

**Conference: 15th Annual International AIDS Conference
Are Intellectual Property Rights a Barrier to
Increased Access to ARVs?
July 13, 2004**

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[START RECORDING]

BRIAN BRINK: The title of today's session is what some people would regard as controversial, "Are Intellectual Property Rights a Barrier to Increased Access to Anti-Retroviral Drugs?" But there's a subtitle to the session, which is the more important part, and that is, "What Practical Solutions Exist to Insure that Anti-Retroviral Drugs Reach All Who Need Them Whilst Insuring that More Investment Into New Medicines and Vaccines Urgently Happens." My name is Brian Brink, I come from South Africa, I'm a doctor, I work for a mining company called Angler [misspelled?] American. We have a large number of employees in Southern African and we have a big burden of HIV disease and AIDS. In our company we perhaps have the biggest employer-sponsored anti-retroviral treatment program in the world. We have some 1,600 employees who are on anti-retroviral and 95% of them are back at their normal jobs. So, I'm a customer in my capacity down there, we buy these drugs. And obviously we have a very great interest in the subject and would like to be part of insuring access to good quality drugs for all the people that need them. So we're interested to find the solutions and we hope that everybody in the audience will be part of the spirit of trying to find the answers.

I'd like to introduce my co-chair, Giles Ji Ungpakorn.

GILES JI UNGPAKORN: My name is Giles Ji Ungpakorn, I'm a lecturer in the faculty of political science at Chulalongkorn

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Access to ARVs?
7/13/04**

3

University in Bangkok and a social activist so I will be co-chairing with Brian today.

BRIAN BRINK: And then if we can go straight into the session, the plan is that are speakers are going to take about an hour, we hope perhaps a little bit a less and there will be at least half an hour for audience participation.

This program, this session, is part of the leadership program at this conference. I'm very please today to be able to introduce to you a leader from the research based pharmaceutical industry, Hank McKinnell, Chairman and CEO of Pfizer.

From my side, I'm very please that a leader in a research based pharma is prepared to come to this conference, be part of the proceedings and is prepared to stand up in a session like this and talk to the subject and be part of trying to find the solution. So, Hank from my side, thank you very much for being here and we look forward to your presentation.

[APPLAUSE]

HANK MC KINNELL: Thank you Dr. Bink, for that welcome. Honored guests, colleagues and friends, good morning everyone. I appreciate the opportunity to be with you here because my company Pfizer and I are committed to listening to everyone in this conference to understand how we can become a partner in the fight against HIV and AIDS.

I, too, see HIV/AIDS as the worst public health crisis in

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history. No one can visit the regions of Africa and Asia as I do many times and not be moved by the suffering of people living with HIV and dying from AIDS. Although the pharmaceutical industry has been quick to discover and develop new medicines to treat HIV and its complications, we have been slow to offer realistic solutions to the multiple challenges of making these medicines available to all who need them. I couldn't be here today without acknowledging the efforts of many of you and so many others who have helped to insure that my industry and other members of the donor community respond more effectively to the access challenge.

Since Barcelona we have seen a steep decline in anti-retroviral prices in the poorest countries and new models of access, such as no profit pricing, volunteering licensing, and increased generic availability. As well as the growth of donor programs to further increase access to medicine. This is clearly real progress, and yet we all recognize it's not nearly enough. So the question today, I think, is what is the logical next step?

And that brings us to again to the discussion of the value of intellectual property. This issue is loaded with emotion, and I understand the anger. IP has become a proxy to explain the reasons for health disparity and economic inequality around the globe. Certainly in a world where most AIDS patients die out of sight of even a paved alone, IP alone is too simplistic an answer to these disparities and inequalities. Still how we do insure that IP is not

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a barrier to access today while serving the needs of patients, both today and tomorrow?

