s probably at the heart of the challenges we have. But country capacity is limited. We’d be less than honest if we didn’t say that it’s a challenge. And with GAVI, to date, we’ve operated more on a wholesale model of one size fits all. But moving forward, and given the variable capacity, we are going to move to a more customized approach with countries, giving a special priority to under-performing and fragile countries.

In addition to vaccines, which is the bulk of our business, about 85 percent of our funding goes out in vaccines. We do provide cash grants to countries to strengthen the capacity of health systems to deliver immunization. And I would have to say, because I’m anticipating questions people might have, that we would describe this, in the GAVI alliance, as a work in progress. We do have cash grants, but we are still working on how that’s best done to get the best value for money.

In a recent slide by Seth Berkley, who is our new CEO, he talked about achieving – putting GAVI within the center of the immunization landscape. To date, we’ve tended to move

vaccine-by-vaccine, starting small with hep-B, but moving forward, to maximize impact and efficiencies, we'll also be doing more horizon-scanning across the global immunization landscape to ensure we benefit from the synergies with those working in other vaccine efforts.

That's not to say GAVI – it's all about taking them over, but it's about better synergies. And I think polio and measles are probably the best examples of where there are synergies, both in terms of experiences, in terms of structures on the ground, in terms of shared data, et cetera. And we also want to follow the developments in R&D – a lot of discussion about that – and to adjust our focus as new vaccines become available.

So every time the GAVI board makes a decision, they have been clear to us they want to know, first of all, about the decision, rightly, is that specific decision justified in its own terms, in terms of impact and value for money? And secondly, what are the tradeoffs by making that decision? Will taking that decision prevent future opportunities that might be a better investment? So we want to better understand, moving forward, where GAVI sits in the current vaccine landscape and where, potentially, we might be moving.

So we want to be looking forward, saying, well, what's happening with the malaria vaccine? What's the sort of timeframe? Where would GAVI fit with that? What about dengue? What about IPV when we eradicate polio? I say when because everybody is wanting to be bullish. What about cholera? So we're going to be moving to a broader – more landscape-scanning.

To go back, then, to the specifics of the vaccines that we are focusing on rolling out that are going to make a very major impact, the slide up there reflects our plan to introduce the powerful pneumococcal vaccine, which a number of speakers have talked about this morning, to more than 50 countries by the year 2015. As I said, we're ramping up very rapidly. Pneumonia is the biggest killer of children before their 5th birthday, and the pneumococcal vaccine can potentially prevent half of those deaths.

This slide – yes, it's working – shows a similar plan for the rotavirus vaccine, which protects against the most deadly form of diarrhea. And three weeks ago, the GAVI board approved the rollout – with some very clear caveats, I should say – of the HPV vaccine, which people have talked about this morning, and of rubella. And I'm not going to go into detail, but I'm happy to answer questions on that later.

Now, moving to financing and affordability of vaccine challenges – first of all, talking about financing – as many of you will know, thanks to the hard work of many people, including a lot of people in this room, GAVI had a very successful pledging conference in June, from which we raised an additional \$4.3 billion for the period to the end of 2015. And that brings our total resources for that period – this five-year period – to \$7.6 billion. And that's what's going to enable us to get on with our ambitious agenda.

However, I want to stress to people that we're not resting on our laurels. We recognize that as the demand has grown and the complexity of our programs has expanded, we must be able to look and plan further into the future with regard to program financing. And this is to give

predictability leading to sustainability. A number of people on the earlier panels said, for vaccine manufacturers, for market shaping, that long-term visibility and predictability is extremely important.

It's also extremely important for recipient countries to have the confidence that when they take on a vaccine, what it's going to be, what the likely price is, et cetera. So we're looking much further than we have in the past. We have expenditure and resource projections out to 2020, and we are working vigorously with our existing donors to improve predictability of the receipt of pledges and to seek new ones.

And we're also going to continue to try and diversify our sources of funding by focusing on new champions and funders, including particularly focusing on the emerging economies. But it's also very important for us to have contact with a vibrant and successful private-sector resource mobilization effort.

And some of you may be aware of the newly created matching fund for private-sector contributions, which aims to bring in new corporate and foundation partners, not just as funders but also as champions. IFFIm – those of you who know what IFFIm is – IFFIm is the International Financing Facility for Immunization, where, using sovereign-donor underpinning, we buy bonds on the capital markets to bring forward money.

That's going to continue to be a key part of our long-term strategy because it gives confidence to countries and manufacturers that there is longer-term funding, and it also provides flexibility to move money through time as needed because we can go out to the bond markets when we have a particular need or a gap where donor funding is delayed or is coming in at a later time.

So moving, then, on to the affordability of vaccines and market challenges – and I think there's already been a lot of discussion about this – we have seen progress with vaccine prices. For example, the AMC, as a pool mechanism, has made it possible for us to fund pneumococcal vaccine. This shows the pentavalent vaccine with the lower prices there. And that protects against five deadly diseases, and it offers significant price reductions over time.

We have also seen a big drop in the price of rotavirus, which has made it possible, and the HPV vaccine, although we still need a lower price on that. The pentavalent price is important because it is a major cost driver for GAVI, and it will allow GAVI to immunize more children over time. But it also sends an important message to countries about the prices they can expect to pay once they graduate from GAVI.

I'm going to use – using the pentavalent example, the predictable, aggregated demand that GAVI ensures has also attracted more manufacturers – so not just lowering prices, but more manufacturers, which increases competition. And most importantly, it's attracting in emerging-market manufacturers, you can see from that slide. But we are now moving to a much more proactive effort. And we, recently, at the board – the board approved a strategy for supply and procurement, which entails a tailored approach for each vaccine to stimulate innovation, competition and new, quality manufacturers.

And through this new strategy, we aim to, first of all, ensure sufficient and uninterrupted supply of high-quality vaccines; secondly, to promote low and sustainable costs for developing countries; and thirdly, to foster an environment for innovation. While price is important, other essential factors include reliable supply of high-quality vaccines, shortening the time it takes for products to become available to developing countries – I think that’s one of the things we’ve really been able to achieve – and ensuring optimal product formulation to meet countries’ needs and distribution systems.

And that still continues to be a challenge and needs to be built in early in the development stage. Country financing is another key GAVI policy. All countries receiving GAVI vaccines must pay a copayment. And this has been quite innovative. And that has a dual aim, the co-financing. It has the dual aim of ensuring country ownership of immunization and vaccines that GAVI funds and to put countries on a trajectory towards financial sustainability by getting immunization funding as a budget line in order to prepare them to phase out GAVI funding. And we have 16 countries who are actually graduating out of GAVI funding, so the co-financing has a very important part to play.

And that really brings me to my final part. GAVI and partners are beginning to explore ways in which the specific challenges of GAVI graduating countries, and also low- and middle-income countries that may never have been GAVI-eligible, can be addressed. There’s an increasing challenge about those countries being able to continue to supply vaccines at a price that’s manageable for them.

First and foremost, to be able to do this, there’s a need to have a strong political will and commitment at the highest government level to sustain immunization programs. And we heard Julie talk about Zambia this morning. Political will cannot be underestimated for a commitment for immunization. Other elements include gaining commitment from manufacturers on pricing, the possibility of pooling procurement for low- and middle-income countries. Increased transparency on prices and products also help countries to make informed decisions.

Given the central importance of country commitment and ownership, my final slide is a picture of the president of Kenya, President Kibaki, at the launch of the pneumococcal vaccine that Orin and I both attended earlier this year. Awareness and commitment at the highest level to health as a driver of development is critical. Then we can help realize the power of vaccines to save children’s lives and protect people’s health. Thank you.

MS. GLASSMAN: Thank you very much, Helen. (Applause.) OK, after that keynote, we’ll turn to Orin Levine to talk a little bit about the Decade of Vaccines.

ORIN LEVINE: Thanks. And thanks to Steve and CSIS for hosting this very important discussion. I’m going to talk a little bit about the Decade of Vaccines, but before I do, I want to actually start with just a couple of sort of personal reflections on what draws me to immunizations and what – or sort of rehashing some of the themes that have come through today and which are woven into the work of the Decade of Vaccines coming through in the next few minutes.

First of all, you almost always hear the words vaccines and success together. Vaccines are the part of global health where we apologize for 50 percent effectiveness. If we don't get 90 percent efficacy, we're disappointed. It's where we talk about big, hairy, audacious goals like making the germ go away from the world, and people don't laugh. Vaccines have been successful and continue to be successful.

They are successful in part because they are tools for social justice, that when we apply vaccines and deliver them and develop them and all those things, and get them out there, we essentially eliminate disparities and inequities. And you know, you only need look at the front page of any newspaper to know that inequities, on many levels, are really one of the challenges ahead in the next decade. And so vaccines are one of those tools. In addition, they help to break the cycle of poverty.

When you vaccinate a child just two or three times, you reduce the likelihood that the kid's going to get ill and that the parents are going to have to dig into their savings and somehow pay for their child's treatment. In addition, research from David Bloom at Harvard and others have shown it's a great investment in the economy of a country, probably through multiple ways but including direct benefits to the child and the family, the household. Children who get vaccines are less likely to be disabled, more likely to have better cognition, to become better-educated and to be more productive in the future.

And when we break that cycle of poverty, when we break that cycle of infant mortality, we lead to the demographic transition. Fertility rates go down and economies grow. And so vaccines are one part of the whole development approach that we take to try and break that cycle of poverty and improve societies. They've been successful. We have seen really tremendous progress over the last 20, 30 years, and especially in the last decade. But with the decade ahead, we will also have some new challenges.

And I think that's part of the reason why Bill Gates challenged us in 2010 with this decade of vaccines. On the one hand, he said, I'm personally committed to it. Bill and Melinda pledged \$10 million over 10 years in order to spark this Decade of Vaccines, but I think it was also trying to challenge us to say, remain successful in the decade coming forth. Examine what you're doing well that needs to keep going – that needs to be amplified and expanded.

Also, examine the things that have worked but might need to change to stay successful in the decade ahead. And he has really challenged the community, I think, to think ambitiously about what kinds of transformative actions could be employed in the next decade that would really make a very big difference and might bring something very new to the field.

So before I talk about the Decade of Vaccines action plan and the collaboration, I just want to point out one of those trends, I think, that is on us. It's upon us, and we can predict it's going to be an issue for the next decade that we need to anticipate now. And that is the expansion of emerging economies. So in 1990, when we set the benchmarks for the Millennium Development Goals and all those sorts of things, 90 percent of the world's poor people lived in

poor countries. Remember debt relief, highly indebted poor countries? That's where the poor people lived.

