

**International AIDS Society:  
Leading African and European AIDS Researchers  
Teleconference on IAS Conference  
July 3, 2003**

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**OPERATOR:** Good day ladies and Gentlemen, and welcome to the IAS AIDS conference call. At this time all participants are in a listen-only mode. Later we will conduct a question and answer session and instructions will follow at that time.

If anyone should require assistance during the conference please press star then zero on your touchtone telephone. I would now like to turn the conference over to your host, Mr. Michel Kazatchkine. Please begin.

**DR. MICHEL KAZATCHKINE:** Thank you. Good afternoon everyone. Good afternoon to my colleagues and to all participants from the press.

My name is Michel Kazatchkine. I'm the Director of the National Agency for AIDS Research in France -- the ANRS -- and the Chair of the Paris second IAS conference on HIV pathogenesis and treatment that we will be discussing, and that will be held from July 13 to 16.

This is the second of a series of conferences that the International AIDS Society organizes and a conference that is focused on basic science and clinical science - what we call tracks A and B from the International Conferences on AIDS, for those of you who are familiar with those international conferences.

That is a conference that the IS felt that there was a need for since the large international conferences which take place every second year are more of a advocacy conference now,

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and the scientists - the scientific community felt that there was a need for a specific forum for basic scientists and clinical scientists to meet.

And the - the other emphasis that we would like to give to this conference is to give it - to be - for it to be a truly international forum, we - we're expecting at least 5,000 participants at this time, and probably almost 30% of those will be from the developing world.

We have a large scholarship program, thanks to particularly the CDC and the NIH. We have over 350 full recipient - recipients of full scholarships awards from the developing world.

This is a conference that has gathered a lot of interest. We have received almost 2,000 abstracts submitted to - to the conference and we're very pleased indeed that it is held in Paris as 2003 marks the 20th anniversary of the discovery of - of the discovery of the - of the virus.

ANRS, the hosting agency is the largest AIDS - public AIDS research organization outside the U.S., um, and let me also say that this conference will be one of several events on AIDS that we'll take in Paris between July 10 and July 17.

And among those other events there is a symposium by the World's AID Foundation that will mark the 20 years of the patent on HIV tests that will now go public, which I think is an important date and a symbolic date. And also, as I'm sure

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all of you know, on July 16 the G-AID has called for a conference of - where the funding of the Global Fund to fight AIDS, malaria, and TB will be discussed. And that meeting of July 16 will be co-chaired by the Chairman of the Board of the Global Fund, Secretary Thompson, and the - his French analog [phonetic], the Minister of Health of France, [unintelligible].

So that - that's a few things about the conference and maybe I'll turn now the - to - to Joep Lange, the President of the International AIDS Society, who is the co-chair of the conference and he'll say a few words about the scientific content of the conference.

**DR. JOEP LANGE:** Thank you very much, Michel. My name is Joep Lange and I am currently President of the International AIDS Society. I am extremely pleased to be organizing a conference together with the ANRS, and a pleasure to do that.

And I think we have a very interesting program. Dr. Kazatchkine already alluded to the fact that there is quite a bit of participation from developing countries and I think that makes this conference so special. In fact we look at the contributions, the abstracts, that were sent to the conference, 37% of those come from Africa, which is - which is unique and which is also very timely given the fact that there's a lot of activity with regard to scaling up access to antiretroviral therapy [unintelligible] in developing countries. So that is something that stands out at the conference.

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As Dr. Kazatchkine says this is a scientific conference and there is definitely a lot of interest in the science that's going to be - to be discussed here. There's different types of sessions, there's classical plenary sessions by, uh, by renowned speakers, experts in their field, on issues such as HIV vaccine research, new antiretroviral drugs, and [unintelligible] fibers mechanisms in molecular pathogenesis for HIV, et cetera, et cetera.

But in addition there is a - quite a new novel - novel sort of session, which is a forum where several issues are discussed in, uh, in that by - by several renowned speakers. And then there's a controversy, which are sessions where people can take a pro or con - people will take a pro or con stance with regard to a - to a relevant issue.

But I think the real highlight of the conference is actually a - is actually a talk by the next person to speak in this conference, and that next person is Dr. Tony Fauci, who is currently Director of the National Institute of Allergy and Infectious Diseases at the National Institute of Health in [unintelligible].

And as you're probably aware he's one of the foremost medical researchers of our era, if not the foremost medical researcher, and has made significant contributions to elucidating the pathogenesis of HIV/AIDS among many other things that - that he has done. And we're actually extremely

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pleased that Dr. Fauci will give a lecture and - on 20 years of HIV study during an extraordinary plenary session on - at the conference.

That session is going to be chaired by Doctors Gallo and Montagnier, who are the co-discoverers of HIV, which occurred about 20 years ago.

And we also have the honor to have the former South African President, Nelson Mandella, and - as a guest at that - at that session.

So I'll gladly hand over now to Dr. Fauci to give us a brief summary of his lecture.

**DR. ANTHONY FAUCI:** Thank you very much. It's a pleasure to be here with you on this call. When Michel came to me some months ago and we discussed the possibility of doing something like a lecture on 20 years of AIDS science, there were some interesting issues that came up.

How do you encompass in 20 to 25 minutes 20 years of some of the most exciting science in the face of one of the most perplexing and problematic public health challenges that we've had in our history? And as you might imagine it's a situation where you really cannot do justice to all of the wonderful science that has occurred.

So I'm not attempting to do that, but what I will be doing is framing the broad issues of scientific advances over the 20 years since the discovery of HIV.