Here are some points to illustrate my view. First and foremost people living with AIDS and the tens of millions who will sadly become infected will continue to need new treatments. As you well know, this virus is very smart at ultimately outwitting even the most sophisticated treatments. In many ways we're in a race against time to develop new ones. And we're about to see an intervention. Enjoy.

AUDIENCE INTERVENTION: [INAUDIBLE] FREE THE PEOPLE.

[CHANT CONTINUES]

BRIAN BRINK: Okay. Can I bring to attention the people in this meeting that we have time for contributions at the end. And I think that we all welcome valued protest and I would ask that after a short period that you sit down and you take part in the debate. And you will be called to contribute.

AUDIENCE INTERVENTION: [YELLING, CHANTING] Let us speak!

BRIAN BRINK: As far as the people in the red shirts are concerned, could you please move to the back of the room? As a socialist I have never killed anyone, but people who have lived as capitalist countries have engaged in war all the time on a continuous basis.

AUDIENCE INTERVENTION: [YELLING, CHANTING] Let us speak!

AUDIENCE: [Inaudible]

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BRIAN BRINK: Ok, we need to have some quiet here please.

AUDIENCE INTERVENTION: Let us speak, let us speak

[chanting]

GILES JI UNGPAKORN: I think you've got plenty of opportunity in this session to speak and you should have the decency

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BRIAN BRINK: People will have chance to speak.

GILES JI UNGPAKORN: You will have plenty of opportunity and that will be fixed later but can first proceed with the speech from the first speaker.

AUDIENCE INTERVENTION: [inaudible]

GILES JI UNGPAKORN: If you want to meet with the people of the community later at 5:00, you better stop this, because I am fed up this, I'm really fed up with this.

AUDIENCE INTERVENTION: Let us speak, let us speak, let us speak [chant]

MALE: Hello, hello.

AUDIENCE INTERVENTION: Let us speak, let us speak, let us speak [chant]

BRIAN BRINK: In order that we can continue with the debate, I'm going to allow HIV positive activists to speak for 2 minutes, 2 minutes only. So could we have some quiet please? And then we can carry one with our debate. [APPLAUSE] Let me introduce Youn Niam [misspelled?] the activist, from the group Khir

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7

Khai[misspelled?], the chair HIV from the network of people living with HIV. He will speak for only two minutes and then we will carry on with the debate. [APPLAUSE] Could everyone so that we can carry on with the debate as well? And I will translate into English.

BRIAN BRINK / KHIR KHAI: I want to use two minutes of your precious time just to explain the position of the network of people living with HIV. To explain why we are opposed to intellectual property. Twenty years is plenty for intellectual property, we don't see any expansion from twenty years in Thailand. [APPLAUSE] Expensive ARVs prevent access for all, we need cheap ARVs. [APPLAUSE] The free trade agreements result in monopolistic set-ups, they prevent access to information. We want the government to actually produce drugs and compulsory license. Thank you.

BRIAN BRINK: Thank you very much, now I'd ask everybody to go back to their seats and allow the debate to continue please. Could you please go back to your seats at the back? A number of people holding banners can hold them at certain parts of the room but could you please not block the front of the podium.

AUDIENCE INTERVENTION: One free pill, [inaudible]

[CHANTING]

BRIAN BRINK: When I introduced the session, I did say that part of the idea was to get audience participation and I think we've had some of that, and we welcome that but we also want to hear the speakers. So, Hank if you could get back to presentation. Thank you.

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[APPLAUSE]

HANK MC KINNELL: Thank you, thank you. That was interesting, I too believe in free speech. Yours and yours and mine.

As I was saying, this virus is very smart at ultimately outwitting even the most sophisticated treatments. In many ways we are in a race against time to develop new ones. IP is an enabler in that race.

