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I. INTRODUCTION—EXPANDING THE REACH OF BREAKTHROUGHS

I'm honored to give this lecture today. To me, NIH represents one of America's core competitive advantages: advancing science, technology and innovation aimed directly at improving human welfare.

And I believe, if we can harness that capability for the poorest communities in the world, we can leave an unparalleled legacy in global health in this next decade.

To seize this opportunity, we will need to do things very differently.

First, we need to improve the efficiency of our efforts and focus on building country-led health systems instead of donor-driven disease control programs.

President Obama's Global Health Initiative is making real progress in this effort—proving that in global health, saving money saves lives.

In Kenya, we worked with PEPFAR to couple HIV/AIDS treatment to maternal and child health services. As a result, we've extended access to reproductive health services from 2 to all 8 of the country's districts, at no increase in cost.

And in Mali, we were able to integrate five separate annual health campaigns into one streamlined program. The program boosted provision of Vitamin-A supplements and NTD treatments while cutting the cost of delivery in half.

These efficiencies—from dollars to lab time to hospital beds to specialized labor—allow us to extend services to more people in need, delivering greater progress at no extra cost.

But integrated service delivery alone will not achieve success. Our real opportunity rests in harnessing the power of invention—scientific, technological, and behavioral—on behalf of the developing world.

Doing so will require us to redefine our role in Global Health.

We cannot simply seek to do more of the same in an effort to provide services using currently available tools and technologies. Instead, we need to focus our efforts on facilitating a continuum of invention and innovation from bench to bush.

This will not be easy. Our politics will tend to prioritize doing what we can achieve today over inventing, introducing, and scaling up new solutions for the future—often criticized as unproven, and costly. This is why new technologies often take two to three decades to reach those they would benefit the most.

But we can build a new global health system that better connects what is happening in labs here at NIH with what is needed in USAID field sites and produces real breakthroughs in our capacity to improve the health of the poor.

If we can target the freed resources provided by GHI toward the expansion of these new scientific breakthroughs, I believe by 2016, we can save the lives of over 3 million children, prevent more than 12 million HIV infections, avert 700,000 malaria deaths, ensure nearly 200,000 pregnant women can safely give birth, prevent 54 million unintended pregnancies and cure 2.4 million people infected with TB.

II. AN AMBITIOUS BUT DAUNTING AGENDA

This is an ambitious agenda. And while hopeful, I realize it is also daunting.

But it's an agenda we must embrace because the challenges we currently face in global health are extraordinary. This year, more than 350,000 women will die in pregnancy or childbirth, 8 million children will die of preventable diseases before their fifth birthday, and 2.6 million new people will be infected with HIV.

It's difficult to comprehend what such a massive degree of human suffering those statistics actually represent.

It means that a woman in Southern Sudan is more likely to die in childbirth than finish high school.

It means a child born today in Swaziland will live half as long as one born 11 years ago, due to a rampant HIV epidemic.

And it means that a girl born in Chad is only ten percent more likely to learn how to read than she is to die before her fifth birthday. As Secretary Clinton has noted, this undermines social stability and threatens our own long-term security.

Compounding these challenges are a number of deficits that limit the effectiveness of health systems in exactly the countries where these challenges are greatest.

Poor infrastructure limits the ability of people to reach sparsely distributed points of care; health facilities are dangerously understaffed; and health ministries have limited access to funding, unable to rely on consistent tax revenues or donor flows. In Malawi, per-capita spending on health is only $17.

But despite these current challenges, expanding the reach of scientific and behavioral breakthroughs has driven huge global health gains, proving that US investment in global health can deliver results.

III. AN INSTRUCTIVE LOOK AT THE PAST

In recent decades, we have witnessed the most impressive global health gains the world has ever seen.

The invention of vaccines for smallpox and polio have led to the eradication and near eradication of tremendously debilitating diseases.

The invention and widespread propagation of oral rehydration salts—spearheaded by USAID—prevented 3.6 million child deaths in communities and villages.

And innovative work by the Clinton Foundation to lower the cost and increase the volume of anti-retroviral therapy—together with investments from PEPFAR and the Global Fund—have turned HIV from a death sentence to a treatable illness for millions of people.

In each instance, specific breakthroughs in diagnosis, treatment, and prevention technologies—or their production or cost— led to massive progress in global health. They unlocked political support as heads of state and donor governments began to see what was possible. And most importantly—they extended beyond the reach of formal health systems and touched people directly in their villages, schools, and homes.

