

**The First and Next 25 Years of AIDS Science and Medicine:
The Next 25 Years: Research and Development
National Press Foundation
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BOB MEYERS: The way this program has been designed is to take a look in two panels keyed to the 25th Anniversary of the MMWR publication on June 5, '81. Take a look first at our research and the development, take a look at what has happened in the past, and just sort of help us anticipate what we think we can expect in the next few years. Twenty-five years in this particular disease is an awfully long time. And then in our second panel to take a look at the clinician, patients, and the epidemiological perspective.

So for our next panel we have three people who are devoting their lives to the subject of research and development. Mitchell Warren is the Executive Director of the AIDS Vaccine Advocacy Coalition. Zeda Rosenberg is CEO and Chief Executive Officer of the International Partnership for Microbicides, and Dr. Paul Stoffels is Company Group Chairman, Global Virology at Tibotec Pharmaceuticals.

First I want to thank Tibotec for its vision in helping us put this program on. I apologize for not having done it earlier. It was in my notes, and I never read my notes. So let me ask Mitch Warren if you will start us off and then we'll go across. Each panelist will speak for about 10 minutes, and we'll have Q&A. Again, we'll always on the record.

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MITCHELL WARREN: Do you need me to come up there,
Bob?

BOB MEYERS: I think it's actually up to you,
wherever you feel most comfortable.

MITCHELL WARREN: I'm comfortable anywhere. Is it
easier for people for me to get up perhaps.

BOB MEYERS: Then I would go for it.

MITCHELL WARREN: Well thanks very much, and thanks
for inviting me. It's a great pleasure to be here, and it's
funny, I think about technology and research and development.
Twenty-five years ago we didn't have screens that went up and
down, we didn't have PowerPoint and wireless microphones.
And it is actually remarkable how meetings have changed
because of all of that technology. We even have
Blackberries, and imagine how that would affect our work
lives today if we didn't have those.

And in the midst of all of that transformation, all
that technological development, we surely would have hoped 25
years into the epidemic we would have had an AIDS vaccine.
And I stand here before you, and you heard from Dr. Fauci
quite clearly that we don't. And the question I think we
have to be asking ourselves on this fairly tragic anniversary
is will we be 25 years from today, celebrating the 50th
Anniversary of the MMWR report and wondering, do we have a

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vaccine, will we have a vaccine, why didn't we have a vaccine? Why did we have a vaccine, but it didn't get widely enough used? Why is the epidemic still raging on?

Or will we, perhaps more optimistically, stand here 25 years from now and look back and have sessions, and meetings, and 160,000 articles about how we stopped this epidemic, an epidemic that not only defies medicine and science, but has clearly defied communities and cultures and political systems of all sorts.

And I don't have the answer to that. And one of the reasons - I'm not sure if any of us are using slides - one of the reasons I didn't want to use slides is it's easy for Dr. Fauci to have 25 years looking back, and have slides of headlines and pictures. I'm not sure what slides I would put out for looking forward into the next 25 years. But I'm going to try in the next few minutes to at least give you my sense of where we might be generally, and certainly with specific reference to an AIDS vaccine.

I want to start by just framing it and saying how delightful it is to be on this panel here with these two colleagues. I often go to meetings where we talk about vaccines, and we talk about vaccines, and we talk about vaccines, and one of the things that's clearest to me is that those are really boring, and the second thing that's very

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clear to me is that this epidemic isn't going to be stopped because of any one technology, any one treatment, any one prevention paradigm.

In my understanding of the epidemic in my work over the last 15 years, it is clear to me that we need combination approaches, and you heard Dr. Fauci describe and show a wonderful slide of how the epidemic on an individual level really changed going from monotherapy, to double therapy, to triple therapy. And that combination approach for treatment is what we need to be doing in a combination approach to prevention, and what we need to do in a truly comprehensive response to the epidemic.

And so often those of us that do work in AIDS vaccines are kind of an exclusive group because a vaccine is going to end the epidemic, because that's the only thing that does end viral epidemics. We know that from public health history. But what I think we more importantly know from HIV and AIDS in these last 25 years is this epidemic will only end when prevention that we have today – condoms, needles, abstinence, fidelity – all of that is packaged with new technologies – vaccines, microbicides, male circumcision, if we can think of it as a technology, a service, with treatment, and what for me is important over the next 25 years is that we not only develop the technologies for

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tomorrow, but that we constantly reflect on delivering what we've got today.

It's always easy in R&D to think that the best product is the one you don't yet have. The product that we think is really going to be the best is the one that hasn't yet been developed. It's always that one on the drawing board, and we need to be sure that we always maintain that momentum forward, but we can't ever do it at the expense of delivering what we've already got. So perhaps in looking forward for me in the next 25 years it is important that we reflect on what we've done in 25 years, and ensure that all of the prevention and treatment that we've got is scaled up as rapidly as possible while simultaneously developing these new technologies.

So it's really important for me to be sitting here with what we actually call often in our work, the MTV approach, and that is not the network. That is Microbicides, Treatment, and Vaccines – three areas both of existing work and of future work that in many ways are going to determine the course of the next 25 years of the epidemic.

I'm going have several lists over the next few minutes. My first is what I think of as three constants over the last 25 years. The first constant is that the need for a vaccine can never be overstated. The need to end this

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epidemic through a vaccine and anything else that we can get can't be overstated, and you saw Dr. Fauci present that data.