Now, the majority of poor people live in middle-income countries. And middle-income countries have somewhat more resources – not as few as the low-income countries, not as many as the high-income countries – but somewhat more resources to be able to make decisions about their own internal allocations for health and other investments in their population. and so the types of approaches that we've used successfully may need to continue for some countries, and for some countries, we may need to evolve and adapt.

So the Decade of Vaccines collaboration, which kicked off last year, is fundamentally aiming at trying to develop a global vaccine action plan – a set of coordinated, transformative and important actions or activities that will help to bring about the kinds of success at the end of this decade that we would all like to see, success in trying to bring about improvements in research and development so that the vaccines that historically have vexed us for protection, things like HIV vaccines that are being talked about today, might be legitimately vaccine-preventable by the end of the decade; drawing innovation through the enterprise of vaccines – not just in research and development, but in delivery and financing and in other areas; trying to establish a much firmer country ownership of immunizations.

We've seen, so far today, several pictures of presidents and first ladies and those types of things, and we're trying to establish that kind of leadership and commitment through the Decade of Vaccines that builds country ownership but not just at the top but also at the community level. We heard about the sort of community response to vaccines when we deliver the things that they want, that prevent the diseases that they feel and see – the kinds of ownership at a community level that bubbles up as a response.

The Decade of Vaccines collaboration is at a very exciting time right now. It's at a point where it's very actively soliciting input and feedback on the actions that should be priorities that can be undertaken in this next decade. I think you heard about a team that is in Namibia this week soliciting input from immunization leaders and constituents all throughout Africa. There will be other interactions in other parts of the world throughout the year and some right here in Washington, D.C.

So I really encourage you, if you've not already gotten engaged with the Decade of Vaccines collaboration, you can find out more on the website. You can find some of the people here. Laurie Werner, a colleague of mine from the Decade of Vaccines collaboration, is here. And there are a lot of ways to get involved and participate, and we need that if we're going to build out a successful plan.

I want to quickly talk about just one or two of the sort of innovative ideas that are emerging out of the Decade of Vaccines collaboration and that are particularly – one, just one, as I said – just one thing – (laughter) – about the Decade of Vaccines collaboration. And that is around financing because it keeps coming up in the questions and the comments that we're in a tough financing time, and we are. So one of the things that we're working on is actually an idea

pioneered by Amanda Glassman, my colleague here, about the idea of a fair-share financing pledge.

And this is, in many ways, an extension of what the GAVI alliance has been trying to do, which is to say, yes, we need external assistance from places like the U.S. government to help countries build up systems and introduce new lifesaving vaccines. But they do not need that assistance forever, and we should not be obligated to provide it forever. We need an intentional and strategic approach to building out the increases in domestic funding and the shaping of the market to make it easier for developing-country government financing and the needs of vaccine manufacturers to be met so that, over a period of time, our investments, our responsibility goes down and theirs goes up.

And I think these are the kinds of discussions that we are having through the Decade of Vaccines collaboration that are going to be really, really important. And they're really important here for people who are involved with the U.S. government to know that in vaccines, they're successful. They're tools for social justice. They help break the cycle of poverty. And we have a way of structuring our assistance so that, over time, our responsibility goes down and country ownership goes up.

MS. GLASSMAN: Thank you, Orin. And I just want to add one footnote to that idea, and that is that all countries need to contribute their fair share according to their contribution to the world economy and the benefits that they'll perceive from eliminating some of these vaccine-preventable diseases. But that also means that the U.S. actually is a little bit below its fair share at the moment and could actually increase its funding to GAVI, as well. (Laughter.) So Dr. Schuchat, it's timely that, you know, you get to sit on the hot seat at the end, but go ahead.

ANNE SCHUCHAT: Well, I'm going to make a few comments about public trust and confidence, and it's a huge area of personal interest and one that can really bring down all of the fabulous potential that the immunization program and vaccines of the future have. So I think people here have seen the headlines: HPV vaccine project halted in India. Pentavalent introduction interrupted in Sri Lanka. WHO attacked for concerns about the role of pharma in pandemic vaccine and antiviral plans.

Maybe you've seen the videos – a so-called Redskins cheerleader who develops a very odd gait after she gets the H1N1 vaccine. Maybe you guys are too old for that, but when that video aired on YouTube during the 2009 pandemic, college student acceptance of the H1N1 vaccine stopped. Or maybe you've been following the blogs or Twitter, or maybe some of you have personal experience taking your baby to the doctor and wondering, does he or she really need five injections today, and how do I feel about that?

It's pretty difficult to generalize about vaccine resistance and hesitancy and confidence because every particular episode investigated can lead to multiple narratives. But this is not a problem that we need to sit back and react to. It's something that we do have the ability to prepare for. So I think that public trust is difficult to earn, but it's very easy to lose.

And preparedness for sustaining the incredible confidence and trust that immunization enjoys today is really important as we look to the next decade. I think this has been said a couple different ways, but there's no intervention that reaches more of the world's most vulnerable, youngest, marginalized people in the world on a regular basis than immunization does. So you know, talk about trust. On the other hand, from one day to the next, a program can be shut down.

And a lot of the international community and the U.S. is ill-prepared for managing one of these episodes. So as I said, it's risky to generalize about what's going on in these events, but I think there are a few different factors that can occur. There can be questions about deception. Is this vaccine to protect me against this particular condition, or is it actually a plot to sterilize the population? There can be questions about the program. Is this an immunization and health program, or is this a program being run to change the religion of the community where it's located? There can be questions about the government itself.

Frequent strikes can really erode the confidence that a community has in the people who are out there giving vaccines. It's easy to become tainted by a different part of the system, and immunization really needs to protect against that. Sometimes, it's a question of the messenger. The wrong sex/nationality/religion of a person delivering a vaccine or talking about vaccines can be challenging.

And maybe it's a question of the success. The vaccines, in some communities, have made the disease disappear. The question of whether this is a priority, whether the threat is still there. How do you sustain demand and value? And a key answer there is sustaining immunizations as a social norm. In most of the world, parents think that immunizing their kids is the best thing they can do to keep them healthy, and that's a norm that we really want to protect.

Think about smoking and how long it took for people to stop asking, would you like a cigarette, and saying, would you mind if I smoked – you know, two generations, I think. But immunizations – we're already there, but we do have a lot to lose. So what do we – just a couple more points about the generalizations. There are a few kinds of vaccination efforts that are really lightning rods and that you have to take special effort to prepare for.

One of them is mass campaigns. It might be a mass rubella introduction in the future. It might be a mass H1N1 vaccination response to a pandemic. But whenever you're vaccinating a large population over a short period of time, things happen. And those things can have nothing to do with the immunization program, or they may be causally related. You need to be ready to respond, and you need spokespeople, investigation teams and a strategy before you actually roll out your program.

Another lightning rod is targeting. You can be targeting just women because that's who should be getting the HPV vaccine. Or you can be targeting the police and military because they're special and they're supposed to get the product, and no one else gets to. But people don't really like inequity, and that's something that you have to be ready to explain and support and defend. Another issue is something new.

And this was something I just learned fairly recently, but you know, when you think about Apple products, new is really good. When you think about vaccines, new is really scary. In the U.S., we did not use adjuvants in the H1N1 flu vaccination effort because our population was not ready for them. We got letters. We did community engagement. There was this massive program of, you know, fear about what was in those adjuvants and what was going to happen with them.

And we felt, even though they would be likely – or theoretically – dose-sparing or could get us more product up front, the acceptance was going to be low here. They were used more successfully in other places. But new can be concerning, and so I think all of us want to reduce the gap between when vaccines are used in rich countries and poor countries, but we have to be careful with that and make sure that people are confident that this vaccine has been safe and tested. I think the meningitis-A introduction in Africa was a great example where there was large-scale safety testing done before the launch, and the vaccine was very highly valued.

And another lightning rod is pharma. So I think Tony has gone and, you know, big pharma may be family for Tony, but I think for some communities, there's suspicion. And we really need to reconcile that because we can't get vaccines without the pharmaceutical industry, north and south. So I think understanding what's the relationship between the program and the profit is very important.

So what are we supposed to do about all these problems? I think there are really three areas that are very valuable. One is the idea of champions. It might be tempting to think of a president or a first lady as a champion, and that might work really well in some places, but often, it's the champion next door. It's the person who lives in your neighborhood who understands your values and your culture. I visited the D.C. health department earlier this week, and they have a program here, I think funded by the city council, that's finding immunization champions that are doctors that visit other practices that help explain what really needs to happen.

In Nigeria, the sultan of one of the northern states was a key champion who really learned about the program and explained it to his followers. I think champions are often most effective when they're closest to the community of interest. Another key strategy is communication, and I have sort of this wonderful job where I'm promoting immunization in the U.S. and helping us be more prepared and worrying about international vaccine initiatives. And there's a total relationship between all of these things because when you're worrying about a pandemic or dealing with a crisis, you use risk communication.

When you're talking to a parent about their child and the five injections that you want to give today, risk communication is also a good strategy. And the key principles of risk communication are being open and honest, being empathetic and caring. The line is, people don't care what you know until they know that you care. And that's a critical way to talk about vaccines. You can't explain, diseases are bad, here's how much money we're going to save, until somebody trusts you.

So I think with our immunization efforts, we really need to learn those principles and really deploy that in terms of the international immunization community in every country. The third key point, I think, about public trust and confidence in immunization is to try to keep politics out of it. It's fantastic to have political will and country ownership, but it's not sustainable if that's identified with a single individual or leader who may have a certain tenure. It's really important for there to be a health-and-science, sustainable defense for the program or support for the program and not just a temporary leader.

So when there's an adverse event following an immunization, you really don't want the president on TV explaining why that is and what happened. You want Tony Fauci, kind of, explaining what happened and what we're doing about it. And I think those are concepts that we used very aggressively during the pandemic flu response here and that I think many countries around the world are learning to deploy, themselves.

I think the last thing to just say is that as much as the Internet and other sources make us nervous about the future of confidence in vaccines, how easy it is to bring things down, we're working with such a strong base. We have such a successful program in every country of the world that we really can sustain that if we pay attention.

MS. GLASSMAN: Thank you so much. I think that was a really, really interesting perspective, also, on how the institutions that exist in a country like the United States help promote the public trust in immunization and that it's not really a political – or it's related to politics, but it's not only about politics. So now we have about four minutes for questions from the audience, so I would ask you to be very concise and introduce yourself. We'll take two questions. And there's two here.

Q: Peter Hale. I'm with the Foundation for Vaccine Research. There's an anti-vaccine movement out there whipping up a frenzy, and we know that people have doubts in rich countries and in poor countries. My own foundation, we have a raging, continuing debate: Should we take the anti-vaccine movement on directly? We know they are a minority. Or do we ignore them and focus on the 20 percent or 30 percent of the population who have some kind of doubts?