But the truth is, we cite these examples because they are outliers. More often, our community sees massive delays in getting new technological breakthroughs to the poor. Two decades after Hib vaccines reached all kids in the rich world, they are just now reaching developing countries where their health impact will be much more profound.

Today, we stand on the cusp of the next generation of science, technology, pricing, and operational breakthroughs. If we can find the courage to do things differently, and quickly deliver these breakthroughs to the field, we can usher in a new decade unprecedented global health gains.

V. SUPPORTING A MIRACLE: VACCINES

The most transformative new breakthroughs we have at our disposal are vaccines. By expanding the coverage of existing vaccines and introducing new immunizations, we can save the lives of 4 million children over the next five years.

To do this, we need to deliver pentavalent vaccines combining immunizations against Diphtheria, Pertussis, Tetanus, Hepatitis B and Hib to the 60 percent of children born every year without access to them.

We also need to dramatically expand the reach of new pneumonia vaccines. Every year, over 1.5 million child deaths can be directly attributed to pneumonia, the leading killer of children in the developing world.

If countries are successful introducing a pneumococcal conjugate vaccine widely, they could save up to 500,000 of these lives every year.

Similarly, a rotavirus disease that combats diarrhea could save 300,000 of the 1.5 million children who die every year of diarrheal diseases.

Currently pneumo costs $3.50 per dose thanks to advanced market commitment negotiations, while rota costs $5. Even at these prices, these vaccines represent a fantastic bargain, but with rapid, widespread introduction, we can generate higher product volumes and lower costs for the poorest countries.

Finally we also need to reach the remaining children worldwide who suffer from polio. The US has been the largest supporter of polio vaccination worldwide, and will continue to be a leader as we finally eradicate polio. USAID hopes to use our current extensive programming in Afghanistan Pakistan as a unique platform to tackle polio outbreaks and immunize children in regions where conflict limits the global health community's reach.

The work we do today to build cold chains and last-mile delivery systems will also prepare us for the transformational vaccines of the future. Even establishing simple technologies like bar code labeling and computerized inventory tracking will make a world of difference the day we are able to produce an effective and safe malaria or HIV vaccine.

The evidence is clear; vaccines are the best public health investment we can make. Our best hope of sustainably eradicating malaria, preventing TB and closing the chapter on AIDS will depend on their development.

But despite the evidence,

- Despite the fact we have proven mechanisms like GAVI to procure vaccines at the lowest-tiered price for the poorest countries

- Despite already having a vaccine manufacturing base that reliably produces 100's of millions of doses each year for pennies

- Despite having delivery systems in place to reach 100 million children each year

- Despite the case for vaccines being so compelling that warring factions lay down their arms to immunize their children

Despite all of this, we struggle to find the resources to invest.

For USAID, this will change. We will build up our vaccine team in the Agency so that we become leaders in developing the innovative procurement and financing solutions (such as AMCs) that make vaccines available and affordable.

Each of our missions will identify weaknesses and invest in improving cold chains and delivery systems and we will support countries in developing aggressive plans to introduce new vaccines for rotavirus, pneumococcus, and meningitis.

We will focus on product development partnerships such as the Malaria Vaccine Initiative and the International AIDS Vaccine Initiative.

And we will double-down on one of the best life-saving investments USAID ever made—the first public funding of GAVI, the Global Alliance for Vaccines and Immunization.

That initial investment in GAVI has led to the prevention of more than five million childhood deaths, a mammoth return by any account. We will expand our support of GAVI and help it address its current funding shortfall.

But going forward, we will do more than simply provide funding. Our field staff has a strong sense of what interventions are needed—and of the financial, operational, and behavioral constraints that define the environments in which we operate.

We will begin publishing target product profiles that can serve as a guidepost for developers—describing our sense of the realistic cost, formulation, and performance characteristics of new vaccines.

VI. OVERCOMING INEQUITY: WOMAN AND CHILD HEALTH

When a child cannot get a vaccine and dies of a preventable disease, it offends our conscience. When an AIDS patient cannot access or afford life-saving treatment, it affronts our dignity. But when a woman in the developing world dies during childbirth, we consider it a fact of life. We find it—somehow—acceptable.

I've given a lot of thought about why this is the case. I've heard many experts say that reducing maternal mortality is too complex, that it's too difficult to achieve in countries where most women will never see the inside of a hospital.

But I cannot escape the conclusion that our current state of affairs—where a pregnant African woman is 135 more times more likely to die during childbirth than her Western counterpart—exists simply because she is a woman.