The second constant is the scientific challenge to developing an AIDS vaccine. Every time we think we've learned one more piece of the puzzle around this virus, and we have unlocked and uncovered many of those puzzle pieces over 25 years, every time we do that, we continually are defied in turning that information into a vaccine. So the second constant is that challenge scientifically.

And the third constant over the last 25 years, except for one outlier, but the other constant is that we'll have a vaccine in a decade. That's one of the great truisms of 25 years. You can always say we're going to have a vaccine in a decade, and you know, you can wait long enough, and another decade will come, and you'll say we'll have it in another decade. The one exception to the rule was Margaret Heckler, the Secretary of HHS, under President Reagan, who thought we'd have it in a couple of years. And I wish she'd been right, but she clearly was not.

It's interesting about this idea of a decade and the fact that we're celebrating a 25-year Anniversary. I always liken it to my experience being a parent. I was told early on that when you go on car trips with your children and ask "Are we there yet?" you tell them 20 minutes. And I said,

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"Why is that?" And they said, "Well, if you tell them any longer than that, they're going to haunt you every couple of minutes - "Are we there yet? Are we there yet?" - and if you tell them two minutes or five minutes, they get that, and they'll come back in two or five minutes, and say, "Well, you told me we were going to be there in two or five minutes," but 20 minutes seems to be that perfect period of time that keeps them guessing, keeps them coming back for more, and I think we do that with the research for an AIDS vaccine.

We'll have it in a decade. And I'm not going to stand here and make a prediction that we'll have it in a decade. In fact, I can tell you we won't have the ultimate vaccine, the one that we really long for, a safe and efficacious vaccine delivered once, ideally without a needle, delivered cheaply, with 100-percent prevention. That won't happen in the next decade. We might be further along the way. And that may sound rather cynical, but what I want to make very clear is I think we are at a really critical turning point in the search for an AIDS vaccine.

And my second list, then, are what I think over the next three years are going to be really critical answers we're going to get. Will they be the AIDS vaccine we long for? Most likely not, but they will move us much further along. So what are they?

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One is really a sense of where we are with our current pipeline of candidates. Over the next three years we are going to get some answers about what many regard as the lead vaccine candidate, or the lead vaccine concept, and it's currently developed in two different places with the same vector, the same delivery mechanism using the cold virus of adeno – the adeno virus.

And the Merck Corporation has a product that is currently in a large-scale test of concept trial, which is a very exciting effort in collaboration with the NIH and its HIV Vaccine Trial Network. And NIH's Vaccine Research Center is working on a very similar construct using what's called Add 5, this Adenovector.

We will know in the next three or four years if that technology might work. It doesn't mean it's going to be a licensed vaccine in three or four years, but we will have a sense in the next three or four years, because of the trials currently going on whether that approach, and whether the approach looking at what we call cell-mediated immunity, whether that type of vaccine for HIV can make a difference in the epidemic.

And that is a huge, huge issue. A lot of people liken a search for a vaccine to a marathon. We say it's a marathon, not a sprint. Well, it's actually not a great

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analogy. In a marathon you know that in 26.2 miles, you're going to end. We don't know where that stopping point is with an AIDS vaccine. But knowing the answer to does Ad-5 work, does cell-mediated immunity vaccine work against HIV in the next three or four years is probably the most important cup of water one gets along the marathon racecourse. So it's a critically important question.

The second important thing we're going to find out in the next three years is can we do this work internationally? Can we do it well? Can we do it efficiently, and can we do it ethically? And this is not unique only to an HIV research, but it's very true, and I think what we'll hear from Zeda around microbicide research, how we do this in responding to the epidemic. Research takes place where the epidemic is, and that's true in the US and it's true in the developing world, and understanding how to do research in resource poor settings with people and with communities that are already marginalized is an incredible challenge. So in the next three years we will have a better understanding of can we do it – which I think the answer is yes we can – but how we do it, and how we ramp up capacity for the next decade to ensure a constant flow of resources and ability to do that research.

I should say in particular we will understand a

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couple of important groups of individuals, groups of communities in that research process. Someone asked a question earlier about adolescents and pediatrics. We have very, very limited experience about HIV vaccine research with adolescents and pediatrics. We need to do it better. We need to be ahead of the curve, because as Dr. Fauci said, we're going to want to vaccinate people before sexual activity to really be successful. So we're going to need to do research with adolescents, and that's not as easy as it may seem, and we need to spend a lot of time doing that.

And I should say also that in the next three years we're going to learn a lot with the rollout of the HPV vaccines. As you may know, over the coming months we expect two HPV vaccines, one from Merck and one from Glaxo Smith Kline to be licensed, and how those roll out, how they get delivered to adolescents, perceptual debut is going to be a critically important precursor to how we do research with adolescents and HIV vaccine research, and how we eventually deliver an HIV vaccine.

And the third effort, the third issue that we're going to come to learn a great deal about over the next three years is less about what we do and more about how we do it. Some of you may have followed over the last three years the advent of the Global HIV Vaccine Enterprise, an effort that

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brings together the NIH, the Gates Foundation, the International AIDS Vaccine Initiative, and many other agencies to try to get the world to do this work better, in a more collaborative fashion.