Consider this, AIDS first burst into public consciousness around 1981. Within 7 years the first ARV was approved for treatment and many more followed. Today we have 19 different ARVs available for treatment and there are more than 80 new medicines in development by Pfizer and other pharmaceutical companies. And IP has played an essential role in creating these options for treatment. IP is what allows us to organize and sustain broad scaled R&D efforts. Pfizer alone, 7.9 billion dollars this year to invest in the latest equipment and technology, the very smartest people, and to move quickly on promising approaches. IP drives innovations which creates new therapies, which benefits patients. In my view, the real issue of IP is one of balance. IP must not be a barrier to treatment. And it is a vital incentive to help us find new treatments and cures.

In looking at the global picture we should ask ourselves this question, "What is the right balance between the needs of patients now, today, and the needs of patient who will require new treatments in the future?" As you will see in a moment for those

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with HIV, that balance will affect the same person. As Uganda's President Museveni puts it, "How do we feed the hungry without eating the seed corn?" The answer is not either/or, we can and must do both. People living with HIV are going to need a steady stream of new therapies as the virus mutates and currently available treatments fail patients.

If access for all, the theme of this conference, is all that we do in the first sense, access to those needing medicines today then the theme of future IAS Conferences surely be, Why Are Treatments Failing Patients? Already the rates of resistance and problems with toleration are increasing at an alarming rate. This slide shows that within 2 years of starting first line heart 40% of patients experience virological failure. And within 2 years of starting the third heart regiment fully two-thirds of patients can no longer achieve control of viral replication because of resistance development and inability to tolerate increasingly demanding regiments. Put more simply, currently available treatment regiments for 50% of those in the developed world receiving heart within the next 5 years. This increasing trend of treatments failing the patients means we must invest in discovering new medicines to stay ahead of these trends.

So what is the right balance for those who need access to medicine today and those who will need new medicines tomorrow? Here's Pfizers answer, we will work with any government anywhere who

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requests access to any Pfizer medicine needed in the fight against HIV/AIDS, malaria, and tuberculosis for those who cannot afford access. We will not agree, however, where the goal is to appropriate our technology for sale by others at a profit. [APPLAUSE] Thank you.

Let me make one further point and this may seem at odds with general perceptions of a company like Pfizer. The HIV/AIDS problem is of such enormous magnitude that it's equally important to focus on prevention. In fact, right now prevention is by far the most cost effective weapon in our arsenal HIV/AIDS. [APPLAUSE] We must apply the same energy around prevention as is beginning to emerge around treatment. We must invest more in the development of vaccines and microbicides and optimize the use of medicines to prevent what is totally preventable, mother to child transmission.

In terms of less costly options we also need creative and dynamic partnerships to deliver locally based education, training and awareness programs to help prevent infection. Pfizer, by the way, is doing just that. Supporting prevention efforts in places from the southern states of the United States to sub-Saharan African particularly for youth and for women, who now account for more than 50% of new infections.

Finally, whatever your views about the role of IP, whether you're for it or against it, whether you believe it's a barrier or an enabler, I know that we cannot defeat this virus if we maintain this polarizing atmosphere. We cannot be at war with each other. IP,

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whatever it's limitations is not the enemy. Research based companies like Pfizer are not the enemy. HIV/AIDS is the enemy. And the way we will defeat this virus is through innovative partnering, both to find new treatments and cures and to identify creative and effective ways to prevent transmission in the first place.

Towards this goal, I'm here to listen, to learn and to help. Thank you.

[APPLAUSE]

BRIAN BRINK: Our next speaker will be Jonathon Berger [misspelled?] from South Africa, from the Low End Treatment Access Unit. Jonathon provides legal services for the treatment action program.