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Of note, I didn't realize it at the time but when I began the work almost immediately after Michel gave me the mandate, that there are more than 125,000 papers that have been published related to HIV and AIDS that are cataloged in the pub-med database of the National Library of Medicine here in the - in the United States, so the amount of input by so many diverse scientists is extraordinary.

Let me just spend a couple of minutes outlining in broad strokes - and again it's impossible and, I think, in appropriate to try and cover each and every scientific advance that brought us to where we are right now. But some of them obviously stand out.

And it goes from something as low-tech early on in the epidemic of the realization that we were dealing with a disease, which brings you to the science of classic epidemiology - the epidemiology of the awareness of new cases of pneumocystis carinii Kaposi's sarcoma first occurring in a rather restricted epidemiological group.

That lead to, by the basis of clinical observation, the kind of effect - of defect, namely an immunodeficiency predominantly of CD4 positive T cells that lead investigators on the trail of something or - either identical to or related to a relatively newly appreciated type of virus that had only recently been established as a cause of human disease, namely a retrovirus.

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And it was in that context that labs like Montagnier's lab and Bob Gallo's lab and others directed their attention to something that would fall into the broader category of a retrovirus. Little did they know that in fact it turned out to be a newly described retrovirus somewhat similar to, but certainly in - by no means identical to our experience previously.

Following the, uh, the identification of the virus was the extraordinary amount of work that went into identifying the molecular virology, namely the various structural and regulatory genes, which lead then to a relatively new field of molecular virology blending in with molecular epidemiology, so that two things emerged from that. Not only the delineation of the fallogenic [phonetic] relationship among the different viruses, and the heterogeneity, which took a few years for us to truly appreciate the extraordinary heterogeneity of the virus, as well as the ultimate origins of the virus with HIV II coming from West - in West Africa, originating in Sooty Mangabeys, and the HIV I only recently within the past few years understanding that that came for - originally from the chimpanzee.

Rapidly upon the discovery came one of the most important scientific issues, ranked up there -- but not quite - - with the actual discovery of the virus, was the blood test for HIV, which had two major contributions.

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One, it was used for diagnosing individuals, but also for understanding the large scale scope of the epidemic because we didn't appreciate early on that this was, as we used to refer back in the early 80s, as the tip of the iceberg. We don't hear much about that any more. The tip being the people who are clinically ill and the iceberg being the countless numbers of individuals who are infected but not yet clinically ill. So that was the conclusion of that.

Simultaneous with and up to the present day is the whole field of HIV pathogenesis from a virological and immunological standpoint. The complexity and multi-factorial nature - things like aberrant activation in this - the - in the context of a disease of immunodepression. The role of cytokines, the role of the receptor, the understanding early on very soon after the discovery that there is, as with other viruses, a specific receptor on cells - target cells, predominantly T cells and monocytes, the CD4 molecule.

And then years later, though there was a lot of activity going on suggesting that there may be another co-receptor, particularly since if you transfect the gene of CD4 into a mouse cell you did not get good infection, suggesting there were other receptors, which lead to the appreciation of the co-receptor. That was a wonderful era of science where two converging fields - the field of receptor biology - of individuals who were looking for receptors for chemokines to

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understand the broad field of chemotaxis, which con - converged with those individuals who were looking for soluble factors that could suppress HIV.

And that came together within a very short period of time with the understanding that the chemokine receptors, particularly CXCR4 and CCR5 were the recept - co-receptors with CD4 at the same time that chemokines like RANTES MIP-1 alpha and MIP-1 beta and others could be suppressive of HIV binding.

This is a truly beautiful merging of two different types of sciences, and then the appreciation of people who have genetic defects confirmed that but also opened up the way.

Another important area of pathogenesis is the development of highly sensitive assays for the detection of small amounts of nucleic acid, the RPPCRs, the BDNAs, and others, which really led to several things - the appreciation that viral replication occurs together with the studies of lymphoid tissue very early on and continues throughout the course, even of asymptomatic disease.

That also led to the classic, now, observation by Owen Shore [phonetic] about the viral dynamics, which gave us a much better picture of the extraordinary nature of virus replication. Understanding reservoirs, understanding the immune response, and the confusion that still lingers on today as to what the true correlate of immunity is, if indeed a true strong correlative immunity does exist. Understanding the role

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of antibody versus cell-mediated immunity is something that is still one of the major areas of intensive interest.

And recently over the past few years the marriage of classic immunology with modern day structural biology has opened up the doors of the appreciation not only of the capability, or lack thereof, of the body to mount an effective immune response of the humoral [phonetic] fashion, but also the complexities of things like cryptic epitope and conformational changes in the molecule of the envelope that allows it to enter.

Understanding what the - what the virus has, the structure of the envelope, the glycosylation, the hypervariability, which was the virus and nature's way of evading the immune response. Studies on the role of CD4 positive T cells, both in their cytolytic functions and in the secretion of soluble factors are areas that are still going on.

Perhaps the greatest triumph is in the area of therapy. Here again starting from the simple - just the screening that went on in the mid-80s to discover drugs like AZT, to the actual, more sophisticated targeted design of therapies such as the identification of the protease molecule, its crystallization, the design of inhibitors leading to the protease inhibitors, which is now an important part of the armamentarium.

And only recently we've seen something similar by

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understanding the structural biology of the fusion process leading to the latest in the new class of drugs, namely Fuzeon, originally referred to as T-20. And the list goes on.

And then two other issues finally before closing is that understanding the science -- and I - and I include this as a science -- the science of education and behavioral modification, which has been so effective in an arena in which we don't have an effective vaccine, of prevention by understanding how it's transmitted, the relationship between viral load and transmissibility. Understanding the ability to block mother-to-child transmission with the same mechanisms that we bring viral load down in people who have chronic infection.