To me, this is unacceptable—the death of a woman during childbirth is unacceptable—regardless of where it occurs.

That's why we have scoured our data to identify best practices to improve care. We have now asked each of our 28 missions in high-burden maternal mortality countries to implement these practices, and effort we appropriately call BEST.

It will require first addressing the significant unmet need for family planning in the developing world.

Innovations in products can allow us to provide a broad range of family planning options to women. And innovations in service delivery like social marketing can leverage the private sector to reach well beyond traditional health systems. New approaches to counseling can result in better health outcomes and help women ensure healthy timing and spacing of their pregnancies.

We have entered an important partnership with DFID, AusAID and the Gates Foundation through which we can avert 54 million unintended pregnancies in the developing world in five years.

And for pregnant women we have to invent a technologically capable support structure—built around trained birth attendants —that can eliminate childbirth related deaths for women and save newborn lives.

By training community health workers and midwives, providing them with new uterotonics like misoprostol and uniject-administered oxytocin, rolling out active management of third stage labor, and using mobile text messages to deliver targeted information to pregnant women and new mothers, we believe we can save more than 200,000 women from dying in childbirth.

And by employing basic newborn resuscitation techniques and technology, we can combat birth asphyxia, which accounts for a quarter of newborn deaths. It was an NIH-funded study, First Breath that first provided the evidence that USAID should increase its involvement to combat birth asphyxia. As a result we are now working with Laerdal Medical to help roll out a cheap new newborn resuscitation device for community use.

This and other new technologies will allow us to save the lives of nearly 2 million newborns.

These advances don't lie in building more hospitals or training more doctors. Frankly that will take decades. They lie in bringing quality services directly to women in their own communities.

Development professionals spend a lot of time extolling the virtues of investing in women and girls; USAID is no different. But when it comes to maternal and neonatal mortality, we must ensure our investments, our scientific inquiry and our politics live up to our rhetoric.

VII. WHAT SUCCESS LOOKS LIKE: MALARIA

One area where our commitment has clearly and successfully lived up to our rhetoric is in the progress we've made fighting malaria.

The previous administration created the Presidential Malaria Initiative because they realized an effective campaign of scaling anti-malarial breakthroughs beyond health facilities could fundamentally change the disease's epidemiology.

Just 5 years ago, we all noted that malaria killed 1 million children a year in Africa and cost the continent of Africa $30 billion a year in lost economic productivity.

Today we've helped cut malaria cases in half in over 40 countries, reduced childhood malarial deaths by 200,000, and even seen a reduction in all-cause childhood mortality in seven PMI countries. We expect to see that same result in the remaining countries once more data become available.

I find that last statistic astounding. It means that through one intervention, we are generating an entire cascade of public health benefits.
By preventing children from contracting malaria, we're reducing comorbidity, making them healthier over the long-run and freeing up resources to attend to other needs. In development, successes that impressive are far too rare.

The main reason PMI has been so successful is that uses a number of outlets, including schools, community theater and woman's groups to target people where they live.

Last September, UNICEF released a study detailing progress against the Millennium Development Goals with regard to inequality. It won't surprise you to hear that almost all progress against the MDG's has

favored richer people over poorer, urban residents over farmers, men over women—except when it came to the reach of malaria interventions.

The community-driven approach of PMI has led to a remarkable result: an equitable distribution of malaria prevention and treatment interventions. Equal access amongst rich and poor, urban resident and villager, men and women.

To distribute the same kind of gains across our global health portfolio, PMI's efforts must serve as a model.

In the meantime, we can push the Initiative's success even further. The global health community is now poised to remove malaria as a major public health problem across sub-Saharan Africa, saving an additional 500,000 lives annually, most of them children.

To do this, we need to increase the distribution of insecticide-treated bednets, boost indoor residual spraying, expand provision of artemisinin-based combination therapies, and target pregnant women for preventive treatment.

Then we must invent new solutions. We need to give community health workers a point-of-care diagnostic that can quickly determine whether a fever is a result of malarial infection. We need to develop new classes of insecticide that can deter mosquitoes without harming human health or local environments. And we need to explore ways to lower the cost of artemisinin, either by breeding higher-yield varieties of the plant or making it synthetically.

Finally, we need to seek the ultimate biomedical answer to malaria: a cheap, effective vaccine. The RTS,S vaccine currently in phase-3 trials seems promising, and through the Malaria Vaccine Initiative, USAID will support other candidates that may show even more promise.