JONATHON BERGER: Good morning everyone. While I have the floor, I'd to like to first make a brief announcement and to raise a particular concern that we in South Africa, particularly at the Treatment Action Campaign has at the moment. Yesterday our Medicines Control Council effectively de-registered Nevarpine [misspelled?] as monotherapy for the prevention of mother to child transmission of HIV. Apparently without regard for the consequences of their action. The Treatment Action Campaign will be going a meeting of all South Africans and other interested parties, including government and all researchers tomorrow at lunchtime. We will make an announcement as to where the meeting will be held. We are very concerned at the confusion and the potential for chaos that this public release of

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this statement can cause. Most importantly we are very concerned about the implications of de-registration of Nevarpine [misspelled?] in South Africa for other developing countries, where at present Nevarpine [misspelled?] is the only drug which is being used to prevent mother to child transmission. So everyone who is interested, please, tomorrow at lunchtime there will be a meeting to discuss this issue, we are very concerned about our government, about the way in which it is going ahead, it is creating chaos, creating confusion and not acting responsibly and not acting in the best interests of people living with HIV. [APPLAUSE]

Having said that, I'll now move on to the topic, which is, "Are Intellectual Property Rights a Barrier to Increased Access to Anti-Retrovirals?" In my view, this is the wrong title. This is the debate we should be having: Why are we still debating whether patients limit access? Particularly 4 years after the Durbin conference [applause], thirty-two months after the DOHA [misspelled?] Declaration on TRIPPS and Public Health, and a mere [inaudible] weeks before the first anniversary of the August 30 decision on paragraph 6 of DOHA. What we should be [inaudible] moving to effect a permanent amendment to the TRIPPS Agreement, how we should be implementing these agreements and what should be happening in that regard.

The debates on IP versus innovation versus access have largely been settled. It's interesting to note that the previous speaker, Hank McKinnell, spoke about the need for balance

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particularly given that he is the CEO of Pfizer. We all know very well the very strong role that Pfizer played in the Uruguay round of negotiations, which led up to the adoption of the TRIPPS Agreement. An agreement which was never intended from the side of the pharmaceutical companies to strike the type of balance that DOHA finally brought to us.

I'll begin by providing a brief overview of the presentation that I'm going to make. First, I will on the issue of patents still limiting access to anti-retrovirals and 3 issues under that. Then I will look at, when we think of finding a practical resolution, what do we talk about. And finally what are the current obstacles that we need to overcome in insuring access to anti-retrovirals?

But before I can do so, I need to consider briefly a few issues relating to the creation incentives to develop new drugs. It's important to note that opposition in South Africa is not an attack on patents per se, but rather an attack on the abuse of exclusive rights in patents and other forms of intellectual property. For us the issue of patent protection is a domestic matter, balance that Mr. McKinnell spoke about is a balance that needs to be struck at national law, not a single standard for all countries. It is not about patents versus no patents, but understanding the relevance of patents, where they can work, where they do not assist and allowing developing to strike their own balance, without the influence of

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countries where the particular balance of developing countries may not necessarily be an issue.

Before I can continue, I think it's important to ask a few questions. If we're looking at the role of IP I think it's important that we recognize the limitations of IP. Particularly the questions you see in front of you: Who funded what research? When? At what level? How risky was the research when it was done? Government funded research in the United States under the Bayh-Dole Act. How the United States government not used that act to insure that the research that it funds is properly controlled and that access to the benefits of that research is insured. Have patents delivered for disease of the poor? We talk about incentives for innovations, what incentives does the patent system provide for innovation to deal with diseases of the poor? HIV/AIDS is not a good example given the high numbers of people with HIV in developed countries. Absent those numbers of people in developing countries, patents or no patents, in developing countries, the drugs would not have been developed. And then I think a very important question, what was happening before TRIPPS? When countries were free to determine the balance for themselves, was there no innovation? I think the answer to that is quite clear. And then final question, is the developing world really the kind of market that will create the incentives under the current patent system? We all know Africa's share of the global pharmaceutical market is a mere 1.5%. So with those few questions, I

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would like to go on to my next slide.

Patents still limiting access to ARVs. What is important to understand here is that it is not just an issue of price. Price is very important but it is not only the issue. It's about price, it's about reliability and sustainability of supply and it's about the role of intellectual property in stifling innovation. We talk about creating incentives for innovation through intellectual property but the reality, as we know with the whole debate around a fixed dose combinations, is that intellectual property has served a barrier to further innovation.