And then finally, the whole arena of Vaccinology, which has certainly been a roller coaster effect from understanding and appreciating that it is likely antibodies that do it. So switching the pendulum over to cell mediated immunity and now back again in our current appreciation that we need to have both, but it's not going to be an easy issue because there are many scientific - I would say landmines and scientific gaps that we need to fill before we really can truly get to the road of safe and effective vaccines.

So in conclusion, although I've certainly left out many important contributions, I believe that those are the major landmarks in the scientific road to where we are now, but also

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appreciating that there is still a considerable way to go from the scientific standpoint before we get to the level where we would feel comfortable that we truly have had the kind of impact on this disease, this terrible pandemic, that we must have from the arena of science.

So I'll stop there and later ask - answer any questions that you would like.

**DR. JOEP LANGE:** Thank you very much, Tony. A standard overview remark with all of this happen in just 20 years. There is still a lot to be done.

Our last speaker was going to be Professor Souleyman Mboup, who is a professor of microbiology in Dakar in Senegal, and he's one of the scientific program chairs at the conference. But I'm not sure whether Professor Mboup is here. Souleyman?

**MALE VOICE:** I'm afraid we're still having trouble getting through to [unintelligible].

**DR. JOEP LANGE:** Yeah, I guess we - we will have to skip this - this. Maybe Professor Kazatchkine wants to - to elaborate a lit - elaborate a little bit on - on the developing country aspect in the absence of Professor Mboup.

**DR. MICHEL KAZATCHKINE:** Yes, thank you, Joep. Tony just spoke about the - the science of epidemiology and - and how epidemiology developed from the very first clinical observations and then how we learned about the - early on on

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the epidemiology of the disease as - as when we succeeded in having the appropriate tools - that is the test for anti-HIV antibodies.

I'd like to emphasize that the epidemic in the developing world, that is the first cases of AIDS in Africa, namely, where it was reported as soon as 1985, and that then most of us have somehow underemphasized the rapid growth of the epidemic in developing countries.

And it's only when the impact - the considerable impact of the epidemic could be felt in Africa -- that is in the mid 90s and second half of the 90s -- that the world really took the measure and understood the magnitude of the epidemic. I'm sure everyone is aware of the numbers. Over 42 million people currently being infected with the HIV virus in the world, 90% of whom live in the developing world.

In the - in addition to just recognizing the epidemic and - and its terrible impact that is already felt and that is still to come, and the rapid growth of the epidemic in new parts of the world such as Asia and previous countries of the Soviet Union and Eastern Europe. We have witnessed also in the last two, three years a true effort of the international community to - to act and to try and change the face of the epidemic in the developing world.

This mobilization started with the call from Secretary-General Kofi Annan in Abuja in 2001, followed by the

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extraordinary session of the United Nations in New York in June 2001. And then in January 2002 the first session of - meeting of the board of the newly founded Global Fund to Fight AIDS.

And that was followed by a number of initiatives, particularly bilateral initiatives in decreasing the depth or the recently announced - President Bush's initiative to devote 15 billion U.S. dollars over five years to the fight against AIDS.

All of these efforts -- the Global Fund, the bilateral initiatives -- are aimed at both strengthening prevention and treatment, as we now understand that we do not have choices between prevention and treatment, but that the two activities are fully complementary.

In the last two or three years -- and this will be one of the focuses of the meeting -- we've witnessed a new type of science based on operational research, which is the scientific - the science of access to treatment in the developing world where not only we analyze the efficacy, the tolerance of antiviral drugs as we give them to patients in the developing world, but also this - all of what we learned with social scientists and economists about all the complex issues that this access - expanded access to treatment in the developing world raises. The cost of drugs, the determinence of prices of drugs, the issue of generic drugs, the issue of how to give these drugs on large scale to people, the issue of monitoring

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treatments in populations in countries where the infrastructures are - are very different from what we know in the north. And also learning about the impacts of the treatment - impact on the stigma, on how the disease is viewed by the people, by the government.

All of this - all of these complex issues is an entirely new area of science based on - on what are generically called operational research. And this is where - this certainly will also be part of our meetings in Paris.

**DR. JOEP LANGE:** Thank you very much. Mason, Souleymane is still not here? In that case we'll now actually opening up to questions.

**OPERATOR:** Thank you. If you have a question at this time please press the one key on your touchtone telephone. If your question has been answered or you wish to remove yourself from the queue, please press the pound key.

Once again, if you do have a question please press the one key at this time. One moment for questions, please.

And our first question is from Susan Dentzer of the News Hour. Please go ahead.

**SUSAN DENTZER:** Yes, I have a question for Dr. Fauci. Is - are there general lessons that can be derived from your overview about blind alleys that might have been avoided over the years that the scientific community inevitably went down for a while that could have been avoided? Activities that

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should have happened sooner rather than later? Obser -  
observation that if frequently made in the case of vaccine  
research.

Are there general lessons that can be derived and put  
to use going forward as we continue to advance the science of  
HIV/AIDS?

**DR. ANTHONY FAUCI:** Okay. Thank you, Susan. In the  
scientific endeavor to try and - science, as we all know, is  
discovery and in the process of discovery one can always  
retrospectively look back and say, gee, if we had not gone down  
this alley we may have actually saved some time or we stayed in  
the blind alley a little bit too long.

But for every observation in that regard, it's very  
clear that there are alleys that if we didn't stay in them --  
and this is in science in general, not just in HIV -- we may  
not have come to an important discovery.

So having said that the answer is I'm sure there are.  
Could they have been avoidable without damaging discovery and  
other reviners [phonetic], I'm not entirely sure. But I think  
there have been some lessons that have been learned, and that  
is lessons that are applicable to all of science. And that is  
keep an open mind.