DR. SCHUCHAT: Yeah, I think that's a great question. Or do you want to take lots of questions?

MS. GLASSMAN: Why don't you answer, and then we'll go to the second question.

DR. SCHUCHAT: Sure. I mean, I think there are actually several different movements and groups, and I do think it's difficult to generalize. But I actually think we need to be careful about giving more attention to some groups. In the U.S., some of the attacks and concerns are actually diminishing and losing a voice. Some of the science really has – for instance, in the U.S., the vaccines and autism issue was a big question for parents – you know, rightly – a question for many years.

There's been so much science completed, now. The scientific community has made conclusions. Many leaders within the autism community have moved on from that to other, more promising areas. And going back to the old arguments and the old attacks just keeps that concern alive. So I think there are really decisions that need to be made locally, nationally for a foundation.

I do personally think that reaching that 20 percent we're not reaching and getting to the hardest-hit places and figuring out strategies for conflict settings and fragile states is the biggest challenge for immunization right now. And that's where I'm putting my attention. But I wouldn't say any EPI manager around the globe can live in 2011 and not learn how to do risk communication and think about their safety tracking system and have a system of local voices that can talk about things that's separate from themselves.

MS. GLASSMAN: OK, and one more question. There's a woman towards the back on the left side. Go ahead.

Q: Hi, thank you. My name is Kelli Cappelier, and I work with JSI and the USAID MCHIP project. And I just had a question about as – we've talked a lot about new vaccines and the future of vaccines, but I'm wondering how the strengthening of routine immunization systems fits into this conversation and sustaining the benefits and introduction of new vaccines in the future.

MS. GLASSMAN: Do you want to say something about that, Helen?

MS. EVANS: Yes. I mean, the GAVI alliance was set up to look at and to introduce new and under-used vaccines. So that's our primary focus, but you know, there's a whole merging continuum. And as I said, we want to look at GAVI in the center of it. The fact that we fund the pentavalent vaccine actually picks up three – DTP – which are at the core of it. We are now taking on rubella, which is actually going to be a rubella/measles.

And from the GAVI perspective, one of the other aspects we've had in terms of trying to reinforce the importance of the basic immunization is that we've had a filter for eligibility for GAVI vaccines. So it started off at a 50 percent coverage for DTP3, and that was for two reasons. One was to ensure – because people were concerned that the focus would go away from the core, routine vaccinations – to ensure that countries maintained that focus.

So you had to have at least 50 percent coverage. But also because it's an indicator of the health system's capacity. And we have now actually increased that to 70 percent as routine immunization has gone up over the last decade. And it averages at about – in GAVI countries – at about 79 percent. So yes, it's absolutely core, but I think it goes to the point I was making about whatever aspect of immunization we're in, we really need to look at the synergies and the full landscape.

MS. GLASSMAN: Orin?

MR. LEVINE: Just one quick follow-on. This is an issue that's come up for a long time, and our group has just recently completed analysis of DTP3 coverage over the last 20 years in all countries and tried to relate it to new vaccine introduction. In other words, does new vaccine introduction either increase your coverage with routine vaccines or decrease it? And the answer is neither.

There are huge fluctuations in immunization coverage, but they're not associated with the introduction of new vaccines. And what that points out is we need to stay focused on the key drivers of immunization coverage – strengthening the systems, both supply- and demand-side, that help to do that and recognizing that and recognizing the need for immunizations to be part of primary health care and a package of services.

The Decade of Vaccines collaboration has a whole delivery working group that is just dedicated to trying to figure out how are we going to strengthen those systems and increase our coverage – and sustainable coverage – of vaccines in the years ahead.

MS. GLASSMAN: OK, well, thank you very much to our panelists for a great talk and to the people who asked questions. (Applause.) So I'm to tell you that lunch will be served immediately outside the grand ballroom, and you should bring your food back to your seats for the next part of the program, which will begin promptly at noon. OK?

MR. : That's exactly right. Amanda is exactly right. You'll find a variety of lunch stations right outside. There are some café tables along the side here, space to eat out there. And you're welcome to bring it back to your seats. And I will reiterate what Amanda just said, which is that we are going to start promptly at noon with an exciting afternoon with Admiral Fallon's panel and then the closing keynote from Administrator Shah. So thanks to you all, and see you in half an hour back there.

(Break.)

ADMIRAL WILLIAM FALLON: OK. Ladies and gentlemen, if you could tear yourselves away from the dessert line and come on in here. Your colleagues are ready to go.

(Pause.)

ADM. FALLON: Slowly they stagger in. So the china and flatware were authorized in here during this next 45 minutes; eating's permitted; drinking, to an extent.

I can't imagine why folks would want to miss the next event, which is really a quiz. And we're going to find out who really knows what about antigens and epitopes and – (inaudible) – and a few other things. It's a way to try to focus your attention.

I think we've got a quorum, so I'd like to go ahead and get started. It's a treat for me to be here. Some might ask: What's the old salt admiral doing here? And I think the real truth the matter is that 45 years of travel and engagement around the world, I'm living proof that a human pin cushion can absorb many scores of vaccines and still function, at least to some extent – (laughter) – so we'll give it a try.

In truth, this panel is here to try to make a connection between something that became pretty obvious to me, and that is the link between health and security. And specifically today we're talking about vaccines, and the role they play in this business. To me, it's pretty much of a no-brainer. If you were here this morning and you saw Dr. Fauci's slides, it doesn't take a math major to see the benefit of vaccines, and what they've done for people here and certainly can do for others.

I think one of the challenges of a group like this in a meeting is that sometimes we – because you have an awful lot of expertise – we're blessed with that. And you're going to see with our panelists up here this afternoon that we tend to dive down into the weeds and we start arguing about which vaccine is going to be the best, and what ought to be the priority here, and how much money from this pot goes to that, and so forth.

To me, I would suggest, as we open this discussion, that we maybe back out of that, and let's just talk a little bit about security. And if you would accept that security runs the gamut from the usual suspects on the international stage with state boundaries and all those things that one tends to associate with militaries and state actors – and the other side is something that's very real and very close to each of us, and that's personal security. And the role that health plays in personal security is quite dramatic. And so as we get into this discussion, tying these things together and seeing what we might be able to do and what we might appreciate in this, I think, is really important.

So if we go back to Tony Fauci's comments, he showed some data that was, I thought, really compelling. And then he had some numbers and he talked about billions, and I'm here to tell you that that's an understatement. And if you look at it in this context – since I spend an awful lot of time around the world in the military, I learned a couple things very early on. One of them was the value of prevention – preventive maintenance, preventive interaction. And the thing I learned was that a minimum amount of resources devoted to prevention pays huge dividends.

And so what would you rather have? Would you rather have some – if you, in the big scheme of things, look at the amount of resources that are actually applied to this issue of vaccines, it's pretty minimal compared to some other resources that are devoted to problems that have gotten out of hand. And now we're trying to dig ourselves out of a hole. So it seems to me that if we keep in mind that – we can do a tremendous amount of good with a relatively small amount of resources, in advance of problems becoming the kind of challenges that cause us trillions of dollars to dig out of very deep holes.

And so, as we kick this off, we're really fortunate here to have three particularly well-versed and expert people that really cover the gamut in this business of vaccines and security in global health. So first we're going to hear from Dr. Steve Cochi, who is the walking, talking encyclopedic expert in vaccines, Centers for Disease Control. He's been in this business for a very, very long time. He's a medical doctor with a great pedigree, and he's going to start us off.

And then we have someone who's actually been down there with his sleeves rolled up, getting his hands dirty, if you would, in the field, and that's Markus Geisser from ICRC, International Committee of the Red Cross. He hails from Switzerland in the high mountains, and he's spent an awful lot of time in some pretty dirty, dusty places the last several years – last two

years, in particular, in Afghanistan, doing the Lord's work out there in some very, very difficult situations.

And to try to put a bow around this discussion, we're very fortunate to have Eric Schwartz here. He's currently the dean of the Humphrey School up in University of Minnesota. He's a man with a very, very extensive background that spans the policy world. He used to be here at the NSC, he used to be an assistant secretary of state. In the academic world, he's been with NGOs, with the U.N. He's got a resume that just goes on and on that touches many of you here.

And so, with these three gentlemen, I think we're pretty well placed to have a discussion about this – (inaudible, background noise) – security, and tying it to vaccines. So if I could ask Steve to go up here to start us off. Thanks very much for your attention. The place is full. Over to you, Steve.

DR. STEVE COCHI: Thank you, Admiral Fallon. And I'd like to kick things off with a few – just a few comments and some ideas that I'd like to throw out there to get the discussion flowing. Now, I'm going to divide my comments into general issues, and then taking the U.S. perspective, and finally issues that conflict-affected countries face.

First of all, from the general perspective, I hope it's clear today that we're not talking about bioterrorism-related vaccines like smallpox vaccine or anthrax vaccine, but the broader issue of how vaccines promote both global and national security. It all goes back to the fact that social inequities drive conflict and unrest – civil unrest – and vaccines are a tool for achieving health equity. And this is true both on the global level as well as on the national level.

Vaccines and immunization are a global public good. Now, what exactly does that mean? That means that vaccines are near universally in demand. The benefits of immunization transcend national borders. And we see this come home to roost every time we have importations of vaccine-preventable diseases from one country to another, from one region of the world to another. Also, no one need be or should be excluded from receiving these global public goods. So pursuit of global immunization is a huge contribution to global health security and equity.

And finally I'm – in general terms, from the point of view of political leaders, good health is good politics. So effective health interventions such as vaccines – in the view of many, if not most, political leaders – dramatically improve the health of the population, contribute to economic productivity and foster economic development. So this promotes national security through both political and economic stability.

Now, if we look at the U.S. perspective, the U.S. has both a humanitarian and a national security self-interest in reducing the global burden of vaccine-preventable diseases. The U.S. has been free – here's some examples: the U.S. has been free of polio since 1979, but the polio virus is just one plane ride away from the few remaining countries where the polio virus still circulates. We're all very familiar with the national security threat of a potential pandemic influenza epidemic. And, in terms of measles, the U.S. has experienced the highest number of measles cases since 1996, all of these due to importations of measles virus and small outbreaks

that have occurred as a result of traveling – U.S. travelers – to other parts of the world and visitors to the United States.

So these ongoing outbreaks of measles in the U.S. highlight the interconnectedness of the world today, and show that outbreaks of measles around the world leave the United States vulnerable to imported measles virus. And these cases cause serious illness, hospitalization, disruption of the community and of the health infrastructure, and they are very costly. And I can get, later on if time permits, to some examples of this. So if we don't support the global side of the effort to reduce measles, then we're being pennywise and pound-foolish in the way we approach protection of our citizens.