The important step right now is that there is a clearly defined scientific agenda that all of the different stakeholders involved in AIDS vaccine research understand, and it's interesting – that agenda is largely driven by what the questions are. We don't have agreement on what the answers are yet, but it's very important in such a long road ahead, to at least know that we're asking the same questions and we're working in a similar methodology. And that Vaccine Enterprise idea is just beginning to take off. A new executive of that organization has been selected and will start on the 1st of September, and how that Vaccine Enterprise brings together role players from around the world where hundreds of millions of dollars are being invested, and how we ensure that's it's being done well, and answering those questions that we have all through consensus defined is going to be the real test. So the next three years will tell us that.

It's important also to understand why we do this, and I think you saw with Dr. Fauci's slide why we don't have an AIDS vaccine. You may well ask yourself, "Well, why do we do

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this?" And over the last couple of years right as the Vaccine Enterprise was coming together as a concept and a framework, there were a lot of people, or at least some people in the scientific community beginning to say, "Well, maybe we need to imagine a world without an AIDS vaccine." And there was a great deal of cynicism in the field at large. And that's been largely debunked, and there is a sense of optimism in the field, in part because of the Enterprise, but in part because of a couple of key things that we do know scientifically, and I think it is going to chart the course for the next few years of vaccine research.

One of the key things we know scientifically is that in monkey models, in animal studies, there are attempts, there have been studies that show that you can stop the simian equivalent of HIV, SIV in monkeys with a live attenuated vaccine. Now for a whole range of scientific and ethical reasons, we aren't going there at least yet in human trials with live attenuated HIV vaccines, but the fact that it can work in monkeys tells us something's going on there. We don't always understand why. So I think one thing to be watching over the next three to five years is how do we translate that finding of a live attenuated simian vaccine into a human setting, and how do we transfer that knowledge, and how do we replicate that.

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One of the other reasons scientifically why we think this is possible, is we do know there are people who are continually exposed to HIV, but do not become infected. And the most famous examples are sex worker groups in Kenya, and a group in Gambia, and there have been groups in the US as well identified, who are constantly exposed to HIV but never become HIV-infected. Why that is, how that is, is something we need to better understand, and there's a lot of work now looking at that, and looking at very early infection, and how do we get in at the very beginning of infection, and using knowledge from people who remain uninfected.

So there are great reasons, good reasons, to be excited about the prospect for a vaccine. It is not an easy process, as you can imagine. It hasn't happened in 25 years. It likely won't happen in the coming years. It's not around the corner, and the challenge then is to ensure that we stay on that marathon path, that we continually redefine the map of where we're going. This is not an Olympic racecourse that's been preset. This is one where we do a lot of empirical trial and error, and whereas the global community of scientists and policy makers, and communities working together trying to navigate that course, and reach into the end.

I just want to end by saying that one of my favorite

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comments came from a colleague, Emilio Amini, who's now with the Wyeth Corporation, and he likens the search for an AIDS vaccine to Christopher Columbus and the voyage looking for the new world, and no one knew where that new world was, and Emilio talks about the person who stood at the top of the ship and said, "Land ho, it's there," and until that point, we didn't know whether we were in the middle of the sea or whether we were right there at lands end. And that is very much where we are with an HIV vaccine, and that Global Enterprise now sits somewhere at the top of that ship, and is hopefully going to help us call out where that land is and where that marker is. And we hope that travel, that ship, goes quickly and expeditiously, and well here in the US and internationally.

Thanks very much.

ZEDA ROSENBERG, SM, Sc.D.: I'm going to sit and talk. I'm speaking about microbicides, the "M" word, which you all have been hearing a lot more about, which is relatively new technology, and Dr. Fauci mentioned that when he was talking about prevention, and I echo everything that Mitchell has said about keeping this as an umbrella of prevention strategies, which includes treatment if we're ever going to end this AIDS epidemic.

The reasons for microbicides, and I'll define them

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first. Microbicides are vaginal products that women can apply vaginally that will prevent HIV infection, and so these are drugs that can interrupt the transmission of HIV very similar to how we would interrupt the replication of HIV as a therapeutic, but here we are stopping the virus locally, and preventing it from becoming a systemic infection. Some of these products actually stop the virus from ever touching a target cell. Some of them actually act once the virus enters into target cells in the vagina. But they are all designed to prevent the virus from ever becoming a systemic infection, which you heard from Dr. Fauci, you never can eradicate, at least at this point in time with the current treatment strategies. So you really need to prevent, and you need prevent your way out of an epidemic in addition to compassionately treating and caring for all of those who are ill.

Now why focus on products for women? I think you also probably have all heard about the increasing feminization of the epidemic, and there are several reasons for the feminization of the epidemic. One is that when HIV is transmitted sexually, women see more virus than men. There is more virus in seminal fluid than there is in vaginal secretions, and so the risk of transmission from a man to a woman is much higher than from a woman to a man. So just by

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biology alone, women are going to get the short end of the stick here.

In addition, in the vagina there are more target cells for HIV, and vaginal tissue is more easily damaged, and especially for young women the vaginal tissue is more immature, it is more easily damaged during sex, so in the population of women, young women are at increased risk of infection. And so you have young women being the most vulnerable biologically for HIV, all else being equal, and then you enter into the social and economic reality of women's lives throughout the world especially in developing countries where there are social, and economic, and political reasons women cannot negotiate safe sex when they want to. So that they cannot insist that men use condoms, they cannot insist that men allow them to use female condoms, and as Tony also said, reproduction is kind of one of the all-encompassing things in the world. If everyone in the world used a condom consistently, correctly for every sex act, we wouldn't exist as a species. So you have to be able to have children, so right now women throughout the world have to choose between putting themselves at risk of HIV infection and having children. That's not just women - it's couples that have to choose that.