We - I think the experience we've had with the HIV/AIDS  
epidemic has fortified us in our capabilities and our resolve  
and how we approach other emerging and re-emerging diseases.

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Everything from the appreciation that you are dealing with something new to appreciating the potential scope.

And I think retrospectively, if you look back then, some - some things that some of us said, uh, and probably a lot of us said, but it - I - it wasn't fully appreciated. And that is when you're dealing with a sexually transmitted disease or a disease that's blood-borne, that to think that it is going to stay confined to an epidemiological restrictive population when in fact sexual activity is as human as humanity can be. That that was a bit naïve, I think, broadly among the people in the world who were perceiving what HIV is. That's sort of an epidemiological, phenomenological, open-mindedness that's needed to be applied.

Scientific things, I think, are important is that be careful of what is current and trendy in science and how we must continue to maintain that individual curiosity and not rule something out unless it has really been ruled out. And I think an example of that which we have seen is the roller coaster effect of what is the - what do we need to pursue in the arena of protective immunity? Is it antibody? Is it CTL? Or is it both?

And we've seen interesting sways up and down in the field, almost like the ad for a certain type of a beer. It's less filling, better tasting, that kind of thing. What is it? We need to avoid that in the future.

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On the positive side, a lesson that hasn't been learned that has certainly been confirmed is the importance of that translation of fundamental basic science to a real live clinical and public health problem. And I think the drug development capabilities that have evolved, of taking targeted drug development, by understanding things like the crystalline structure of a molecule and targeting it as a target for drug as we've seen with the protease and some NNRTIs, and now with Fuzeon. Those are important confirmations of lessons that have been learned in other areas of science.

So, Susan, that's just a few of them. So, you know, in a broad sweep.

**SUSAN DENTZER:** Thank you. Just to follow up, could you expand a little bit more on where we are now on the roller coaster of understanding the - the different forms of immunity that will need to be sum - first - first of all the different forms of immunity that are affected with the disease, and then different forms of immunity that will have to be summoned forth in order to protect against...

**DR. ANTHONY FAUCI:** Yeah, I think most people, Susan, are realizing now that you absolutely - if you want to prevent infection you really must have antibody that neutralizes the virus. If you want to prevent it in a way that a cell that could somehow slip through, which in other diseases if you have an exposure and antibodies essentially neutralized almost all

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of the microbes in question, a few can sneak through and your immune system handles it reasonably well. But if you do get infected you can eliminate that.

It's much more problematic with HIV because once you establish infection, we know that it is almost impossible given the current immunological responses for the body to -- once there is chronic established infection -- to eliminate it. So therefore that's the need to have good CTL.

So it's not one or the other. It's the realization that it's going to have to be both. But the early studies that discouraged investigators, these would be neutralizing antibody, because we found that the antibody that was made seemed to neutralize cell adapted strains but not primary isolates.

There's now good scientific explanation for that. It's sobering, but the virus, by the nature of the structure of its envelope, with cryptic epitopes, by its ability to glycosylate well the envelope, by the hypervariable capabilities of the virus. Those are all things that we need to scientifically overcome. And there are a number of people who've addressed that. Probably the one of among many who have articulated this well has been Dennis Burden [phonetic], who really now argues that we need to modify the immunogen to circumvent the mechanisms that the virus has evolved to avoid the immune system with regard to antibodies. And we also need to figure

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out ways how we can boost with new agivens [phonetic] the ability of the body to make hitiders [phonetic].

So we now have a better scientific explanation of the failures, but we realize we need to have both antibody and cell mediated immunity.

**SUSAN DENTZER:** Okay. Thank you.

**DR. JOEP LANGE:** Next question?

**OPERATOR:** And our next question is from Alice Park of Time Magazine. Please go ahead.

**ALICE PARK:** Hi, this is a question for any - or for anyone on the panel, but it was mentioned that there was really an understanding and appreciation now of the need of prevention and treatment going hand-in-hand in dealing with the HIV/AIDS epidemic in the developing world.

Can you address in terms of the - the funding that is now being brought to bear on this problem? Give us a sense of what kinds of programs will be needed to, um, to address this issue. For example there are places where it's not even know what the incidence rate is and there is - there are regions where there is so little infrastructure, where it's not even known how many people are infected, where they're getting infected, how they're getting infected.

How - give us a sense - is there going to be a 50/50 split with prevention and treatment programs? Is there going to be a greater emphasis put now - slightly greater emphasis,

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perhaps, you know, 60/40 on prevention and education programs?

Any sense of that yet?

**DR. JOEP LANGE:** Michel? You want to go?

**DR. MICHEL KAZATCHKINE:** Yes. Well, thank you for that question. I think it is quite difficult to answer whether it's 50/50 or 60/40. There are two - two things I'd like to say with regard to this complementarity with - between prevention and treatment.

One is that we - we realize that prevention, when it's just prevention by trying to change behaviors, has its limits. And prevention when it is based on trying to have people know about their serological status has the obvious limitations that if someone knows about his serological status but that there is no hope at all for treatment, and the only prospect is really stigmatization, we - we will go nowhere.

So the current view is that by bringing progressively - by expanding progressively access to treatment in the developing world, we will truly provide an incentive for - for people to test themselves. Just as we learned that it is the case when pregnant women go for tests to know whether they're positive and when - in settings where they know that they can then receive the appropriate drugs to prevent mother-to-child transmission.

And it is a clear observation that it is those countries in the developing world that early directed their

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efforts to bring treatment to their patients, such as Thailand, Uganda, Senegal, Brazil, Cote D'Ivoire. These are the countries that have also been the most successful in their preventive efforts.