And, finally, some of the issues that the conflict-affected countries face: and I'm going to focus a bit on polio eradication since that's the model for delivery right now of immunization services in conflict-affected areas of the world. One of the greatest challenges for polio eradication in the few remaining countries has been getting access to children in conflict-affected and security-compromised areas.

We've had a very successful effort in many countries that goes back to 1985, during the civil war in El Salvador. And, at that time – and this has been sustained through today – the development of what's called “days of tranquility” where there are negotiated ceasefires between the warring factions to allow vaccination teams on either side of the conflict to reach children with vaccination.

During mass campaigns where this has become a feature and in countless countries that have been affected by civil conflict leading right up to today, this has been a strategy that has proven effective: to get into these areas, at least, for a brief interval of time – perhaps one to two weeks – to deliver, in this instance, for a polio vaccine, but also, in many instances, to deliver other health interventions where appropriate and where feasible. And so this is taking advantage of, I think, the primacy of immunization as one of the bedrocks of primary health care, and using what health infrastructure is available on the immunization side to deliver health interventions, including vaccines, during these ceasefires.

So I'll conclude just by saying that, with polio eradication as a model for working in areas of conflict, we have been successful in many, many countries. And this carries over into our work in vaccines and immunization – in achieving equity and access to immunization, in establishing disease surveillance systems and mechanisms – special mechanisms for delivering health intervention in these very unusual areas, and, in some instances, in revitalizing and strengthening immunization systems through additional externally provided resources, and delivery of additional vaccines besides the polio vaccine. So I'll stop there, and I hope that that gets the discussion ideas flowing.

ADM. FALLON: (Good ?). Steve, thanks very much. So you've certainly, I think, got – captured now one aspect of this security, the value of vaccines and interventions to helping security. There's another dimension too that we might be able to get – draw out from Markus here because actually doing the health intervention in the field has a couple of prerequisites, one of them being actual local or (tactical ?) security. And so he's the man that's actually had to deal with this. Markus, if you could come and tell us how things really are out there.

MARKUS GEISSER: Good afternoon, everybody. First of all, yes, I do come from Switzerland – not from the Swiss mountains, from the Swiss lake. Nonetheless, my Swiss-German accent, of course, will remain – (laughter) – so I hope you will forgive me.

First of all, thank you very much to CIS (sic) for having invited the ICRC to come to this event. International Committee of the Red Cross, very briefly, we are an international humanitarian organization based in Geneva. Our mandate is to protect, to assist victims of war all around the world in all conflict zones. Our mandate is steeply enshrined in the Geneva Conventions, one of the foundations of the law of armed conflict.

ICRC is facilitator for the delivery of vaccination in Afghanistan, very broadly. It's the issue I want to very quickly touch upon, and what Steven said: access. Yes, indeed. It's the question of access. How do we reach people who are in need of vaccination in very complex environment? (Inaudible) – in Afghanistan probably is one of those.

Let me say what the ICRC is doing for us to follow. How do we actually facilitate delivery of vaccination? The ICRC's involvement as a facilitator in the polio campaign started in 2007 in Afghanistan. At that time, the Afghan minister of public health suggested to WHO to contact the ICRC for support to access areas with strong armed opposition presence – that means Taliban.

ICRC distinguishes itself – to consider itself as a neutral, independent humanitarian actor. I do not want to talk about these concepts at length, but nonetheless what do we mean by that? I think we from the ICRC have to realize that aid is always injection into a social, political, and also economical environment, so principles of humanitarian action are here very important to provide an organization like the ICRC guidance and regulation.

Humanity stands for respect for human being. Impartiality means assisting those most in need with no discrimination. Neutrality involves no taking part in military operations or ideological controversies. Neutrality in that sense is an operational posture. The independence is the obvious operation of previous position that's the result of those principles. That explains why the ICRC has developed contacts with the armed opposition, the Taliban, in Afghanistan over the last few years.

Let me now quickly go back, again; ICRC is a facilitator for the delivery of vaccination in Afghanistan back in 2007 when we got this explicit request by the Afghan MOPH – this was, by the way, authorized by President Karzai – to actually see the ICRC – to see the ICRC as a – as a – as a facilitator, to bring other actors such as WHO, UNICEF, and of course, first and – first and foremost, the Ministry of Public Health into those disputed areas. For each polio campaign the ICRC, receives a letter from the Taliban with a letterhead, “Islamic Emirate of Afghanistan” as they call themselves. And this letter is handed over to WHO, and this letter is then handed over to the teams of vaccinators that actually can carry this particular letter in all those areas where they think – disputed areas, OK, where the Afghan Ministry of Public Health would not have an easy – an easy access.

And this all sounds very simple. Of course, on the ground, reality is things are a bit more complicated. For example, when I was working for the ICRC in south of Afghanistan in our office in Kandahar, we would indeed bring together in a meeting room representatives of the

Afghan Ministry of Public Health; of course representatives with UNICEF, WHO; and of course also people that we know through our work, through our network who are close to the armed opposition, who are tolerated by the opposition, at times even are members of the armed opposition.

The ICRC was considered to be, and still is considered to be, a credible actor as this facilitator just because in the southern part of Afghanistan the ICRC has a really comprehensive approach in how to actually access – respond to needs, health needs. We support the second-largest hospital in Kandahar. We run a very complicated network of private taxis that retrieve wounded, bring them over the front line, and bring them to those hospitals. And we also run a few first-aid posts.

That particular – and I conclude on this – that particular response to the needs of health – health needs, I'm sorry – of course made us a very credible – a credible actor to indeed have – (inaudible) – facilitator. And of course we from the ICRC believe strongly that our neutral, independent, humanitarian action – the way I explained it – actually helps us to do that.

I would conclude with a few challenges. Today, it is very clear that in many areas in Afghanistan the provision of health, in particular vaccination, is very complex. I think it has gotten more complex. A simple letter unfortunately does not always do the job anymore. We see the fragmentation of various parties to the conflict, the armed opposition. We also see the proliferation of irregular armed forces; they are nonetheless accepted by the – by the government of President Karzai, also supported by NATO forces. We continue to see, unfortunately, a rather dysfunctional Ministry of Public Health, where there's a very clear center and periphery divide. If you talk to the – if you talk to the minister of public health in Kandahar, he may not have leverage of what's going on, of how actually the teams of vaccinators operate, OK. Same – and I conclude on this one – same (with ?) the armed opposition. Again, a letter from the Quetta Shura of the Taliban doesn't necessarily mean that the small commander, if I may say so – who may not even be able to read that letter – may actually accept that.

So yes, the role of facilitator depends very much on the commitment of all of those who are around the table, the various health actors, or also the political actors or the armed actors. Thank you so much.

ADM. FALLON: Markus, thank you very much. And to try to tie this together, I'd like to invite Dean Schwartz to share, among other things, the perspective of how policymakers view this nexus between health and vaccines and security, and what factors go through their minds as they're making decisions regarding resources and allocation of effort. Thank you very much.

ERIC SCHWARTZ: Thank you. And I'd like to thank CSIS as well for putting on this important meeting. I should say parenthetically, as I was preparing for this in my new perch at the University of Minnesota, it was heartening to see how serious that institution, as I know so many other institutions, have taken on the challenge of dealing with infectious diseases.

Let me – let me offer five observations in this area from the perspective of somebody who spent most of the last several years dealing with international humanitarian response. First

– my first observation would be that those of us who are concerned about this issue should adopt “Sutton’s law,” which is that you should consider the obvious before you look to other alternatives. Willie Sutton, the bank robber, is responsible for that law, which – when they asked him, why do you rob banks, he said, that’s where the money is.

And the analogy of course is obvious: Why is it important to pursue vaccination in situations of conflict and failed state – failed states? And the answer is that that’s where the people in greatest – the large number of people in great need are. These statistics may be somewhat outdated, but in review – in – for this presentation, statistics from several years ago suggested that 65 percent of internationally significant outbreaks of vaccine-preventable diseases are in areas of civil conflict and collapsed states; that the leading cause of morbidity and mortality in such settings are such diseases. And so I would say we should start with Sutton’s law, and – which underscores the importance of focusing on this area, even if it’s hard to do.

The second point that I would make from a policy perspective in the – with respect to international humanitarian response is that movement matters. What I mean by that is, we need to address the problem due to its migration impacts on issues with humanitarian but also national security implications. And this plays out in several ways. First, people on the run, who are not – who are not vaccinated, who have not – encounter host populations. Refugees encounter host populations, many of whom then thereby become far more susceptible.

Secondly, as we’ve seen, diseases easily cross borders and have implications for foreign populations. We resettle upwards of 75,000 refugees every year from places like Dadaab in northeast Kenya. So the idea that the impact of the absence of immunization on us might not be significant and profound, I think, may be very shortsighted.

And then third, there are humanitarian implications, because people who are at – who are fleeing, who cross borders, hopefully – and in many cases, at least a couple of million cases in Africa within the last decade – they go home. They go home. Better they should go home having been vaccinated rather than go home and increase the risks to those who never left in the first place. So my second proposition is that movement matters.

My third proposition is that – in – we need to tailor solutions to meet problems. Be aware of the need to modify interventions to the special dimensions of humanitarian settings. For example, there is evidence – and I’m not the expert on this, I just read the evidence – but there is some evidence that in humanitarian settings, there is a stronger rationale for vaccinations for diseases for – to vaccinate children to a higher age – to a greater age, because many of them – many of them who are refugees or who have suffered conditions of poverty and conflict may not have been – may not have had access to vaccinations. So there is some evidence that increasing the age level for vaccinations in those settings makes sense. There’s evidence that a focus, if you have limited priorities, on those diseases that spread most easily or have the gravest consequences – so, without trying to dictate the specific outcomes, I think the point is still – is very valid, that you need to tailor interventions to the special circumstances of humanitarian settings.

The fourth observation I'd make is that not all humanitarian settings are created equal. And that's – this is sort of a codicil to the previous point. For example, beyond the urgent quick-onset emergency, there are millions and millions of people – of people in humanitarian distress who are in protracted humanitarian situations where their circumstances may be tragic, but ironically there may be opportunities for the building of local capacity in circumstances where – on – in quick – in contrast to quick-onset emergencies, where that possibility may be more remote.

Similarly – not similarly, but along the same lines – we have the challenge of urban refugees, people who are fleeing who may – who may be in need of immunization, but who are not in camp-like settings, increasingly in urban environments with host populations. That also imposes more significant challenges. But – and different challenges. So my fourth point, again, is, not all humanitarian settings are created equal.