So you need another prevention technology. Ideally,

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the vaccine would be that kind of a technology that everyone can use – women and men – and it can be universal, and all of the perfect things. But that isn't happening, and so in the early '90s as we are seeing the difficulties with the development of vaccines, and we're seeing this increasing feminization as the epidemic, which was predictable very early on, just from what we knew about the biology of HIV infection, new tools were needed, and that kind of was the genesis of the whole microbicide research effort.

So the early generation of microbicide products were based before we knew a lot about highly active antiretroviral treatment. So this first generation, this early generation of drugs, have made it through the whole development process with all public sector funds, very slowly, because it was an effort that was driven by the public sector, but in a relatively low scale because of the hope for a vaccine, and those products now are all in large-scale efficacy trials in developing countries, mostly in Sub-Saharan Africa, also in India.

There are five efficacy studies currently ongoing. A minimum of 10,000 women have already been enrolled, and it will probably be increased to 20-25,000 women by the time these initial studies are done. They started in 2004-2005, and they will end at the end of 2007-8 and 9. Should those

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trials show significant efficacy with the early generation of products, you will see a microbicide on the market within five years. And again, everybody hates to do this five- to seven-year to ten-year range, but if these trials show significant levels of efficacy, then there will be a product on the market.

The next generation of products, and Paul knows this quite well, because we've licensed one from Tibotec, the next generation of products for microbicides is based on highly active antiretrovirals. So we're taking all of the successes that have been achieved in treatment, and putting them into topical formulations, and delivering them vaginally.

Now delivery of products vaginally is not something that the world knows a whole lot about, and it's not something that topical formulations were meant to be used over a woman's entire life span, so there's a huge amount of work ongoing now in how you design gels, creams, foams, vaginal films, patches, intervaginal rings that will deliver these products in a consistent way, and will be acceptable, and useful, and user-friendly to women for their entire sexual lives, and right now the gels that are being designed are being designed to be used once daily, they're long-acting, sustained release, so if we can move more towards the notion of the vaccine, which is the one injection for the

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life, at least here to have something that would be useful once a day, divorced from having to negotiate it during sex, once a day, once a month. I think many people in the US and Europe are familiar with intervaginal rings that are used for birth control. There are monthly methods for post-menopausal hormone replacement, there are three-monthly methods – these could actually be designed to deliver microbicides over extended periods of time. So there's a huge amount of work ongoing right now, and the novel drugs, and thinking also ahead when there was one antiretroviral, it did something. When there was two, it did more, and then when it was three it did even more, etc. We're going to have to think the same way about microbicides.

The first products that will be shown to be efficacious will be partially effective, and then we will be able to improve upon them with more and more drugs, different mechanisms of action to be able to complement. And so I think that this is kind of where the whole field has evolved, and in the last five years the funding levels have increased, although when Tony was talking about 12 percent of 23 billion – I can't remember all the numbers – but microbicides have been moving along amazingly well at very low levels of funding. In 2004 a total of \$140 million US was being spent for all of this work. And there have been suggestions to

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politicians, the G8, to at least double this every year for five years to be able to kind of put all of these new generation of products into these large-scale trials, which Mitchell mentioned.

What the vaccine effort has done has also allowed others to figure out how are you going to do these studies internationally. And the building up of the clinical trial sites, the building up of the capacity to be able to do these critical late stages of drug development in resource poor settings, in the populations where you want these drugs and vaccines and microbicides out there first.

And that's another kind of paradigm shift, I think, that what we want is we want in order to interrupt an epidemic, you have to go to where the virus is being spread the fastest. And right now that is in Sub-Saharan Africa, in Asia, and you have to be able to get these products out there quickly. So we will have all failed if we come up with a highly successful product, either a vaccine, microbicide, or therapeutic, and we can't get it to the people who need it. And if it takes 10 or 15 years, which is the classic paradigm, then we will have failed in our mission, and it will be that much harder to be able to control this epidemic.

PAUL STOFFELS, M.D.: Thank you Zeda, and also thank you Mitchell. I think this was a very good first practicum,

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and at the same time a tremendous challenge to make this work, because I think in drugs we have an easy task. It seems that in microbicides it's a very complex task at the moment to get to new products quickly because that's what the world needs in order to get HIV under control.

I come from a completely different perspective. I was very lucky to work the same time Anthony was talking about the emergence of the HIV epidemic here in the US, I was working as a medical student, and a junior doctor in Africa, in Canchelsa[missspelling?] and in Rwanda, working really in the field, seeing patients with HIV, and not knowing what was happening over there.

And we learned through the press, through literature, what was ongoing in the US, and as a junior doctor doing surgery, and with a lot of people, we were very worried about what was happening, because we saw just a massive epidemic in the hospitals in Canchelsa and in Central Africa, but we couldn't do much about it. We could just treat a little bit of TB, cryptus sporidium[missspelling?] fungal infections of the brain, auto-candidiasis was a very common, even the diagnosis at this moment, someone with capsicism and oral Candida, it was a predictive test of being HIV positive.

So for many years I spent my life there and worked on HIV, and then unfortunately needed to return with the first

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war in Rwanda and started in the pharmaceutical industry working on HIV treatment and trying to find new drugs, because I had made it a mission in life that I have to make a difference here, and so we started working on HIV therapy a long time ago – around 15-16 years ago.