In a time of fiscal austerity, it may seem wise to look at recent gains and decide we can draw back our commitment to assistance. Current budget proposals circulating Capitol Hill are suggesting just that. But we should be very clear about the impact that decision.

If major donors withdrew their support, malarial infections wouldn't hold at current levels, they'd regress, devastating an entire continent, unwinding half-a-decade of miraculous progress.

This actually happened in Sri Lanka and Zanzibar; a lack of sustained funding prevented the elimination of the malaria and led to surges of new infections and deaths.

So our choice is clear—continue to build on a bipartisan legacy and eliminate malaria as a public health threat, or unwind that progress and put millions of children's lives at risk.

VIII. TURNING THE TIDE: HIV AND TB

PMI's success has helped chart a course to one-day end the threat of malaria. But despite dramatic gains in the last decade, we unfortunately can't say the same thing about TB or HIV.

Unless we aggressively develop and introduce a series of new biomedical and behavioral health innovations against both these diseases, we will not turn the tide against them.

TB

TB has always been the signature disease of the urban poor. In a world that is urbanizing at a rate of 200,000 every day, we must fight TB now before it becomes an unparalleled global killer. The frightening growth of drug-resistant strains of TB—some of which cannot be treated—make the case for combating the disease more urgent than ever.

But continuing to do more of the same—often the result of a relentless drive to report on the number of people in treatment—will not work to turn the tide against TB.

The reason we've seen such a rise in drug-resistant TB is because we are simply not able to accurately detect infection. Current diagnostics require specialized lab facilities, trained personnel and weeks to deliver results. And they frequently yield false positives.

Our current best hope is to improve TB detection using rapid genetic diagnostics that can identify the presence of tuberculosis and its resistance to antibiotics. These diagnostics, such as the gene XPert genetic assay, are quick, easy to perform and accurate.

But they are not cheap—the gene XPert machine costs $25,000 and each diagnostic can cost between $20–$60. USAID will use its commodity procurement capabilities to accelerate the distribution of gene XPert and other cutting edge diagnostics that are in development so we can deliver economies of scale and lower costs, replicating our experience with vaccines and ARVs.

But even if TB is accurately detected, our current treatment regimens require direct observation and a long course of treatment—up to two years for MDR-TB. This makes patient compliance extremely challenging, leading to incomplete treatment and further drug resistance.

Late-stage clinical trials of shorter-course treatments are currently underway, and within five years will be registered and ready for use. The shorter regimens will result in improved adherence and higher cure rates, decreasing TB transmission and antibiotic resistance.

USAID is strengthening its capacity to assist the development of these new courses of treatment. But we need NIH, CDC WHO, and others to focus on dramatically reducing the length of treatment regimens, the effectiveness of new combination therapies, and on integrating TB control tightly into health systems.

HIV Prevention

The most important letter in the acronym PEPFAR is E. When the previous administration introduced the program, the world truly was in a state of emergency. HIV was killing 2.1 million people annually, and infections were raging out of the control, ravaging sub-Saharan Africa and leading to significant drops in life expectancy.

PEPFAR's push to treat HIV-positive patients has saved millions of lives, and crucially, it has given the world a sense of optimism that the war against AIDS is a war we can win.

But to win that war, we must engage on other fronts. Having achieved success in our campaign to treat millions with ARVs, now we must sharpen our focus on preventing new HIV infections.

Our administration has conducted analysis describing what it would take to turn the tide on HIV, bringing the current number of new infections below the number of patients treated.

First, we must start with behavioral campaigns aimed at curbing risky sexual practices, similar to the successful models we've seen in Thailand, Senegal and Uganda in the 1990s.

More recent data from sub-Saharan African countries suggest that rapid declines in HIV infection rates have primarily been associated with behavioral change: delaying sexual debut, reducing the number of sexual partners, and practicing safe-sex.
The greatest potential for future rapid declines in HIV lies in supporting these population-level behavior shifts.

Here, last year's landmark CAPRISA trial provided us with a preview of the next crucial tool in this fight: a gel microbicide that women can use to protect themselves from HIV infection.

By giving women the power to protect themselves against HIV, we can counter the pernicious gender imbalance that limits a woman's ability to protect herself from the risk of transmission.

There has been some debate about next steps. The reality is—like contraception—women should have many different options available to them through health systems, private sector, and community distribution channels.

We will work with the FDA, NIH, the Government of South Africa, and others to accelerate further testing, regulatory approval, and widespread availability of this and other products. This is a transformational breakthrough and we all need to act with a much greater sense of urgency to push its success.