And my fifth – my fifth and final point is, don't assume that doing the right thing is an inadequate rationale to do the right thing. Did everyone get that? (Laughter.) What I mean by that is, you know, I think the national-security rationales for action in this area are clear and convincing. But also sometimes I felt in government – I certainly did it – sometimes I felt that we made these rationales – I said probably a thousand times as assistant secretary that if we address humanitarian suffering and we create conditions for peace and reconciliation, then we offer the prospect of stability and circumstances where despair and chaos can ultimately undermine our national security interests. I said that – I probably said that 300 times. And I believe it. But sometimes I think policymakers say it because we feel that it resonates with those who are going to be funding us.

And I would submit, at least in the case of humanitarian response, response to people who are in the most desperate need, the evidence that I'm aware of is that it's really the doing-the-right-thing rationale that has resonated more significantly with our strongest supporters in the Congress and our strongest supporters in the nongovernmental community. And I think that's important. That doesn't – that's not always the case, I think, with development, but in the area of humanitarian response, that's been the case. And so to the extent that, you know, there is an interest in pursuing greater resources in this area, in the area of humanitarian response, I would not assume that doing the right thing is necessarily an inadequate argument to get the right outcome. Thank you.

ADM. FALLON: (Applause.) Eric, thanks. (Applause.) Eric, thanks, great point on which to end the tee-up here. So I'd like to open it up to questions or comments from the audience. Any additional thoughts or ideas that you might want to toss in front of these experts before we let them get into a dialogue? I think we've got some mics, yeah, coming up (at your six ?).

Q: Thanks, Admiral. Since so much of the narrative of enemies (from ?) an open society is that the West doesn't care enough about the poor and the disenfranchised, how much of the policy issue can you bring to the Hill about things like inoculations and the like, and how much can the military help encourage the benefit that vaccinations do in bringing the good of the West to the disenfranchised of the world?

ADM. FALLON: Eric, you want to –

MR. SCHWARTZ: Sure.

ADM. FALLON: – start off with the policy piece?

MR. SCHWARTZ: Yeah, I mean, I think – I think to the extent that, you know – I think if the – if the goal is – if the goal is – and this is a preliminary response; I could be dead wrong, right? So please appreciate that. But – because the stakes are very high, right? And so, if you're wrong and the stakes are high, then the – so take everything I say with a grain of salt. But my – but my reaction to your comment is, if you're talking about increasing the magnitude of resources for vaccinations, for immunization, in humanitarian settings, one strategy might be not to take aim at the Congress but to take aim at the administration.

And what I mean by that is that I think the – I think if there are any foreign-aid accounts that are going to be generously funded, it's the humanitarian accounts. At least that's what history, recent history seems to suggest. My bureau got \$100 million – consistently 100 (million dollars) to \$200 million more than we asked for in an environment that was extremely difficult for the budget, right? And so I think if the goal is to increase the magnitude of resources – and I think this – the goal is to increase the magnitude of resources in humanitarian settings, in addition to taking aim at Congress – of course you should – but I would also – I would look at the administration. I would look at the accounts of PRM and DCHA and USAID and ask the question: Are you allocating enough support for this area? Are you pressing your international partners, UNHCR and others, to – WHO, whatever – are you pressing your partners to commit institutionally and resource-wise? So I think I would – I would, you know – on the humanitarian side, I think I would do both. I would look at the Congress but also the administration.

ADM. FALLON: If I could just add a couple of thoughts on the military aspect to your question. The military certainly can and does respond to humanitarian situations, crises around the world. The key attributes are organization and speed. But for the longer term, the bigger picture, seems to me – someone mentioned this morning – in this for the long haul; set longer-term goals. And that's where you need to be prepping the battleground in terms of, basically, at the end of the day, trying to build host-nation capabilities, it seems to me, to be able to sustain the kinds of things. So we can intervene, we can do all kinds of things – many in this room do magnificent work – but for the long term, key thing I believe is to – is to get folks on the ground to be able to sustain this and keep going. So the military can help, but primarily your speedy responders.

What else, folks? OK, while you're –

MR. GEISSER: If I may just – yes, the role of the military. In Afghanistan of course the military has played an important role, certainly not as a provider of vaccination as (the admiral ?) has just said, yes. I see the role of the military very much as trying to support a environment that is conducive to allow a vaccination to take place, OK. That is, I think – I think this is the unique role that the military can play, yes.

MR. : Sure.

DR. COCHI: I think we have both a challenge and an opportunity in advocating for vaccines and immunization as a – as a very concrete way to gain and sustain trust with communities and build that trust and that engagement over a long period of time. Afghanistan, Pakistan, these are major, complex situations that have a military dimension that goes – it goes far beyond that.

So we have a need to do our best in advocacy to demonstrate that – the way that for the longer term that we gain the – that we win the hearts and minds of the – of the population are through other concrete means, such as delivery of vaccines.

ADM. FALLON: Steve, you mentioned in your discussion the topic of pandemics, and since this is – a widely held perception is a real challenge to security internationally. What would you see as recommendations for dealing with this in advance? What can we do to get prepared – better prepared and be more rapidly forthcoming if we were faced with these in the future?

DR. COCHI: Well, that's a very good question, a very complex issue. I'm certainly not an expert in this, but we need to keep this very high on the priority list in terms of our – in terms of our preparedness. And as Dr. Fauci indicated this morning, from the U.S. perspective, building a strong – as strong as possible a seasonal influenza vaccination program really creates the infrastructure, the vaccine capacity to deal with a pandemic if and when it should occur.

And that applies globally as well. I think our role from the U.S. side is to – is to support developing countries to build that capacity, to implement seasonal influenza vaccination programs, to build the global supply of influenza vaccines so that when a pandemic occurs we have the capacity, both human and financial and from the manufacturing – from the manufacturers, to address that pandemic as quickly as possible.

ADM. FALLON: Thanks. Markus, you mentioned in your remarks your perception that the – things were changing in the arena, that we're making distribution of health services more difficult. Did you perceive this as a local issue in Afghanistan? Are there some structural larger-picture items here?

MR. GEISSER: Of course, in Afghanistan it's very obvious that things have become more complex. And it's simply linked to the fact – to the circumstances that we see very often in internal roles where you have indeed this fragmentation of armed actors – this proliferation of armed actors. And there you also have competing authorities. You have not only state and non-state actors having guns, you have also non-state actors – for example, in Afghanistan, the Taliban who actually run their own ministry of public health.

And what I think is very important is that in such a context, if those who wish to – those who want to provide vaccinations simply talk only to the state minister of public health but do not consider the presence of other actors on the ground, that will simply not allow the provision

of vaccination. I think that's something that I have seen or the ICRC has seen in many – in many contexts, yes. And I think this is a – this is a key issue, (yes ?).

Vaccination in a day – I think it was said, yes, there are more – vaccination doesn't know any borders, yes indeed. Not only state borders between Pakistan and Afghanistan, but actually also within a country, yes.

ADM. FALLON: Steve?

DR. COCHI: Yes, I – just to – just emphasize what Markus has been saying, and to put it in very concrete terms, and it applies to Afghanistan and the cooperation with the Taliban, and it applies in Somalia with the cooperation with the warlords and the clan chiefs. But in the Afghanistan circumstance, for years an agreement was worked out for one round of immunization after another over a period of years.

The Taliban appointed the vaccination teams from the communities, the vaccine was supplied by the government of Afghanistan and international partners, and then the Taliban reported back in on the results. And this was – it was a very workable strategy. And ICRC had a central role in making this happen and keep – and sustaining it over time.

ADM. FALLON: All right, thanks. Yes, ma'am. Can we get a mic up here please? Thank you.

Q: Thank you. Again, my name is Ann Thompson. I'm with the CORE Group Polio Project with World Vision, and my question is just to the panel in general. If you could highlight the three main things that need to happen to best promote worldwide immunization and address those to the U.S. government or the Western world, what would they be?

ADM. FALLON: Anybody like to take a shot at that one?

MR. GEISSER: Interesting. Address – (inaudible) –

ADM. FALLON: So three things – three top priority tasks to (accelerate ?) the value of immunizations to the world. (Laughter.) A panel stopper, huh?

MR SCHWARTZ: Well –

DR. COCHI: (Inaudible) – go ahead.

MR. SCHWARTZ: The problem with answering the question is I think that – at least from my perspective, I think – I think our presence on this panel may suggest, and in my own view you've heard, that a focus on the most challenging environments – environments of conflict, of humanitarian suffering, of state failure – I – my own view is a sustained and substantial focus on those areas, as my comments suggested, is critical because, as I said before, you know, if Sutton's rule – Sutton's law applies.

And if you're going to solve a disastrous problem, you've got to go where the bulk of the suffering really is. And I think it will take a significant commitment of resources, but it will also take a commitment to best practices because the challenges of access in those kinds of environments and significant and substantial.

So there are ways you can address that under any circumstances – a careful serving of the population, careful site selection in these sorts of situations, careful preparation. But ultimately, the most significant challenges, in my view, are going to be challenges related to access. And I would say one thing that the government – our government should be doing, and I suspect we already are doing it, is preparing a very careful look at how we managed – how the international community managed the outbreak – the measles outbreak in the context of the Horn humanitarian disaster.

We've got – I think there are probably going to be some important lessons learned from that experience both in terms of why it wasn't better prevented and in terms of how we responded, how the international community responded, and whether that response could have been more effective. Sort of a non-answer to your question. (Laughter.)

ADM. FALLON: You've got 30 seconds.

DR. COCHI: A very good question. When you put the question, I was sitting here, having done a background paper giving my top 10, wondering, let's see of which three of those top 10 am I going to use? But I think what I wanted to say is the – to me, the most important issue is partnership.

And in the global vaccine enterprise, the road to success is to have a fully elaborated partnership that combines government ownership, industry, community leaders, the private sector and non-government organizations – especially given the topic we're talking about – and NGOs that can work in these conflict-affected areas. And it's – that's the secret to success – the number-one secret to success in my view.

ADM. FALLON: Markus, a quick one?

MR. GEISSER: All right, I just would like to develop a little bit what my colleagues have just said. The value of immunization, I think that was your question. I agree, of course, and I think Eric very well, with his five points, has actually already given you, in my opinion, an answer to your question.

Develop this little bit further – just how do we – as we – as we, from the ICRC, talk to non-state actors, how do we try to – how can we manage to convince them of the value of immunization. That is sometimes quite complicated, yes. And sometimes very simple solutions, actually, are probably the best.

In the case of Afghanistan, if you have someone from the Taliban who's very – doesn't like the idea, it's something from the West, et cetera. What do you do? You make sure that – for

example, it's something what I try to do and have managed a few times – you make sure that he takes his son, OK?