So this is a sort of brief overview of why prevention cannot be dissociated from treatment now, or rather why treatment and expanding access to treatment is necessary in order to back up prevention.

In the - I can tell you that in the very first grants that have been approved by the Global Fund, the overall proportions of prevention versus treatment was - was approximately 40 to 60 or 50 to 50 indeed.

But all the applications that were accepted for funding by the Global Fund were applications with both a prevention component and a treatment component.

**ALICE PARK:** Okay, just to follow up very quickly on that, too. What kinds of programs, uh, the lessons learned from the countries you just mentioned -- Thailand, Uganda, Brazil, Cote D'Ivoire -- what kinds of programs seem to be the most successful? The ones that involved entire communities? The ones that were generated from, you know, government-based institutions such as - or, um, you know, other programs? What seemed to work the best?

**DR. MICHEL KAZATCHKINE:** What seems to work the best is obviously a targeted interventions, so the - the true model we

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have is somehow Brazil where, uh, on a very large scale access to treatment and specific efforts in all areas of prevention - that is prevention of mother-to-child transmission, changes in behavioral - in behaviors in the general population, targeting interventions for IV drug users and subsistive [phonetic] therapy, needle exchange programs, and targets, uh, targeted programs for men having sex with men.

All of these - all the spectrum of those interventions were started in Brazil at the same time as Brazil started a very powerful and large program of access to treatment. And in fact the very first speaker that we shall have at the Paris conference during the opening session is the former president of Brazil, Henrique Cardoso, who should sort of help us try and draw the lessons from the Brazilian experience.

On a smaller scale but still on the very most effective fashion I think Thailand and Uganda and Senegal have launched, again, both therapeutic programs and a broad spectrum of - of preventive interaction.

**OPERATOR:** Thank you. And our next question is from Brenda Wilson of National Public Radio. Please go ahead.

**BRENDA WILSON:** Yes, I have a couple of questions. I guess the first - I apologize if you said what this - at the beginning of the conference. I missed the first few minutes. And that is could you just at least list two or three what you might think would be new breaking developments in the

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scientific arena that may come up at the conference in Paris?

And I guess the second would be there's been this kind of back and forth over safety in the medical setting. And sometimes I hear figures while some - for some countries as high as 25% of people being exposed through unsafe medical practices and use of injection equipment and that sort of thing.

Is - has that pretty much been settled or is it still a debatable question that needs to be looked into in terms of how much of the rates in countries - in Africa, for example, are attributable to unsafe medical practices versus sexual transmission? Thank you.

**DR. JOEP LANGE:** Can I give this first question to Michel Kazatchkine, the second to Dr. Fauci?

**DR. MICHEL KAZATCHKINE:** Thank you. Well, with regard to the first question, there - I wouldn't like to - to be too technical here, and rather than focusing on breakthrough news because those - we - we certainly are expecting and we - of course we - I know from the abstracts in - from the program that we - we will have a number of - significant amount of new information coming in at the conference regarding particular treatment, regarding the way viral transcription is regulated, regarding, as I discussed earlier, the science of access to treatment. Our ability now to reduce considerably mother-to-child transmission in the setting of the developing world where

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- with - where - where - even in the context of breastfeeding and so on.

But I would like to emphasize that the - what I think will be particularly important at this conference is that we will highlight a number of very hot issues of basic and clinical science, particularly through what we call our conservancy sessions. Issues for which we have indeed, at this time, almost as much information in favor as we have information against, and we will have an open debate about these hot issues.

Let me give you one or two examples of those. For example the issue of whether there is more risk than benefit in interrupting treatment for some time in patients who are successful on heart [phonetic]. The issue of whether the viral - the genetic viral diversity that Tony discussed earlier is of relevance or of major relevance or - or not for vaccine development.

Whether the - another debate will be on whether a simple single dose intervention to prevent mother-to-child transmission with Nevirapine, which is a very simple thing to implement, is still acceptable in the light of the recent data showing that a double drug combination therapy is much more effective in preventing transmission, although it is much more difficult to implement.

Or let me give you another one to show the broad

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spectrum of those controversies. For example whether treatment - antiretroviral treatment regimes should be modified in patients based now on the appreciation of cardiovascular risk as we learn more and more about the side effects of - of these drugs when they're taken long-term.

So in addition to true novel information, I'd like to emphasize that we will have an updated debate on some of the unsolved most recent issues in the scientific - in the science of HIV.

**DR. JOEP LANGE:** Thank you, Michel. Then the second question was the one with regard to the contribution of injection equipment [unintelligible] the epidemic. Tony?

**DR. ANTHONY FAUCI:** Yeah. Sure. This recently has come into some discussion and controversy, but we can state some facts and perhaps appreciate how there has turned out to be some debate about this.

If one looks globally, particularly in developing nations, there is no question that the overwhelmingly predominant modality of transmissibility is sexual transmissibility, particularly heterosexual transmissibility. The epidemiological patterns in the disease as well as the observational databases that have been collected over a considerable period of time strongly, strongly argue to that.

There's been some concern about whether a substantial proportion of ongoing spread of virus in developing nations,

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particularly in Sub-Saharan Africa, are due to other modes like contaminated apparatus such as needles and medical practices.

I don't think there's any doubt that at various periods of time, particularly maybe in the earlier parts of the introduction of the virus into different societies, that there were things other than sexual and heterosexual transmissibility. I mean obviously when the blood supply in certain countries was not screened at all, that may have served as the nidus [phonetic] to spread it to the point where then heterosexual transmissibility took over.

But to say that in fact Sub-Saharan Africa, that sexual transmissibility is not the predominant form of - of transmissibility is just not the case. And these data have been looked at by a number of groups now and come up with the conclusion that UNAIDS and WHO and others have, that clearly the predominant modality of transmissibility in developing nations such as in Sub-Saharan Africa is heterosexual transmissibility.