But failed. And we failed why? Because the reason is what Anthony was saying was resistance, In the early days we didn't know what the virus was doing, the biology of the virus. We were testing new drugs and resistance was one of the major reasons why the early drugs failed. So working on that for many, many years, learning what resistance was doing to patients, and how it emerged, and what the epidemiology of resistance was after drug use, we studied so that we could find out that finding new drugs which were active on resistance was probably the way to go, and that's what we did.

Another reason why drugs failed was PK – pharmacokinetics absorption. The first drugs had very poor absorption, and by improving on those two features, the pharmaceutical industry and also ourselves, we succeeded in coming up with drugs which were really making, I think, the difference. Where in the early HIV epidemic, life expectancy was two-three years when diagnosed with HIV, today, with AIDS, with symptoms of AIDS today, HIV patients theoretically

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should not die any more from the disease if therapy is correctly administered and if there is good infrastructure to do the follow up of the patients. So there was a massive evolution by making new drugs available from a deadly disease to a chronic infection.

Now that goes together still with a huge challenge. If we say chronic infection today, people have to take their drugs every day, with very significant side effects over the long term, the safety of the compliance, taking the drugs for 20 years. If we have to take an antibiotic for eight days it's a big challenge. Taking a drug for 20 years is just an enormous challenge, so were going back 25 years, from a drug perspective and a therapy perspective, where are we going to go? I think with drugs we are going to go to make drugs which are much better active on resistance, much simpler to take.

Where we need to bring next generation drugs is on safety. Make sure that people don't have long-term side effects, lipodystrophy being one of the very significant side effects, cardiovascular side effects. So that's going to be the main challenge. Where I think industry can bring drugs discovery and development and new therapies is bringing new long-acting versions of drugs where we probably could go from once a day, to once a week, to once a month. We will never

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be able to get a one injection, one pill, but with chemicals, administering chemicals to people in other diseases, we have seen that you can go from daily therapy, to weekly therapy, to monthly therapy. And if you look forward 25 years, I think that's something which definitely is within the possibility of the know-how and the science today.

Also new mechanism or actions will definitely be very important in order to treat the resistance, new drugs from the same target active on resistance, and making sure that new drugs have a high genetic barrier so that the virus can't definitely overcome it. So what will bring in the next 25 years, I hope, a very simplified therapy, much safer therapy which can be taken by patients. But as said during the whole day, during the meeting here, is the challenge would be bringing that therapy to the developing world and the rest of the world outside Europe or the US where especially the infrastructure is lacking to administer drugs to a massive number of people, and where today we think that by just bringing drugs to the developing world the problem is going to solve itself, those of us who work a lot in the developing world, including myself, we know that probably the biggest task is going to be to train the human capacity to deal with the massive number of people there.

If you go into cities like Dacho-Salam [misspelling?]

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and Tepi [misspelling?] Kampala you have a massive number of patients, and the health infrastructure just can't deal with it. Now the consequence of not having good health infrastructure in the developing world puts a big burden on therapy. We have seen here that by using monotherapy, bi-therapy, and incomplete therapies, we have seen an emergence of an epidemic of resistance in the patient community. And what my biggest fear at the moment is, is that by not having the full package of at the same time infrastructure and drugs, and the right diagnostic tools, we are going to have a second wave of patients in the developing world which are also going to suffer from untreatable or very difficultly treatable disease, and we'll have to go to much more complicated regimens to treat those.

So I think in a combination with industry and the international community, we should find a way to make sure that at the same time treatment and infrastructure is available, simpler treatment becomes available, and that will really make the difference as well, I hope here and in the developing world. And so with that I would like to open the floor for questions.

BOB MEYERS: We have some interesting perspectives. We've got a couple of microphones. We have questions.

FEMALE SPEAKER: Dr. Rosenberg, can you say why you

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think so little money proportionately has gone to the development of microbicides?

ZEDA ROSENBERG, SM, Sc.D.: Well I think if you think of money going into both vaccines and therapeutics, you look at the whole picture of both public and private sector, because you have the drug companies who have been doing a huge amount of work on the treatment technologies. Some of the big ones are actually working on vaccines, not clearly as many as there were at the beginning, and you need more, but for microbicides it has been purely driven by the public sector in funding very small biotechnology companies, so very little private sector money has gone into this at all, and it was just I think kind of a reflection of over time looking at all of these other prevention strategies that people were kind of very, very hopeful, especially vaccines, would be the fix, and if you just kept that focus on, it would work. I think it's coming a little late now, but there's been a huge increase in general in both foundation support, with the Gates Foundation, the Rockefeller Foundation supporting microbicide research since at least 2000 and many, many now European governments stepping up to the plate for microbicide development. The whole public-private partnership, which I'm not sure many of you know about, but the Rockefeller Foundation spawned IAVI, the International AIDS Vaccine

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Initiative, they spawned the International Partnership for Microbicides, which I represent, and then many European governments have been supporting IPM, as well as Canada, as well as now the US, and most of the work as well that has gone into microbicides, because NIH has done a huge amount that's been in research, and you need R&D. Okay? So there's research and there's development, and NIH is great at research. That's what NIH does. And it's the drug companies and the biotech companies that do both research as well as the drug development. They pick the high priority candidates, and they move with it, and that had been lacking in microbicides. There had been some non-profit organizations like Conrad and the POP Council, and the medical research councils of the UK that are now the sponsors of these large-scale trials that are funded by US, dfid, and the UK, as well as Gates, but the big companies haven't been there. And so it's really been that we're trying now to adopt a private sector virtual pharma model to pushing these products into development.