On the issue of price it's important to recognize that price reduction only came about following the introduction of the threat of generic competition. If we look at the current access pricing versus the Clinton Foundation pricing there is still a significant difference in the numbers. I have yet to see a first line regimen using branded products at \$140.00 to \$150.00 per patient per year.

On reliability and sustainability of supply, we all know the importance of adherence to anti-retroviral and the dangers of not having sustainable supply. There's a very important example of what happened in South Africa earlier this year where there was a sudden lack of supply in 50 milligram stockroom, resulting in a number of children in anti-retroviral therapy having to default on treatment. A single supplier of each drug is not enough. We need more than one

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supplier to insure sustainability.

Finally the point in limits on innovation. It's not the simple exercise of the rights in intellectual property that is the problem, it's holding on to the exclusive rights while at the same time failing to cooperate with other patent holders, which has meant that fixed dose combination such as GPOvere [misspelled?], Triimmune [misspelled?], Trivero [misspelled?], are only being developed by generic companies and have not been developed by the brand name pharmaceutical manufacturers. Some have the drugs have been, we have Combovir [misspelled?], we have Trisovair [misspelled?]. But you can speak to scientists when the combinations that you are developing such as Trisovair [misspelled?] are based on what is in your stable, rather than what is the most effective first line regiment then we are in trouble. Then it really is about profits before science.

What is the practical solution that we are proposing? Firstly, domestic implementation of the DOHA Declaration. We need to make sure that the developing countries exploit the public health safeguards and flexibilities in the TRIPPS agreement that existed but where clarified at DOHA. It is important that countries with manufacturing capacities such as my own lead the way. Much is made of the fact that developed countries do not have to implement patent protection on pharmaceuticals until 2016. That might all be very well, but what do those countries do? Where do they get their drugs from? They going to get their drugs from middle-income countries

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like South Africa, like Thailand, like India, like Brazil, countries who's obligations kick in 2005 and in respective other countries sooner than that.

But when we talk about the domestication implementation of DOHA, this is not just about what countries are free to do. It is not just what about TRIPPS permits countries to do. From where we come from it's about the obligations on countries to comply with the international and domestic human rights commitments. This is not about choosing whether or not to insert government use provisions into patent law. It is not about choosing whether or not to issue compulsory licenses or to make sure that you have simple easy to use compulsory licensing provisions for third parties. It is about implementing those provisions, making sure that people get access to medicines at home. As I said not about the options that countries have, it's about the international and domestic human rights commitments.

Very briefly on paragraph 6, we need a final amendment to the TRIPPS Agreement to give proper effect to the problem that was identified in paragraph of the DOHA declaration. Domestic pharmaceutical manufacturing capacity should not be a determinant of access that for me is the bottom line. The resolution that was agreed to August 30 is not a resolution of the problem. The problem still exists. We need a simple solution. A single compulsory license in the importing country should be sufficient. Countries

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without manufacturing capacities should not be worse off than countries like my own that have capacity.

My last slide. What then are the obstacles to implement? Obstacles to overcome? Excuse me. While it's important for us to stress the role that intellectual property plays in limiting access and to stress that countries have certain flexibilities, we cannot let developing countries off the hook. We have to make sure that developing countries are implementing what they are entitled to do under international trade law. And what they are obliged to do under international and domestic human rights law. And yet, developing countries are not implementing what they should be implementing. My own country, for example, has a patents act that offers patent protection significantly in excess of what the TRIPPS Agreement and DOHA requires.

Why then are countries not implementing? South Africa is probably not good example, we have a whole history denialism and unfortunately still a present of HIV denialism at the very highest levels of government. And by highest levels of government, I mean the minister and the president. And that may go some way to explaining why South Africa has not implemented the DOHA Declaration to its full extent.