**OPERATOR:** Thank you. And our next question is from Christy Feig of CNN. Please go ahead.

**CHRISTY FEIG:** Thank you. I'm afraid I'm going to have to push your envelope a little bit more on Brenda's question, and that is can you give us any highlights on the specifics of some of the best new science coming out here? Because our editors aren't going to let us go to France if we can't give

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them some specifics whatsoever.

And the second question I have is are any of these hot issues going to be resolved or are we just going to continue to debate them?

**DR. JOEP LANGE:** Michel?

**DR. MICHEL KAZATCHKINE:** Um, well, yes. Let me list a few of those. They will range from epidemiology - I mean clinical epidemiology such as figures on resistance in the general population - very new figures. For example in - in Europe or the U.S. what's the risk you have if you - if you infect yourself with HIV in 2003 of being infected with a, uh, a resistant viral strain?

We will have of course a number of new data on drug therapy. We will have the 48-week results of the G-20 trials. We will have a number of results of phase I and phase II trials of novel anti - antiretroviral drugs.

We will have novel data on the fact that HIV virus can attack - direct itself to - to cells - to adipocytes - that is cells of the fat. And - and this raises the controversy of whether the lipodystrophy syndrome - how much of these are due to treatment, how much of these are due to - to the virus.

And we will certainly have a number of views on the role of what we call accessory genes on - on viral replication and how those affect viral replication.

We will also - we will not have emphasis on vaccines,

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I'd like to say, at this - we have very few abstracts on vaccines and this is probably due to the fact that there will be a specific AIDS vaccine meeting in New York in September 2003.

Coming back to therapy we will have more follow-up on immunotherapy, on how the - particularly on therapeutic vaccines and how those can help the immune system in controlling the virus.

So there is a very broad range. If - if - if some of the people, the participants, wish to receive abstracts from our late breaker sessions, or from some of our oral sessions - that is what we have selected as the best papers for the conference, they could e-mail their requests to Seth Amgott and we will communicate those abstracts, but ask, of course, you to keep them embargoed until the day of the presentation at the meeting.

**CHRISTY FEIG:** That will be terrific. What's Seth's e-mail?

**DR. MICHEL KAZATCHKINE:** Uh, Seth's e-mail - Seth, would you give your e-mail?

**SETH AMGOTT:** It is seth -- S-E-T-H -- at amgotmitchell -- A-M-G-O-T-T-M-I-T-C-H-E-L-L -- dot com.

**CHRISTY FEIG:** Thank you. And can you tackle the other question, are we going to resolve any of these hot debates or are we just going to debate them?

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**DR. MICHEL KAZATCHKINE:** No. I doubt it - for those topics which I have listed as - as controversy topics, I do really think that we have almost a - as I was saying, a 50/50 split between data in favor and data against.

For example with the hot issue of interrupting treatment, we - we will have a long list of ongoing trials that will tell us that in many patients interrupting treatment from time to time may be relatively safe. But we will also have the report of a failer of one of the trials of, uh, scheduled therapeutic interruption.

So, no, this will - as I said, uh, to me mostly be an update and a hot debate on those issues rather than we will be able to solve them. I don't know, Tony, you - how you feel about this.

**DR. ANTHONY FAUCI:** I think, Michel, that you absolutely hit the nail on the head. The very fact that they are so controversial, I think the sessions will be used to focus in on and highlight the specific areas in which there really is disagreement, perhaps to help better inform future research to help answer those questions.

So I see the - the debates and the controversy sections as more of a crystallization of exactly what the differences in opinions mean and can we do some studies in the future to actually resolve that.

So there may be some consensus in one or another of

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them, but I think on the whole the sessions of the controversies and the debates will be more informative for future direction rather than resolving in nature.

**CHRISTY FEIG:** Thank you.

**OPERATOR:** Thank you. And our next question is from Marsha Clement of Medicine and Health. Please go ahead.

**MARSHA CLEMENT:** Hi. I am wondering in terms of, Dr. Fauci, well, there's I guess also mentioned the change in sense of the burden of disease and where it is and how this disease would progress over the years to sort of, uh, lack of awareness of the - of the problem in Africa and the rest of the developing world that now come so much to the fore.

And I'm wondering how, if at all, you see the new understandings of - of the burden of this disease and of the participation of the access to social science, the economics researchers. How, if at all, is that going to change, or can that change, the course of the scientific research agenda given that obviously you need to go with some scientific opportunities?

**DR. ANTHONY FAUCI:** Uh, well - uh, I'll take a very quick shot at it. I - I think it really underscores some of the things that Michel has said before, and Joep, regarding the whole issue of the relationship between treatment and prevention and the importance of educational and behavioral modification.

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Clearly if we don't have substantial impact type interventions in those countries that are greatest at risk, not only for continuing the terrible course they're on but for entering into a new arena of - of accelerated infection. The - those that are already knee-deep in it, such as the ones we've been discussing - Sub-Saharan Africa, the Caribbean, certain areas of Asian countries, some of the Eastern European countries.

But the future impact of what we might see in China, India, or again in - in, uh, in the Russian Federation, as well as other areas, that we need to learn from what we - what - the lessons that have been recurrent, that nations that think the epidemic is not going to accelerate on their, uh, in their country, just need to look at the repetitive - the unfortunately repetitive patterns.

So there's one of an epidemiological data and awareness of the importance of education and behavior modification, but there's also the point that was made by Michel about when we start getting involved, or continuing involvement in those countries, that there is a realistic coupling and linking of prevention with treatment because you're not going to incentivize people to get into a program that would enhance prevention unless you had something to offer them.