We talk to his son; OK, you can tell him, you may not be interested in that, but you're certainly interested in the well-being of your son. And that usually really brought this – let's say, brought this debate about yes or no vaccination to very abrupt end, because it was very clear. It's also about responsible leadership.

ADM. FALLON: So small, personal things matter. If I could wrap this up, Ann, with one of my own observations – maybe a corollary to where we started with Sutton's first law – and that would be, if we ought to focus on the obvious, then maybe we ought to also take a little bit sharper focus on the obvious low-hanging fruit. And so one of the roles – key roles of leadership is to make decisions, and let's decide there's some things that can be done very quickly to great effect, then let's do them.

So thanks very much for your attention, and thanks to the panels for their views.
(Applause.)

MR. : Thank you.

MR. : Thank you.

ADM. FALLON: Good work, guys.

(Cross talk.)

MR. MORRISON: Hello?

So we're getting to the final section of our program, which is an address by Rajiv Shah, the administrator at the U.S. Agency for International Development. And we're thrilled and honored that the administrator has agreed to come and deliver the closing keynote address here.

A few words of thanks: Several people at AID were very, very helpful and instrumental in helping us to make this happen today – Amie Batson, who's here with us today, Nicole Schiegg, Chiney (sp) Bolton – all of them are here today. We've also of late had a terrific interaction with Ariel Pablos-Mendez, the assistant administrator on health, who gave a major address at CSIS a week back. And we've had great fortune and interaction with the terrific team that Raj has put together at AID in many different ways – Nancy Lindborg, Paige Alexander, Susan Reichle, Don Steinberg.

Today we're going to hear from the administrator, right near the two-year mark in which he joined AID, about 10 days before the Haiti earthquake, which plunged him into a major – a major crisis with a huge health component to it. We'll hear – we'll hear his vision around immunizations and vaccines which, under his leadership, AID has really brought this issue forward in a new and much more profound and visible way, which is a terribly important piece

of U.S. leadership. And it was for that reason that we were so happy and so eager to ask him to come here today and lay out that vision.

He's been – in the period – the two years of leading AID, he's been at the forefront of the internal reforms – the USAID forward, the focus on the procurement, getting the agency back into science and technology in a new way, putting forward a new monitoring and evaluation framework. It's been an exceedingly busy period as AID has gone through this process of strengthening and renewing itself. And we owe Raj a great deal of gratitude for taking that leadership on and carrying it forward.

So please join me in welcoming Rajiv Shah here today. (Applause.)

ADMINISTRATOR RAJIV SHAH: Thank you. Thank you, Susan. Good afternoon and thank you for that kind introduction, Stephen. I'm excited to be here and want to congratulate CSIS on the incredible work that you've done to raise visibility for global health, for vaccination – and not just amongst the community of us that believe in and have believed in and have worked in global health, but in a much broader community of leaders who think about our safety, our security, our prosperity, what drives that around the world, and why health vaccination and basic progress against the milestones of human dignity are critical to that. So I'm very pleased to be here with you and with everybody here today.

I want to thank Admiral Fallon in particular for your strong leadership and for being a visible symbol of how this has become a national security issue and a critical part of how we present ourselves around the world. And I enjoyed catching the final words of the panel with Dr. Cochi and Eric and so many good friends and colleagues.

I know you've heard a lot today about vaccines and immunizations. So I am not sure I'm going to have a lot new to add. But I am very excited that we at USAID, under Ariel Pablos-Mendez and Amie Batson's great leadership, are reinvigorating our own commitment to vaccines and immunization.

And I thought it would help to start by describing a little bit of the history of what brought us here. You know, in 1862 – this is a photograph of a Confederate hospital in Richmond – admitted 250 soldiers with smallpox. Almost 45 percent would die – 110 would die per week. And by the end of World War II, of course, smallpox inside the United States had been almost eradicated. But even in the early 1950s, 150 years after the introduction of a vaccine, an estimated 50 million cases of smallpox occurred in the world each year.

This is a photograph of smallpox vaccination in Ethiopia. And we all know that under the leadership of many public health heroes like Bill Fahey and others, WHO, CDC, USAID all worked together for 13, 15 years, whatever it took, to ensure global success. And the world, in fact, first got the number of cases down significantly and then made that final push in India and other parts of the world, going after those difficult last cases, and fully eradicating this disease.

It's worth noting there've only been two diseases eradicated in human history. The second one was eradicated in the Horn of Africa over the past 18 months through a large-scale

livestock vaccination campaign. And that was called rinderpest. And I don't know how much you've talked about livestock vaccination today, but I would argue that that also belongs in your thoughts as you consider these issues.

This is, of course, a picture that I'm sure many of you are quite familiar with. Treatment for polio in the 1940s and '50s occupied entire wings of hospitals and as patients struggled inside of these cumbersome and mostly ineffective iron lungs. And you can just tell by the sheer magnitude of what's required on a treatment basis that this was not a sustainable way to eliminate the scourge of polio from the planet.

This, on the other hand, has proven to be. And today the focus is on prevention with easily administered vaccines, in large contrast from the fears of even 60, 50 years ago where people worried about going to swimming pools and where they get might infected, what would happen to their children if they got infected. Today the global caseload is down to just those last few cases. Year on year those cases go down or go up, but in the grand scheme of history here, we're on – we're well beyond third base and almost at home plate.

It's been 11 months since we saw a polio case in India. And I know there's been an expansion of cases in certain parts of Pakistan and Afghanistan and they continue to deal with containment challenges in certain parts of Africa and West Africa. But nevertheless, we are on the final pieces of this polio eradication struggle. And we, the United States government, USAID, CDC and all of our partners, are absolutely committed to seeing this through, the way others were committed to see through smallpox and more recently rinderpest.

This is a photograph that needs no introduction, this – in this audience. This is Jim Grant, a charismatic and compelling leader of UNICEF, a – someone who carried in his pocket oral rehydration solution and vaccine vials so that he could show world leaders when he had the chance to meet them the simplicity and the ease of the concept he was promoting – a simple concept, that with enough leadership and enough focus and wiliness to tackle bureaucracy, you could in fact pursue universal childhood immunization. And we saw rates of coverage globally, under his leadership, increase significantly as a result of that energy and that leadership.

But we also saw a decline that occurred after the Jim Grant-era of immunization, in the 1990s. We know that global immunization progress slowed significantly. We know there was a divergence in the vaccine economies of the rich or more developed world and of the much, much, much more populous rest of the world. We chose – they – we chose IPV versus OPV. We chose MMR versus measles vaccines.

And those programmatic choices across all of these different products resulted in a situation where, actually, basic supply of vaccine for most of the world – 80 or so percent of the children born every year – was pretty tenuous. It was dependent on an erratic and underfunded donor system that sometimes had the money to purchase the next few months of vaccine and sometimes didn't. And it was at the verge of falling apart.

And into that context, the global community came together and created GAVI, the Global Alliance for Vaccines and Immunization. And you can see here, if you look at around 2000,

when GAVI was created – and if you look just at the history of haemophilus influenza B vaccine, you can see this is a vaccine that we had and had rapidly introduced in high-income countries from 1985 forward. But 15 years later, barely any of this product – 15 years later – was reaching the bulk of the children, who, by the way, benefit from it much more greatly because we don't have as much child death from HIV here in this country. But around the world it was a major cause of mortality for children.

And GAVI's funding support, the leadership of the global community, the desire once again of the international agencies to break through the bureaucracy and deliver a result did just that. And inside of a decade, you can just look at the progress of coverage with Hib vaccine.

Now, that wasn't the only part of the story. This global alliance unleashed a lot of creativity, new ways of financing incentives to create new vaccines, advanced purchase commitments and pooled procurement systems, a new way of thinking about global demand in countries – it used to be the case that public health experts would estimate the need and then communicate that to manufacturers. Manufacturers would start planning based on that and then the money wouldn't show up because we all know that demand – market demand – is not just need – I need a new Apple product every week – (laughter) – it's about having the resources and the will and, in my case, your wife's permission to purchase that product. (Laughter.) And moving from need to demand-based planning in countries was a big part of what GAVI had to offer.

The result of all that, of course, is seen in this photograph – a child receiving pneumococcal conjugate vaccine. And Orin Levine is here who led the PneumoADIP – the Accelerated Development and Introduction Plan that had a lot to do with laying the groundwork for why we can today go to communities where children don't have the resources that they deserve and see them receive a vaccine product that we know is highly efficacious in saving their life – probably one of the most important interventions we've developed in decades. And we know that it should get to every kid. But because it costs \$54 a dose in this country for so long, it was just assumed to be out of reach for poor children.

Eric Schwartz and I had the chance to travel together to the Dadaab refugee camp at the Kenya-Somali border a few months ago. And we walked through and we met these kids that were barely holding onto life after leaving war-torn Somalia, suffering from excruciating famine and unbelievable human suffering. They were getting Pneumavax in that camp. That's incredible. You know, that's incredible. It just shows you the progress we can make if we put our mind to it. And as the admiral said, we just make decisions and we get the stuff done.

Well, I tell all of that to point out that President Obama has made an absolute, unwavering commitment to childhood immunization and to saving child lives around the world. The childhood immunization commitment was a \$450 million multiyear pledge we made in London as part of a global effort that raised more than \$4 billion to introduce pneumococcus and rotavirus vaccines along with accelerating the uptake of other vaccine products, along with continuing to invest in developing the new vaccines that Tony Fauci spoke to you about this morning: an AIDS vaccine – and I know our IAVI colleagues are here today; a malaria vaccine, and we're continuing to be proud of what the Malaria Vaccine Initiative and its partners like

GSK are accomplishing and what they're going to accomplish in the coming months and years as those products increasingly become real and ready for introduction.

We know now that these questions that were asked 10 or 15 years, but are these new vaccines too costly for poor kids, are questions we can answer with innovations in financing and procurements, in contracting and in management, and how we think about global demand and global supply. And we will be absolutely committed to making sure, as these vaccines become real, that we make them available to every child everywhere.

But our commitment to child mortality will go beyond vaccination because ultimately the goal is to save children's lives. And we've had huge success and progress against that goal: 70 percent reduction in child mortality over the last 50 years. In 1990, 12.4 million children died; in 2000, it was 10.8 million; in 2010, 7.6 million. And it continues, too, and we believe we'll continue to come down so long as we stay focused on achieving great results in saving children's lives where they are preventable.

In fact, if we could achieve the OECD average rate of child mortality all around the world, we would basically have 1 million child deaths a year. We would be saving 6 ½ million additional children's lives every year everywhere.

And so that led us to ask, well, is that achievable? And we now believe it is. We believe the state of technology, the knowledge of how to deliver these interventions, the data around the value of integrated community health in even very resource-poor settings, and the insights that have come from real progress in many, many countries make this goal possible.