But there are two other reasons that probably apply to South Africa as well as, and probably more importantly, to all other developing countries. The first is the bi-lateral and regional free

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trade agreements that are being negotiated all around the world. The United States pushed for intellectual property to become a trade issue, when it's not a trade issue. Now that TRIPPS is not working for the United States we now go the bi-lateral and regional free trade agreement route. Pre-dating TRIPPS, NAFTA, CAFTA, Chile, Jordan, Morocco, Singapore, Australia, it's not just the developing world that's being attacked. And in my own country and part of the world the Southern African Customs Union is negotiating a free trade agreement, we're very concerned that we're going to give up the flexibilities that we have.

And then finally PEPFAR. A lot has been spoken PEPFAR, about the conditionalities, about abstinence before marriage, I'm not going to touch on those issues here. We all know the truth, we all know that condoms work, we all know that ABC killing people.

[APPLAUSE] But PEPFAR is insuring that countries are not free to implement the flexibilities that they have. It is undermining the Global Fund, it is undermining the WHO pre-qualification process. The Global Fund, it is undermining the WHO pre-qualification process are crucial to insuring that countries are able to implement the flexibilities that they have.

One last announcement that I'd like to make. One further abuse of the platform that I'm on. This evening there is a satellite event being hosted by the UNDP entitled, "Beyond Cancun, Whose Access Counts?" Where a lot of the issues about failure to implement

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flexibilities, it's in session room J in the convention center from 6:00 until 8:00 pm and speakers include Achi Achmed [misspelled?] from the Treatment Action Campaign, Maureen Heiser [misspelled?] from UNIFEM, Martin Core [misspelled?] from the Third World Network, Mary Robinson and the Minister of Health from Brazil.

Thank you very much.

[APPLUASE]

BRIAN BRINK: Thank you very much Jonathon. Our next speaker is a voice from the front lines. Dr. Ali Katavera [misspelled?] is the Associate Dean of the School of Medicine at a McCaray [misspelled?] in Uganda. He is also a member of the governing of the International AIDS Society. Ali has been involved with treatment of patients in Africa for a good number of years right from the beginning and he's got good experience of the issues at hand, Ali.

DR. ALI KATAVERA: Thank you very much. When I arrived here, I didn't know that I'd be speaking today. I was told yesterday morning and they said you're going to be talking. For those who have known some time, I usually take time to prepare what I'm going to say to the public. With less than 24 hours I was reluctant to accept. But then I was told something, go out there and say what you do best, taking care of HIV infected patients.

So for that matter, to bring today's discussion into perspective, I will tell you that I trained in Malabo in [inaudible]

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Conference: 15th Annual International AIDS Conference
Are Intellectual Property Rights a Barrier to Increased
Access to ARVs?
7/13/04

21

Medical School in the 70's and went to UK for post-graduate training. And I returned in 1985 with the worst epidemic we all know today. Those are the days I got involved and I started an AIDS clinic in 1987. In those days we knew very little about HIV, but there was something, which we knew very well which we constantly taught patients. That's as we speak today that is no cure for AIDS. So in those other days I also had the unenviable job of telling many of the patients who were suffering then, either based on clinical basis or on based on some best investigations that people had HIV or AIDS. And I always remember the common scenario whenever the patient would ask me, "So Doctor, you say I have AIDS." And I look in his eyes, "Yes, you have AIDS." Then he would say, "So, I'm going to die." And I would pause for awhile because I didn't to say yes on that one, but then over time I gathered courage, and I would say, "You don't need to die. If only you could hang around long enough. Because I know as we speak there are people working very hard to produce something which will cure you." It has taken many years for that cure or close to cure, to come to Uganda. And I feel very sad to learn or to be told by anybody that that cure cannot be accessed by the very patients I promised so many years ago. [APPLAUSE]

I'm a clinician. I'm not an economist and indeed I knew very little about the trade rights, or whatever they call them, until recently. If these are going to be a barrier to the access of anti-retroviral therapy then probably I've failed in my mission of taking

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care of HIV infected patients. But I'm always optimistic and I've been so for the last 20 years. I believe that what we are discussing today can easily be resolved.