And I think the nations that are at the greatest risk, the larger nations, need to learn that lesson that was learned

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with such pain in other nations.

**DR. JOEP LANGE:** I think actually very pertinent point made by Dr. Fauci before was that what we've learned in our country that this epidemic doesn't stay at these ranges. A lot of the newly - the new countries, the new growth - most countries, like the Soviet - former Soviet Union, they're actually neglecting the epidemic because it'll [unintelligible]. That's very important that [unintelligible].

**MARSHA CLEMENT:** Thank you.

**OPERATOR:** Thank you. Our next question is from Sabin Russell of the San Francisco Chronicle. Please go ahead.

**SABIN RUSSELL:** Yes, hello. Thank you for having this. I guess I have some questions for Dr. Fauci regarding the President's forthcoming visit to Africa and what impact that may have on his plan for his Global AIDS Initiative, which you are the architect.

And I guess the first question would have to do with the fact that in the developing world it's difficult to separate the issue of treatment with the issue of cost. And there is concern about whether the President's initiative will allow or rely on the use of generic drugs in order to bring the costs down. And with the naming of Randy Tobias, a former drug company executive, there is concern in the activist community whether generics were still in the picture.

I was wondering if you could address that question of

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whether generics are essential or will be relied on at - only partially in the plan.

**DR. ANTHONY FAUCI:** Yeah. A couple issues, Sabin. First of all let me emphasize that the plan was the President's idea. So I appreciate the compliment that you gave to me, but the - but the - but the plan is truly the President's plan. It was his idea. There was a team of people who helped to put together the actual details of it, but certainly it was the President's idea.

And I think that's an important point because he is committed to seeing that the plan does get executed. That's the reason why - one of the reasons - there's many reasons why he's going to Africa. It's a multifaceted trip. But certainly AIDS is high on the agenda. He'll be bringing Randy Tobias with him, I believe, so that both of them can get an - an even more intense firsthand view of what's going on.

Hopefully the President's plan and its execution will catalyze involvement of funding sources from a variety of institutions, governments, or what have you so that they can synergize and not just have that 15 billion, but a lot more that's needed to make this truly a global comprehensive program.

So there's a commitment - certainly a very strong commitment on the part of the President to make this work.

With regard to your question about generic drugs, in

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the original putting together of the framework of the plan, the funding source had the potential to go to a number of targets. That could be government agencies, governments themselves, NGOs, academic institutions, foundations, or what have you.

So I don't think there's going to be one central source of how drugs get purchased. And again I have to put a big caveat on what I'm saying because the final decision about this will rest with the new coordinator, Randy Tobias, that was just appointed yesterday - or at least the announcement of the appointment was made yesterday by the President.

But there will almost certainly be situations in which certain groups who will apply for funding for the three-part component of the President's plan, which is treatment, prevention, and care, who might already have arrangements to get drugs through mechanisms that would include generics.

So I - I - I'm not - I don't know how that's going to continue to be implemented, but I don't think there's anything in the - at least at this stage that would rule out - I cannot say whether there will be direct purchase of - of generics -- likely not -- from money that comes from the government. But I can't give you a final on that. That's Randy Tobias' decision.

But certainly there are a number of groups - for example the group in Uganda, Peter Mug - Peter Megenyi [phonetic], who - whose - whose situation in Uganda we drew on heavily in the drawing up of the details of the plan, uses

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generic drugs that have been purchased through a variety of outlets for generic drugs.

That certainly would not disqualify him from partaking in the large program. Again, repeating what I said before, it is unclear to me whether or not there would be any direct purchase of that. It is likely -- and this is what I have heard in - in a number of discussions -- that we will try to get the best possible price from drug companies for drugs that have been - that are classic drugs whose efficacy has been proven and whose quality we are sure of.

So I think the first line of approach to the purchase of drugs would be to get the best possible price of the classical drugs. But I don't think that would rule out others using generics at all.

**SABIN RUSSELL:** Thank you, Dr. Fauci, and just another follow-up on the prevention/treatment question. There's an aspect of the - of the President's plan that is going to require, because of Congress, that one-third of the prevention dollars be spent on abstinence programs.

I've been looking into these myself and one of the tenets of the abstinence only programs is that condoms don't work. I was wondering if that runs into conflict with the science and with other prevention programs, and how you might think that could be resolved.

**DR. ANTHONY FAUCI:** Well, I think you just need to look

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at the - the plan that has been embraced by the administration, which in fact does include condoms. So that answers the question.

There's - there's reliance on a number of models. One of the models that has been discussed in detail by the administration has been the ABC model that has worked in Uganda. And in the ABC for abstinence, be faithful, and the use of condoms, includes condoms. So I think your answer, Sabin, is right there, that certainly there's a - there's - there's emphasis on a number of issues including abstinence, including fidelity, but condoms have not at all been ruled out. Not only ruled out, it's - it's an explicit part of the - of the - of the program in the ABC program.

**SABIN RUSSELL:** Thank you.

**OPERATOR:** Thank you. And our next question is from Michelle Port [phonetic] of Ms. Magazine. Please go ahead.

**MICHELLE PORT:** Thank you. How much does the roll of women in the developing world affect the transmission of the disease? And by that I mean their lack of education or their inability to regulate their sexual lives, not having sort of the power to do that, and the poverty leading to prostitution. Are there strategies being developed in terms specifically of women?

And I'm also wondering about the global gag rule affecting the AIDS funding by separating out AIDS clinics from

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other family planning services.