FEMALE SPEAKER: You mentioned that when the microbicides are developed and passed the trials, that the most important is also to get it out to the developing countries, but have you identified what kind of limitations in terms of social and cultural implications, and how

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possibly you're going to solve them, and effectively get women in developing countries to use microbicides?

ZEDA ROSENBERG, SM, Sc.D.: Well, the answer is yes, we've been thinking about it. I don't think anyone has solved anything yet. One of the interesting issues about microbicides is that the call and the need for microbicides actually came from women in developing countries. It is also one of these fields where it was women, and women's groups, and women's activists who brought the notion to scientists and said, "Women need something," and in fact it was working with The International Women's Health Coalition in the early '90s and the global campaign for microbicides, where women were seeing their sisters, their daughters, everyone kind of getting infected with HIV, this notion for many of them they had a single lifetime sexual partner, which was their husband, and so how are they going to abstain, how are they going to change their behavior. Condoms weren't appropriate in the sense of a long-term relationship, and so for them it was like, "Okay, well, what do you have for us?" And so I think the acceptability of these products is going to be much greater because it has been asked for by women, and every place where the current trials are going on, a huge amount of background acceptability work was done in asking women how you can adopt this into your lives. I think what

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is needed more in the microbicide field is market research, the classic – if you were Proctor and Gamble or Unilever, and you wanted to put something out there that somebody had to use every day for the rest of their lives, you would kind of figure out what they want first, and then design it. And so I think that the whole market research approach is something that a lot of us now are taking, because we are looking at this as something that people have to adapt into their lives, but there's a huge amount of community support on the ground in many, many countries.

There was just a microbicide conference in Cape Town, South Africa every two years. It started in 2000, and it was here in Washington where there were like 300 people. And then it went to Antwerp, and there were 500, and then it went to London in 2004, and there were 800, and in Cape Town there were 1,300 people. They had to close registration. And activists from all over Africa, treatment activists, vaccine, as well as microbicide – I mean this MTV things is actually a real group that they meet and they talk about how they're going to integrate, and work all together to promote all of these technologies. So there really is a lot of community support for this, and the notion of how to conduct these trials ethically was raised by women. There's a Society for Women and AIDS in Africa. It was raised by them in the mid-

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'90s, and there are all these ethical guidelines that came from the communities. How are you going to do these trials in an ethical manner that we can all get on board? So it's actually really interesting. I'm a scientist by training, but I was brought into this and told, "This is how you are going to do this work because this is how we need it to be done," and it's actually a really interesting and different paradigm.

MALE SPEAKER: One of the more controversial trials in areas has been using drugs for prevention. I'm thinking particularly of Tenofovir and some of the trials that are ongoing there, and the company has been supportive of that, but it has also indicated that it is not looking for an indication for this use, which according to them in this country has also some implications on willingness of third party payers and etc. How much of the reticence on the part of the company is tied to issues, at least in this country, of product liability? And how significant of an issue is something like that?

MITCHELL WARREN: It's actually a great question and a gigantic issue. Just to make sure everyone is on the same page, this is research that has been going on over the last couple of years to look at what we call pre-exposure prophylaxis, or basically would a pill a day, or a pill a

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week, or whatever regimen in advance of exposure to HIV prevent infection? And it's been dogged by controversy almost from the start. Their research is now – had been planned in about nine countries. Trials in five of those countries have been postponed or stopped for a whole variety of reasons, and in fact I can direct you – there's a website, avac.org/prepwatch, which is a website that we keep up, looking at where those trials are. And each of those trials closed for very different reasons – claims of unethical conduct, claims of inappropriate or lack of community involvement – and I think we still are trying to unravel what happened when, and who, what, when, and all of those types of questions. Here in the US the research is going on in Atlanta and San Francisco, and there are a number of concerns, not least of which is the issue of what happens if you give people a pill a day, and the level of disinhibition – if I take a pill, then I will be less likely perhaps to use a condom, or I'll think I can engage in riskier sex. So this idea of prep has really opened up a whole Pandora's box of issues, and the research, in much like the way Zeda described microbicides, although Gilead, the company that makes Tenofovir was supportive in providing the trial product, the trials were being sponsored by the public sector, and being managed by the public sector. And there is something

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wonderful when a company gets involved. When a company is driving forward, it has a very clear path to licensure and labeling, and in this particular instance it has been driven in large part by public sector, public health interests, and I think we have underestimated some of those challenges around liability, protection, and issues of what would happen if this were to be labeled this way. One of the big differences and challenges that we face is if Zeda or anyone in the vaccine field develops a product that goes through trials and doesn't work very well, it will never get manufactured. With prep, these are products that are already out there in the public domain, and they are available, and what if only works very partially, what if it doesn't really work at all, but already we hear reports anecdotally of people using it? And if it's a product that's not yet licensed, you could control for that, but if it's already out in the public domain, you have a much greater degree of challenge in containing it. So there are a lot of issues there. And the good news is there is a lot of work going on right now with the trial sponsors, with Gilead, and with various community organizations, to try to articulate a robust agenda to get an answer to the question, and then make sure that if the answer to that question is in the affirmative, that yes it does help in at least partially

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preventing infection, then how do we deliver it and manage all of those expectations. And so it's somewhat retroactively coming up with the research agenda, and a clear pathway.