The photograph is – highlights 24 countries that represent 70 percent of total global child mortality. We believe, in those countries alone, we can achieve 5 million lives saved over five years – over the next five years. And we can do that by focusing on a relatively straightforward package of interventions, each of which, like vaccination and including vaccination, can be linked to very specific reductions in child mortality.

It starts, of course, at birth. And at that moment of birth, we tend to lose a lot of kids, about a million children, right before, during or immediately after birth because they don't have oxygen – birth (asphyxia ?). We've entered a partnership with Laerdal Corporation and with a number of other partners, and have rapidly introduced some new technologies. If you look at this slide, you'll see a very low cost: 18-dollar package of newborn resuscitation technologies. The same package, by the way, in a hospital in our country here would cost that hospital about \$400. But for \$18, and we're going to keep driving this cost down, we can provide that package.

We can also provide a doll – that you see, NeoNatalie – and train – I had one in the office, I was going to bring it, and then we said, no, we'll put it on the slide – and we can train a community health worker to help save a child's life from birth (asphyxia ?). Studies have shown – we've rolled this out in Bangladesh, and actually, now it's rapidly taken up in 33 countries as part of this public-private partnership – we expect you can see a 30 percent reduction in birth (asphyxia ?) if we can roll this out at significant scale. And that will save hundreds of thousands of lives.

But we know that the challenge doesn't stop there, that we have a long way to go to save those 1.7 million lost lives at the moment of birth. So we've instituted a challenge grant program at USAID, together with partners – the Gates Foundation, Norway, the U.K., others – the World Bank and Canada. And through that effort, we've issued a call for innovations and new ideas that can save lives at birth. The condition, of course, is the ideas have to be affordable, they have to be practical, they have to become the kind of low-hanging fruit that we can – that we can actually reap and see real outcomes as they relate to it. And this is a photograph of one of our partners in this program that – from William Marsh (ph), Rice University – have invented a low-cost Bubble CPAP System, a continuous positive airway pressure system that, again, would replace a mechanism that costs thousands of dollars here in the United States, do it at far lower costs, and then get it out to as many facilities, clinics, points of service, points of care as is possible.

I'm so excited about this program because in addition to delivering specific results, it's helping us tap the innovative potential of partners all around the world. We had more than 600 program applicants present new ideas. Thirty percent of them were from the private sector. And all of them were winners, in many ways; we were able to support 22 in the first round.

But achieving 5 million lives saved over 5 years takes more than focusing exclusively at that point of birth. It also includes saving children's lives from HIV/AIDS and in particular eliminating pediatric AIDS. President Obama, a few days ago, made a powerful and important statement that we are at the beginning of the end of AIDS. And by doing a number of things together, we can actually begin the decline of that disease and rid ourselves of AIDS entirely.

One of those things was a commitment to make sure we get antiretroviral drugs to pregnant women during their pregnancy and before birth. And we know that if we do this through effective – if we know that if we do this effectively, we can prevent the transmission of HIV from mothers to children, and if we hit global targets that the whole world has already agreed to, has already signed up to achieve, we will virtually eliminate pediatric AIDS. And in doing so, by reaching 1.5 million pregnant women living with HIV/AIDS, we'll save 150,000 child lives a year.

This is a photograph of a mother in a clinic, I believe in Kenya, who's come in for testing and for treatment. And we're now, through the Global Health Initiative, using our HIV clinics around the world to provide this broader package of services and these broader interventions designed to help children and mothers survive.

But we still have to do more and have to help kids get a healthy start. And this is a photograph of a young child receiving a Plumpy'nut, and I know folks in this room are comfortable – are familiar with Plumpy'nut as a product. One of the big scientific advances in this field over the last 10, 15 years has been recognizing that chronic malnutrition is a serious, serious problem, that children who are stunted or who are small for size and age might be – they might be smiling and they might look vibrant, but in fact, they've suffered lifelong and debilitating changes to their brain development, that their brains don't grow as much as they should – their ventricles are larger, they have more fluid, less white and grey matter; that, then,

leads to lower educational attainment and, ultimately, lower contributions to economic growth and for their societies.

One of the solutions to that is to target feeding in the first – in the nine months of pregnancy and the first two years of life, those critical thousand days, and to target those thousand days specifically with high-protein, high-micronutrient foods that can rapidly improve their nutritional status and enable them to have – to avoid chronic malnutrition at that very crucial period of growth. By refocusing our programs in nutrition in that area, we're working in 15 countries where child malnutrition poses the highest risk, and we believe this investment will help reduce chronic malnutrition by 30 percent.

Another easy win, to put it bluntly, is malaria prevention – perhaps the easiest win we have in the entire suite of tools that we deployed to save children's lives around the world. We've seen in the President's Malaria Initiative data coming out of more than 15 countries where we've scaled up our investment to provide insecticide-treated bed nets for children to sleep under; to make sure that when kids get malaria and get the symptoms, that they have access to therapies that can actually work to save their lives – ACTs as opposed to older, less effective alternatives; and to conduct prevention activities – education, indoor residual spraying – a basic package of things that can be done easily that have, in so many parts of the world, including the great American South, helped virtually eliminate malaria – and, in our country, eliminate malaria. I was thrilled to learn, when I visited CDC, that the reason CDC is in Atlanta is because it was part of our final push against malaria in this country, and that's where the burden of disease was.

Well, today, the burden of disease is in sub-Saharan Africa, and a few years ago, we noted that a million children under the age of five every year died of malaria. Today, that number is still too high – it's over 700,000 – but we know with real validity, because we've had rigorous studies, that providing this basic package of interventions country after country, at scale, can reduce all-cause child mortality between 20 and 30 percent. We saw it in Tanzania. We saw it in Zambia, in Rwanda, in Senegal – country after country. And when I meet the leaders of these countries – President Kikwete – first thing he says: Thank you for your partnership in malaria because I can go to our hospitals and they have room for patients and for other things. I can go to our communities and rural parts of the country and children are surviving, and it makes a difference, and they value the leadership we've provided.

In fact, a friend of mine, Dan Glickman, says – he was in rural Tanzania recently and he said, he went into a village and talked to a gentleman there, a tribal elder. The elder came up and said, I have three favorite people in the whole world. And he said, oh, who are they? And he said, President Clinton, President Bush, President Obama. And Dan came back, called me and said, Raj, there isn't – I don't know if there's anyone in this country who would say those are their three favorite people. (Laughter.) But this makes a difference. People value – when they get those vaccines, when they get these improved nutrition products, when they sleep under bed nets, when you save children's lives, people value that partnership.

And that brings me to my conclusion, that we know that this is the right thing to do, but we also know this is the smart thing to do – that when we save lives around the world, we're

helping to usher in a different structure of population growth for economies that need to go through a demographic dividend in order to experience economic growth and development. We've seen that fewer births that – we've seen that, as child mortality improves, families have fewer births. And as they then have a lower number of dependents, they're able to build up more income and assets per dependent. We know that that, then, powers the kind of economic growth that we've seen make important contributions to the emergence of the Southeast Asian tiger economies over the last 50 years. And we know precisely where those countries that we highlighted as high-burden countries for child mortality, those are precisely the countries where we now need to see the demographic dividend take hold and the resulting investment in human capital and economic development take place there.

And there is a reason why it's important that the growth and the stability of those countries remains in our national interest, because when we have trading partners instead of partners where we have to engage with our military, we are better off. We know that today, in Southern Sudan, a young girl is more likely to die in childbirth than she is to complete a secondary education. In precisely an environment where we're engaged to slow the spread or reverse the spread of Islamic extremism, in precisely the environment where we know that droughts and other, more erratic weather conditions create instability, migration, tremendous suffering, and where governments are increasingly democratic but are trying to move in that direction but need continued encouragement to get there successfully, we know in precisely those environments, making these investments now will be one of the keys that unlocks a future of stability and change.

And, in fact, I was in South Korea just last week where the global development community came together – 2,500 people from around the world – in a country where, in the 1960s, they had a lower per capita income than their counterparts in East Africa and they had a lower per capita food consumption, a higher child malnutrition rate, a higher child death rate – a child-mortality-under-five rate. Today, South Korea is a donor country themselves. We have more jobs in the United States trading with South Korea than we do trading with France, and that number's going to go up because of the president's free trade agreement.

So we know that it's in our economic and it's in our national security interest to make the types of investments that keep us going here. But all of what we're talking about – health, food security, water, humanitarian response, diplomatic engagement – all of that is 1 percent of our federal budget. And today we're engaged in a very serious conversation about whether America can continue to maintain its six decades of leadership in vaccination, in health, in the alleviation of human suffering.

And while we know that it's in our interest to do it, and while we know that we can afford it – and in fact, we can't afford not to make these investments – I'll just close by saying – I think both Eric and I had this impression when we visited the Dadaab refugee camp – that when you look these children in the eyes and you meet mothers who have held on to their kids and walked for 60, 70, 80 kilometers to get into that camp, and you know that they get there and they get food from the United States of America, they get medical attention from partners we support, they get a Pneumovax vaccine because of Orin's great work – that's the right thing to do. And

when we lead with our values, and when we demonstrate that that's who we are, that just trumps everything else. And that's how we should be engaging around the world.

So I want to thank you for being here today and for taking it upon yourself to engage on vaccines and immunization. We will stand with you proudly. And we hope you'll be loud and aggressive in trumpeting the need for America to continue with its leadership role, as, certainly, President Obama and Secretary Clinton and I intend for us to do. Thank you. (Applause.)

MR. MORRISON: Thank you so much. Administrator Shah has some time to share now for a further conversation. I'm going to ask you just one question, and then I'd like to open it up to comments and questions from our audience.

My question really is about engagement with the Hill, because I know that you have been intensively engaged for over a protracted period of time in making the case, in understanding the perspectives – in the midst of this budgetary difficulty, in the midst of a polarized, increasingly polarized situation, and in one that's full of angst and fear and uncertainty around the future – in making the case, and finding your way forward, and being very methodical and determined in carrying those dialogues forward.

And I wanted you to reflect a little bit: In this context of talking about the strategic value of vaccines, immunizations, child survival, advancing global health – against that backdrop, what have been your reflections around what works in our current environment?

Not that we're out of the woods or that there's clarity yet on what the outcomes are going to look like, but you spent the better part of this year intensively doing that. And we're very grateful to you for having made that commitment because it's so valuable. But if you could just share with us a bit about that question.

ADMINISTRATOR SHAH: In terms of the communication? In terms of what works with that?

MR. MORRISON: In terms of the communication and how to make the case. And in looking at the state of our current political environment and the state of our current budgetary crisis, how do you navigate that, and how do you make the case, and how do you listen and advance an argument in this environment?