**DR. JOEP LANGE:** [Unintelligible] one of you?

**DR. ANTHONY FAUCI:** Well, I think the first part I - I can - I can address. It's something that one of our colleagues - our - our late esteemed colleague, Jonathan Mann, said years ago about the importance of human rights issues and the propagation of the epidemic. He was referring to a number of human rights issues but he explicitly mentioned in that the - the lack of adequate human rights in some societies for women and their inability to take into their own hands their destiny of being able to protect themselves.

There have been some enlightened countries that have realized that, and hopefully as we go on there'll be an even greater appreciation of the importance of the rights of women to have a very, very direct say in the ability of them - to protect themselves against infection. So that is an important part of the prevention issue.

**DR. MICHEL KAZATCHKINE:** If I could just add one thing. Is - is - as I look through the abstracts that were submitted to the conference - to through our program that was built on the best science that was selected from the abstracts, there's one area that is - I spoke earlier about the vaccines. There's another area that is clearly missing, which is the area of my microbicides. Obviously microbicides would provide us with - with a mean for women to control - to regulate their sexual

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life. And I - I somehow regret that the science of microbicide is not moving faster.

**MICHELLE PORT:** And what - and what about the global gag rule and how that might separate out funding?

**DR. MICHEL KAZATCHKINE:** Hello?

**MICHELLE PORT:** Hello?

**DR. JOEP LANGE:** Yes, the - the second question?

**MICHELLE PORT:** Oh, it's about the global gag rule and how there's sort of been mixed messages, I think, from the Bush administration about saying that the global gag rule won't apply, uh, or - to AIDS funding, and yet it seems that it would apply in that the AIDS funding would have to be separated from any sort of family planning funding that included giving any information about abortion.

**DR. JOEP LANGE:** Dr. Fauci, you...

**DR. ANTHONY FAUCI:** You know, I'm not - that's a very draconian word, the global gag rule. I could tone the word...

**MICHELLE PORT:** Mexico City policy...

**DR. ANTHONY FAUCI:** Yeah.

**MICHELLE PORT:** ...is another name for it.

**DR. ANTHONY FAUCI:** Yeah, it - it's very clear that funding streams will be able to go to institutions so long as there's a separation for that. But I have to say that in - in a way that, um, this is a question that should be addressed to Randy Tobias because he's very new in this in the sense that he

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was just announced yesterday. And I think the ultimate translation of policies will be articulated by him as the Director of the program.

But in the original formulations there was an attempt to be able to make sure that if at least there's a reasonable separation of funding streams that groups that might in another arena be involved in something that might not be acceptable to a particular policy, that they still could participate in the program so long as there was a clear distinction in the funding stream that's used.

That was discussed earlier. How that's going to get translated now that we - that we have a definite program with a leader, I can't comment now. But as you yourself alluded to there was an attempt to try and be able to use organizations provided that the money is used specifically for the program that they described and not in violation of certain policies that have been put forth.

**OPERATOR:** Thank you. And our next question is from David MacIl - MacIlrey [phonetic] of Voice of America. Please go ahead.

**DAVID MACILREY:** Thank you. A few minutes ago before the questioning began, Professor Kazatchkine was speaking of the mobilization of the international community in the last few years towards a greater AIDS funding for Af - Sub-Saharan Africa and to - and - and other countries.

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The other day, just as a run-up to President Bush's trip to Africa, Jeffery Sachs of Columbia University and advisor to Kofi Annan took a stark view in the opposite direction saying basically the world has left Africa to die -- and those are his words -- and that the - the United Nations AIDS - UNAIDS in a press release a couple of weeks ago said despite substantial increases, AIDS funding is still only half of what will be needed by 2005.

So how do we reconcile those views from what Dr. Kazatchkine said to this - this - these other approaches? Is - are we doing enough yet?

**DR. MICHEL KAZATCHKINE:** Yes, those - I don't think there is any need to - to oppose these views. What I was saying is that we were much too late in recognizing the extent of the epidemics in the developing world, particularly in Africa, and that we do witness now a mobilization. But certainly in no mean I wanted to express that I believe that this mobilization is sufficient.

I think the last three years things have changed tremendously. Remember, less than a year and half ago from now there was no Global Fund, and - and now the Global Fund has already engaged into over two point - \$2 billion of programs. And in the next two or three years we will see a - much more commitment, but I fully agree with all the experts, of course, and particularly with - with Jeff Sachs, who pioneered some of

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this work, that we're very, very far from having currently the resources that we would need to have an impact on the epidemic in the short term.

The current goal -- and I hope that we will not be too far from that goal -- is the WHO goal of having three million people on treatment in the developing world by 2005. With the -- the funding available so far from what the applications that have been agreed upon for funding from the Global Fund, we expect 500,000 people to be on treatment in the developing world within the next three years.

So there's still a lot of way to go. And it's precisely because we're too far from the resources that we would need that the G8 and France have called for the conference on July 16. People and governments and all stakeholders, be it the private sector, the public sector, um, have to face their responsibilities now.

**OPERATOR:** Thank you. And this concludes our question and answer session. Please continue with any closing comments.

**DR. JOEP LANGE:** Michel, you want to make a closing comment?

**DR. MICHEL KAZATCHKINE:** No, I'd like to -- to thank you, Joep, for leading the discussion and your comments and -- and thank Tony. It was a pleasure participating in this call. I look forward to seeing you both in the next few days. I'd like to thank the participants. I hope we've somehow answered

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their expectations. And I'd like to re-emphasize for those who wish to have in advance some of the abstracts of the conference that they could get in touch with Seth Amgott and provided that the embargo is respected, of course, we will be happy to communicate them - the, uh, some of the papers submitted to the conference.

**OPERATOR:** Thank you. Ladies and Gentlemen, thank you for your participation in today's conference. This concludes the conference. You may now disconnect. Thank you.

[END OF RECORDING]