MALE SPEAKER: I'd wanted to thank Mitchell for mentioning the need for a focus on a vaccine that would be able to be given to children. And I think a lot of people may not realize that there are reasons why an adult vaccine might not be able to be taken by children, and I wondered if you can comment on that in a little bit more depth.

And then similarly there's the problem that many drugs are not tested at this point, or formulated for use in children, and I wondered if we could just focus for one minute longer on the special needs of children.

MITCHELL WARREN: Absolutely. We at AVAC have called for the last couple of years along with Elizabeth Glaser Pediatric AIDS Foundation for a much greater degree of emphasis on the issue of vaccine research for pediatrics and adolescents, and the good news is that the world is listening. There have been a number of consultations of late, and there was just one in February with the World Health Organization to begin to develop some guidelines for when and how you would do research with adolescents in AIDS vaccines, and criteria is being developed that would look at

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when in the process would you begin to explore a product, and what's important is that there are a lot of vaccine candidates now. There are 30 currently in human trials, and the call for engaging young people in this effort is not to say every product should be tested on young people, but to come up with good, reasonable, scientific and ethical standards for when you would and wouldn't test products, and where I think the world is going is that where you see products that are deemed successful enough to go into what we call "Test of Concept Trials", large-scale phase two, early phase three efficacy trials in adults, we would at a minimum want to make ensure bridging studies are taken immediately to look at the possibility of how that would work with young people. At the same time, we need to accept that some products may work in young people and not in adults, and vice versa, and we need to have very clear scientific rationale for what we do when. The candidate I described with the Merck Corporation that is seen as one of the furthest along is already looking now at "Well, if we get an answer that it might work, or the concept works, how will we know if it applies to young people?" and collectively there are people looking at that issue right now. So it's getting better, but there is a major gap right now, as actually Tony talked about when people were storming NIH one of the biggest problems we

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have right now is getting very clear guidance from regulatory authorities – FDA and other regulatory agencies – about what they would expect and require for licensure for young people, and so while we have some scientific issues, we also have some very clear regulatory challenges, and we need to get very clear guidance from the FDA and others of where the bar would be with young people, and, again, very much a work in progress, but a critical area. It would be tragic to license a product a microbicide, or a vaccine, or a new therapeutic and not have it licensed for groups that need it the most. It would be almost a worst-case scenario, so we want to be sure that that's clear, and while we are still many years from knowing what to put into a trial in some cases with young people, we want that regulatory pathway urgently.

PAUL STOFFELS, M.D.: With regard to drugs, I want to say that it's absolutely a priority to get good drugs and formulations for children developed. Now it happened to be that most of the very potent compounds are lipophilic drugs and so to pharmaceutically technically to make solutions for those drugs, solutions which can be taken by kids, is a big challenge. Not only is the pharmaceutical technology a challenge, if you want to solubilize compounds, you need to use solubilizers which very often are much more toxic for children, so we have to find the right formulation. That's

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one.

Second, doing clinical research in children to develop drugs. Most of the time you want to have at least a good indication of safety in adults before you test new drugs on children, and so the complexity of doing clinical research. And those two reasons are mainly why it is more complex and it takes more time to get children to get formulations and new drugs licensed for pediatric indications. But let me reassure you, for all of the industry it's a priority that that is done.

MALE SPEAKER: I want to ask a question for Dr. Rosenberg. If a microbicide is approved tomorrow for the United States, what would you see the method of distribution being – prescription, over-the-counter, availability to inner city populations – what mechanism would you foresee for that?

ZEDA ROSENBERG, SM, Sc.D.: I think it would be most likely prescription, and I think that's the way the FDA is looking at the licensure currently. Again, there are a lot of unknowns here. It would be the first product of its class, so when you have a first product of any class there are a huge number of unknowns. I think that is also one reason why pharmaceutical companies have been kind of waiting as well to see how this is all going to play out. There are a lot of liabilities that were raised for microbicides as

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well. There are risks about regulatory approval, risks of the trials, etc., and risk of the market. What market is there? And so I think for the US, it would most likely be prescription based. My concerns as well – I know your question is directed at US populations, but our concern as well is how would we get it out in international communities and developing country communities, and whether the same kind of issues apply. Would it have to be provider prescribed? Will it be available on pharmacy shelves? Could people go to family planning clinics? Again, either here or in developing countries, what are the level of providers that you would need to be able to prescribe this? And I think if we think about Plan B, there are a lot of issues that we have to think about. When women need this, they need it. I mean you don't want to have barriers set, and I think that, again, it's going to be women's groups that will be driving how we can get these products out there as quickly as possible. Insurance providers, Medicaid – all the issues that have plagued birth control. There are unfortunately a lot of negative lessons that we can look at that we need to avoid. The positive path forward is a little less well lit.

MALE SPEAKER: Let's follow up on that, Zeda, with the FDA in terms of regulatory guidance. We all know that most of the product formulations for microbicide for use in

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sex would and could also be used engaging in anal sex, and a product that is approved for use in one, the next day is going to be used in the other. Has the FDA given any guidance in terms of at least safety, if not efficacy, for rectal use?