And therefore, because I believe so, I look at another importance aspect. What do we, as health care workers, and our patients can we do to help those who are working very hard like, Hank McKinnell, to produce new drugs? I believe that we have a lot to do ourselves. When the [inaudible] this particular conference puts emphasis on access for all but access is not enough to be just translated into better care and better health for those who are HIV infected. We need to do more after accessing the drugs. And how can we help our patients to do that? On many occasions I have been asked, "Why have you hung in there for that long?" Because there are many examples of people who have been burnt out as a result of getting exposed to the tears of the many patients and dying young. One of the very reasons that why I hang there because I wanted to insure that people learn what to do when I'm not around.

One of the best we can do to help the Hank McKinnell's to produce more drugs, because we will need more drugs there is no doubt that the drugs you have today will fail one way or another, has been mentioned. What we can do is to delay that fail, so that there is enough time in between for the Hank McKinnell's to produce other drugs. And also to press upon them that they don't need to charge them highly, because we will be waiting to buy them and use them.

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One of those which we have been doing through WHO at the local level and HAART international level is to train many people, so that they help those who are affected and infected to be able to use the drugs which you all want them to have. I'm sure this conference will learn more in order to be able to achieve that. We need these drugs and the barriers should be minimized as much possible.

Thank you very much.

[APPLAUSE]

BRIAN BRINK: Our next speaker is Professor Walden Bello, Professor of Sociology and Public Administration at University of the Philippines and also the Executive Director of focus on Global South. In the year 2003 Walden Bello was awarded the alternative Nobel Prize. He's also the author of a number of books, one of the recent ones about globalization, called "De-Globization."

WALDEN BELLO: Thank you very much to the organizers for inviting me to this event.

I need not repeat here the scale of the public health problems with the estimates of the acceleration of the HIV infection rate that have been presented and will be presented in the next few days. Clearly, we need the equivalent of a Manhattan Project to deal with HIV/AIDS one that will unlike the original Manhattan Project be life preserving instead of death dealing. All actors, government, business, civil society, the medical community, need to be drawn into one massive coordinated effort.

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The one actor on the HIV/AIDS scene is big pharma. More and more people have asked the question, is it part of the problem or is it part of the solution? Well, let me not keep you in suspense, it is a very big part of the problem. [APPLAUSE] While the United Nations and other agencies have been working with governments in Africa, Latin America and Brazil over time to stem the tide, what has big pharma been doing? Well from 1999 to 2001 it sought to get the U.S. Government to use mechanisms like aide cut-offs to pressure South Africa to overturn its new law on compulsory licensing that will allow the manufacture of cheap anti-retroviral drugs. It also threatened to sue South African government for infringing on patent rights. It even used then Vice President Al Gore to pressure the South African president on the issue. When in November 2001 the assembled government ministers during the WTO Ministerial in DOHA approved the declaration, saying that nothing in the trade related intellectual property rights or TRIPPS Agreement would prevent them from taking measures to protect health, big pharma spent the next two years trying to undermine the agreement by trying to get countries to attach onerous conditions to the sale of essential drugs by developing countries with manufacturing capacity to developing countries without manufacturing capacity. Indeed, big pharma's hard-line position nearly scuttled the WTO Ministerial in Cancun in 2003 even before it could take place. It was only the concessions made by developing countries that allowed the ministerial to occur.

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I think when it comes to HIV/AIDS big pharma is less concerned about saving lives and more concerned about protecting its patents and advancing its very restrictive interpretation of the TRIPPS Agreement as restricting compulsory licensing. Preventing the export of drugs produced under compulsory licensing and banning parallel imports.