USAID will also embrace the success we've witnessed in reducing HIV infections through circumcision campaigns. It was NIH that first discovered the dramatic effect circumcision could have in limiting the transmission of HIV.

We are now supporting the government of Swaziland's bold strategy to circumcise all eligible men over the coming year. We've been surprised at the success we've already seen in attracting teenage and adult men to join these programs, despite a large social barrier to participation.

We will also need to strengthen attempts to reduce mother-to-child transmission of HIV. The power of this intervention is clear: in the developed world, ARV treatment and safe infant feeding has virtually eliminated pediatric AIDS.

There's no reason we can't achieve this same result in the developing world by focusing heavily on community outreach. In South Africa, we fund a program called Mothers to Mothers, training women who have received PMTCT to promote its benefits and fight social stigma.

Finally, we will need to look to the future. We were encouraged by studies driven by NIH research that showed ARVs taken as prophylaxis could reduce HIV acquisition amongst men who had sex men by as much as 44%. USAID will work to ensure we bring ARV PrEP, as well as microbicides, to market as soon as possible. And we will continue our support of IAVI to build on positive HIV-vaccine results we saw in Thailand last year.

XI. OUR BATTLEGROUND: THE LAST MILE

Last November, my third son was born, in a hospital not far from here. To date, he's received his first dose of several basic vaccines. And even though some of those shots stung, they will help protect him for the rest of his life.

Today, 90% of all children born in Tanzania will receive those same, exact vaccines. They will receive the same protection, and their parents will experience the relief I take for granted, knowing their child won't die needlessly from a preventable disease.

But while my son received his vaccines at the hands of a skilled attendant between hospital walls, a Tanzanian boy is more likely to receive his doses in a village, administered by a community health worker.

To be successful, this is a paradigm we must embrace: a world-class vaccine does not need to be delivered in a world-class hospital for it to be effective.

Our experience with GHI has made clear: our largest opportunities to improve human health do not lie in optimizing services to the 20% of people in the developing world currently reached by health systems; they lie in extending our reach to the 80% who lack access to health facilities. That is where the success of everything I've discussed today will be determined.

That is our battleground.

And I am proud to say: that is where USAID will lead the fight.

But this will require a change in our collective mindset. We cannot focus exclusively on delivering services with current tools — we need to focus much more on inventing solutions that extend the reach of these services.

When a woman dies in a distant village, the blame must not lie on her inability to reach existing facilities, it must lie on our inability to reach her.

We will empower community health workers and midwives to extend deep into rural villages and urban slums, equipping them with foolproof diagnostics and treatments so they can effectively cover the last mile.

We will set goals, design strategies, and cut the time it takes to transform discoveries in the lab to success on the ground—shortening the distance between bench and bush in everything we do.

We will develop a center of excellence to accelerate product development and field introduction, bringing in industry experts and academic fellows to inform our thinking, and investing seed capital in promising ideas wherever they are found.

We will work with firms to make sure their biomedical products can reach the poorest people in the poorest countries, while recognizing their need to profit.

And we will leverage our commodity procurement systems to prioritize buying new technologies to get volumes up and prices down in creative new ways.

To keep us all focused on whether we really are changing the field of global health, we will release an annual accountability review of global health technology, detailing product introduction and adoption, and identifying areas where we can accelerate progress.

And finally across this next year, we will unveil a series of scientific and technical challenge grant programs designed to focus the community on inventing the breakthroughs that can truly span the last mile.

This will range from efforts to invent new ways to empower community health workers with foolproof diagnostics to using mobile phones to improve connectivity to health facilities.

XIII. CONCLUSION: SIGNS OF VICTORY

So I look forward to what we might achieve by 2016. I look forward to our chance to say our collective efforts led to real results…

…that the majority of all children have access to pentavalent, rota, pneumo and meningitis vaccines and that we have eradicated polio…

...that through voluntary family planning services and new contraceptives, we have averted 54 million unintended pregnancies…

…that nearly all childbirths are attended to by skilled health workers empowered with new technologies…

…that declines in malaria deaths are so dramatic, African nations are more concerned with fighting communicable diseases …

…And that we turn the tide against HIV and TB just as new microbicides, new diagnostics and short-course treatments enter markets and distribution channels.

But for me, the real sign of victory will be looking into my son's eyes on his fifth birthday and knowing that children born throughout the world can rely on the same quality of care he can, even if it isn't offered in a hospital.

Thank you.