ZEDA ROSENBERG, SM, Sc.D.: Well, there's actually no written guidance, and again this has come more from activists, community groups, women themselves, gay men, and it's clear that we know that these products will be used in a variety of different ways, and I think all of the drug developers are committed to understanding before licensure, safety. And again it's not straightforward, because how do you measure safety of these products for rectal application? And there's a fair amount of work, again much of it sponsored by NIH and the Centers for Disease Control, that are looking at measures and markers of safety for rectal application of microbicides. And so all of this is kind of going in parallel, and will need to be looked at in parallel, after the efficacy studies are done, and we see that these products actually work to prevent vaginal transmission. During that whole regulatory licensure process, there will be a huge amount of studies done to look at safety for rectal application for both men and women.

MALE SPEAKER: Hi. I have a question about as we

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move forward with research, and we're looking at the MTV approach, and all the new vaccine candidates are going into research and microbicide candidates, what's being done at the local level, in particular in what might be considered hot spots where incidence rates are really high, and places that might be attractive for research to make sure that resources are being coordinated, we're not bumping into each other, we're not going into a community one month, enrolling people in one trial, and going in the next month and enrolling people in a completely different trial and confusing the community? So that's my first question is more on coordination.

My second question is in creating an environment that is supportive locally for this type of research, because a lot of the people that are coming into those communities are from the US, Europe, international organizations, and so really creating an environment that creates support and confidence that these trials are being conducted as ethically as possible, and also with the full coordination and knowledge of local governments?

ZEDA ROSENBERG, SM, Sc.D.: I can start because actually yesterday in New York we did a co-briefing to all of the UNGASS ambassadors on IAVI and IPM – vaccines and microbicides, looking at this as kind of a joined up writing

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of prevention technologies, and I think that it is clear across the board that anything that affects one technology and one trial, will affect everybody else, and so we actually have to work together and make sure that we are all doing this to the highest ethical and community standards, because otherwise we will be hurting other areas. And I think that the lessons learned from the microbicides and the oral prophylaxis are something that – there's an unprecedented amount of collaboration going on with all of the, especially HIV prevention, and even Malaria and TB, and it's something that I think most of us, in fact all of us, are public health people looking at this in a public health approach. So it's not, "I want my technology out there, and you all get out of the way." It's like we want whatever is going to work out there. And so if Merck's candidate vaccine starts looking good, we are all going to be there saying, "Would you like to help in this community with this vaccine." So I think it's more kind of the level of personalities, personal interactions, personal collaborations, and then all of these groups have very clear strategies where you partner with in-country investigators. It is not the US or Europe coming to Africa. So it is coming from the community groups on the ground, it is coming from investigators on the ground, and we're providing a lot of money, yes, but we're not coming in

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there and doing this. The parachute research era is well over, and so I think that it is seen as a collaboration, and before we do anything, I'd meet with the national ministers, the local ministers, the regional ministers. I mean there is a long checklist. And then everyone has to decide this is a place that we want you to be, and then we start the work.

MITCHELL WARREN: I just want to pick up on that.

You know, research has changed for the better in many respects, and I think it's one of those issues that we don't step back and declare success, and I think that the way research happens in not only the developing world, but here in the US, has changed for the better in a number of ways, and I think HIV has really contributed to that. And a lot of it comes down to the issue of how communities engage in research, and not only are we moving away from the safari, parachute research where people go in and they do a trial and they go out. Not only is it about making sure the principal investigators and the research staff are very much part of that research agenda at the community level, but we're seeing an increasing degree of communities getting involved in defining that research agenda. So it's not as if a microbicide trial and a vaccine trial are deciding between themselves, who gets that site, who can call it my site. That site, whether it's in Baltimore or Washington or Bombay

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or Johannesburg is the community, and it's easy to say that, but increasingly we're seeing that really come out in the real world of communities saying, "We actually want to learn about microbicides, so we'd rather be in that trial than in that trial," and at the end of the day that is beginning to happen, and that's a good thing.

And the second thing very quickly is these are incidence, and incidence matter. One of those we're seeing in a number of trials recently are trials that have been conducted very well, very ethically, and they can't get a result because incidence hasn't seemed to be there. I don't for one minute think the incidence wasn't there in that community. I think how we do recruitment in those trials, really needs to be more focused, and that again is true in developing countries as well as here in the US, and we should never for a moment 25 years into this epidemic, think that the epidemic is over in the US, and that research only happens in the developing world. There are pockets of incidents in every one of our cities where trials for microbicides, vaccines, and new therapeutics can and should be taking place.

And the third point, ver quickly, is I think we are beginning to see a blurring of the lines between these technologies. What is a pill a day? Is it an oral

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microbicide? Is it an oral vaccine? A lot of the new emphasis in vaccines is looking at mucosal immunity, and you're seeing researchers who we used to think of as microbicide researchers becoming vaccine researchers, and vice versa. And that is great. We are really moving into a new world where researchers are being prevention researchers, or even AIDS therapeutic and prevention researchers, and the science is coming together in new ways, and I would suggest 25 years from now, these divisions of MTMV will likely not even exist, and we're going to see that continued blurring of the scientific borders. I hope we will.

PAUL STOFFELS, M.D: Well one point as a physician having worked there, the nice side effect of all of this is also that at the same time it does capacity building in the developing world. It gives a lot of training to people, physicians, nurses, and it provides resources, not just for trials, but to have additional scientists trained, and having the connection of people in the developing world with the scientific community here is so important for a capacity building, at the same time for local health care, but also for their science and their research careers in the developing world which is also important.

MALE SPEAKER: This has been a great panel. Thank you very, very much.

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45

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