ADMINISTRATOR SHAH: Well, you know, I'd start by saying that I'm very impressed that on both sides of the aisle, and frankly, in almost all subsections of both major political parties, there is pretty much unwavering commitment and support to the range of issues that we've discussed. So I find that making the case that this work is important is relatively straightforward.

The challenge – and it was best articulated to me by Prime Minister Harper, actually, when he chaired a commission that I had the opportunity to serve on with him. And he said there's no other area of public policy that he has to engage on where there's a bigger difference in how the general public perceives the work and the implications for it.

And what he meant by that is, if you can demonstrate that resources in generate real results, and you can do that in a valid, transparent, open, businesslike manner, the peoples of our countries will rush to support this work. If you don't do that, then they will just assume that the resources are spent poorly, ineffectively, not generating results. He said there's no other area where there is no middle ground.

And that's why we've launched USAID Forward. It's why I've actually spent more time on procurement reform within my agency and within our development enterprise than any other single issue. And it's why we take so seriously the need to be operationally excellent at ensuring that we can take resources, invest them in a businesslike manner, and generate real results.

And I think GAVI is a good example of that. GAVI has built a system that can make an honest case that it does that. And it was able to raise, in a tough global fiscal environment, more than \$4 billion to, for the first time, say to every child on the planet, you're going to get the same vaccines that my son would get when he's born here at Sibley Hospital. And we can continue to have those successes, but we have to make the case and we have to demonstrate effectiveness and results around everything we do.

MR. MORRISON: May I just look forward into 2012? We're going to have the secretary preside at a summit in early May, at NIH, on maternal and child health. We're going to have the G-8 summit in Chicago. We're going to have AIDS 2012 in July here in Washington, D.C., for the first time on U.S. soil in 22 years.

Can you just talk a little bit about 2012 and what these opportunities mean for the agenda that we've been talking about here today, in terms of engaging the American public?

ADMINISTRATOR SHAH: Well, each of these are important opportunities to raise the visibility of what we're doing. I would urge us all, as we think about how to do that, to really engage a broad set of partners in both executing this work and in sharing the message with the American people and people around the world.

It's very powerful when Muhtar Kent and I are able to do something together to demonstrate that our new water partnership with Coca-Cola, for example, is going to reach hundreds of thousands of villages in sub-Saharan Africa. Or it's powerful when Indra Nooyi of PepsiCo, who has announced major investments with our Feed the Future food security program to help reach 30,000 chickpea farmers in Ethiopia – to create products that, by the way, are like that Plumpy'nut product that will go to kids and be a high-nutrition, hummus-like product.

I think the American people – and, you know, we tend to listen, certainly, to the experts that have spoken here today and to all of you that have been leading the fight. But we also tend to listen to corporate leaders and to a broad range of faith-based leaders, leaders at universities. This is an all-hands-on-deck effort. I think we have to do a better job of diversifying the voices we rely on to share the message.

MR. MORRISON: Thank you. I want to welcome comments and questions from our audience. Just, please, put your hand up and we'll bring a microphone to you. There's a hand right there, and there's one right here. (Inaudible.) We'll cluster these comments and questions together, and then we'll come back to you, Raj, in a moment.

Yes, sir?

Q: Thank you very much, Dr. Shah, and thank you, Steve, as well. My name is Steve Kho, and I'm the senior adviser of Taiwan's representative office here in Washington, D.C. And I know Dr. Shah just visited Taiwan, just last week, as part of your trip to Asia, and countries like South Korea.

My question is, is that – could you comment or share with us a little bit about your view about the policy and the mechanism that you wish that USAID could use to, sort of, encourage countries like Taiwan and South Korea – those, you know, in the past, is the recipients of USAID, and now is very much willing to feed back to the global community, but not really know how to do that.

And is there any policy or mechanism that you think that would be kind of useful, and how to, kind of, encourage those countries to partnership with USAID and to do that kind of a thing? Thank you.

MR. MORRISON: Thank you. Armando? Do you have – there's a microphone right behind you. Are there other hands up?

Q: (Off mic, inaudible) – thank you for your excellent speech – (inaudible) –

ADMINISTRATOR SHAH: Yeah, come out here. Thank you.

Q: So if there are cuts (as ?) are anticipated, does AID have to have a protocol for how those types of cuts may be done to protect priorities like Global Health and Feed the Future?

MR. MORRISON: Why don't we come back to you – (inaudible).

ADMINISTRATOR SHAH: OK.

MR. MORRISON: And then we'll see if there are other questions in a moment, once you've been able to take those.

ADMINISTRATOR SHAH: Sure. Well, let me start with the first one. You know, you're absolutely right to point out the donor landscape today is so much broader than it used to be. And that's why I've been to China, I've been to South Korea. We've gone to so many different parts around the world – Brazil, Taiwan – to engage new partners to be active partners in taking on these global responsibilities.

And President Obama and Secretary Clinton in particular have pointed out that these are global challenges, and it's in all of our collective interest to make the necessary investments and to share our experiences. Brazil has some amazing experiences in addressing hunger and malnutrition. South Korea has amazing experiences, many of which – in a partnership with USAID over 30 years – of deepening and expanding its health expertise and its health sector.

So many countries today can join multilateral mechanisms like GAVI or the Global Fund, or any of the other ones that are demonstrating real results, in a way that's relatively efficient for them to do, and frankly, at the level at which they're able to give. And so we've made a major priority out of broadening the global partnership to get this work done.

In terms of U.S. assistance and reductions, we, of course, continue to fight every single day for the president's budget. And I would say to you that President Obama, in a very difficult budget environment, has every single year proposed the world's most robust global health and global development budgets in our country's history. And he does it, as he reminds me and my colleagues regularly, because this is ultimately about who we are, and this is a smart down payment on building a safer and more secure future.

And, you know, so we're going to keep doing everything we can, as Stephen points out, to get there. Of course, if we're unsuccessful, or if there are significant reductions, we have a plan to address that. And it wouldn't – we wouldn't – the level of reduction we're talking about is so significant that really everything would, unfortunately, be on the table.

We'll make tough priorities. We've proven that we can make tough choices. We've shut down, under my leadership, 14 missions, a number of – dozens of programs around the world, repositioned our health portfolio into those places where you get the best results and the highest mortality, child mortality – it's these 24 countries – and maternal mortality; it's 28 of the highest maternal mortality countries.

We're going to keep making those tough reallocation decisions because that's how you get better results. But, you know, at some point, when you're looking at 20, 30 percent reductions, it will touch everyone.

MR. MORRISON: If there are other comments – I wanted to add that, you know, over the course of last night and today, Pakistan's surfaced at many different points, right? The discussion last night we had around polio was – you know, it brings us back to the difficulty and the intractability, it seems at times, of managing polio in Pakistan. We heard during that – during our discussion around operating in unstable and conflict settings.

I know from the strategic – the U.S.-Pakistan Strategic Dialogue – that you've been very involved, along with the secretary, on that whole prospect of trying to really engineer a different approach on immunizations.

But we're in a point of crisis right now, obviously, in the internal condition in Pakistan, and the difficulty of understanding that, but also in the bilateral relationship. So can you comment a little bit about, you know, how you think about all of these challenges right now?

Because they do keep surfacing as terribly important challenges in front of us from a number of different angles. I know you've been very involved.

ADMINISTRATOR SHAH: You mean Pakistan in particular?

MR. MORRISON: Yes.

ADMINISTRATOR SHAH: Well, you know, Pakistan is – we obviously have a very complex, important and difficult but durable relationship. And the challenge, from the perspective of those of us in this room that have worked on child mortality and vaccination, is that the birth cohort in Pakistan is about 5.4 million children. It's significantly larger than the birth cohort of our country here in the United States. So any time you think about global child mortality statistics, Pakistan becomes an immediate priority.

The backtracking in progress on polio is, as you know, very significant. I think you had that conversation yesterday. And it has to do with the ability of effective vaccinators to get access to communities in a trust-based way in some very difficult-to-access parts of the country near the Afghan border.

They also are dealing with a structural change in their government. They've chosen to devolve a lot of administrative authorities from a central government to the states, their provinces. That's the right thing for them to do over time because it is part of their larger constitution and politics and trend towards democratic governance and accountable local governance. But it's more challenging in health, because they had a very technically capable central ministry of health, with some very capable partners.

And so the state – the provincial departments of health have more variability in their capacity to take these programs forward, and we're working through that programmatically in a number of different areas. We've supported 18,000 lady health workers that have had a huge impact in reducing maternal mortality, improving birth spacing, helping to reduce the total fertility rate. But all of these things are going to go through this difficult transition.

MR. MORRISON: Well, I think we've gotten – we have one more hand. Peg?

Q: Thank you. Peg Willingham with United Nations Foundation. Dr. Shah, I wanted to ask you about HPV vaccines. It's something where my understanding is, health ministers in developing countries regard that as a high priority. I know you know it's a leading cause of cancer death.

And yet here, in the political environment in Washington, advocates sort of quake at the idea of talking about HPV. And I wonder how you bridge and send the message that this is what countries want and need, versus very different political considerations here. Thank you.

ADMINISTRATOR SHAH: Sure, and thanks for the question. In the global system, especially through GAVI, the countries have the ability to construct their own priorities – to set market demand, as I used the term earlier, based on their, kind of, actual plans. The introduction

of HPV, of course, is very different than the introduction of a basic childhood vaccination, so they need a public health and a health system delivery strategy that can support their aspiration to use that product, if they have that aspiration.

And I was pleased that GAVI has begun a very serious process to help countries with the planning and the demand development, and then supporting the distribution in an appropriate way as they do that. So there are a lot of questions that have to be asked, because it's not – it's not going to be delivered through a traditional childhood immunization system.

So you can't just say, OK, we cover 70 percent of the kids, and so here's how much we need and we're ready to roll. It has to be done thoughtfully and methodologically. And ultimately, countries themselves, taking into consideration data and what's best for their populations, need to be the ones accountable for making the decisions.

MR. MORRISON: I think we've reached the conclusion of our program. (Inaudible.) Please join me in thanking the administrator. (Applause.)

ADMINISTRATOR SHAH: Thank you.

MR. MORRISON: (Inaudible) – it's great to have you.

ADMINISTRATOR SHAH: Thank you very much.

(Off-side conversation.)

MR. MORRISON: Thank you all. We're at the end of our program, and I'm not going to do a wrap-up commentary. I just want to thank all of you in the audience, all of our speakers, and all of the staff work that made this a success. We welcome any thoughts you have. The video will be available online at CSIS and other linked institutions. And thanks again. (Applause.)

(END)