Now, what is behind this callous attitude? Well big pharma's rationale goes this way; without the very drug protection it wants for its patents, without the super profits it derives from patent protection there would be no research and development, no innovation and thus more and more people would die from AIDS and other deadly diseases. So, they tell us when you learn from the WHO the most patented medicines retail at 20 to 100 times their cost of manufacture remember that this is not about market pricing but monopoly pricing to support continuing research and development.

Big pharma's position about the necessity and efficiency of corporate R&D is based on a number of myths and outright distortions. Let us look closely at some of this. Big pharma tries to project the fact that it is its efforts alone that are key to drug development and that is why we should accept its monopoly pricing of drugs. Typical was the claim of Barros-Wellcome [misspelled?] now part of Glaxo-Wellcome that it discovered AZT. In fact it was the staff of the publicly funded National Cancer Institute of the United States working with Duke University researchers that did it.

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Conference: 15th Annual International AIDS Conference
Are Intellectual Property Rights a Barrier to Increased
Access to ARVs?
7/13/04

26

Governments in the U.S., Europe, Japan spent three times more money than private firms on basic science, drug development and clinical trials that produced the protease inhibitors, the second generation of drugs, that has led to some control of HIV/AIDS at least in the north.

Big pharma today says it is developing 73 AIDS drugs, then it quietly admits that most of the firms doing this research are in fact substantial help via publicly funded researchers within the national institutes of health. In other words big pharma says it is doing R&D but it is actually siphoning off taxpayers money for much R&D in essential drugs. [APPLAUSE]

Big pharma says strict patent protection is necessary because it takes 500 million dollars to bring a single drug to market. Mr. McKinnell's estimate is that it's a billion dollars. Now this is a bogus figure for various reasons. Not least of which is the fact that most of the so-called new drugs are not innovations, indeed in excess 40% of the industry's R&D is aimed at producing minor variations of existing drugs, not turning out new ones. Also much of the cost of so-called drug development are in fact marketing costs designed to convinced people to buy different versions of the same drug. The fastest growing sector of big pharma is the marketing sector, not R&D. There are now in 90,000 sales people in the industry to pester doctors to recommend their drugs. With Pfizer alone accounting for 11,000 of this. And 12 billion dollars now goes

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to this non-essential layer of wages and sales. A third cost which is factored into the 500 million dollar figure, is the massive the salaries of the top executive layers of the different drug corporations. But more on this later.

The pharmaceutical industry is the most profitable industry in the United States as the following slides will show. Big pharma makes a 20% return on investment, making it the most profitable industry in the United States. Yet, even as its profits leap upward the productivity of the industry has plummeted. In 1996 the FDA approved 53 new drugs, last year it approved just 17. Increasingly, according to the Toronto Star and I quote, "Big pharma doesn't invent drugs. It licenses them from smaller firms around the world or buys them outright by acquiring the firms the hold the rights, passing along the high takeover costs to consumers." Drug consumers all over the world in terms of higher prices Pfizer's recent acquisition of Werner-Lambert and Pharmacia Corporation. Not innovation in making, not innovation but making variations of the same drug or medicine or treatment is what the industry is settling into. Which is why it must hold on tightly to existing patents whether it is in HIV/AIDS drugs or in tropical disease drugs or cancer drugs. Every group at this point, not just those suffering from HIV/AIDS, are up in arms against big pharma. Indeed Republicans in the House and Senate of the United States have tried to push laws that would make legal imports of cheaper drugs from Canada because people in the United

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States itself are in rebellion against the high monopolistic prices at this point.

As everybody knows, even with compulsory licensing HIV/AIDS treatment costs are still too high, relative to the resources of patients and governments. R&D breakthroughs are needed that will produce effective, affordable drugs. To expect this sclerotic industry that is increasingly dependent on rent rather than competition to make the breakthrough in HIV/AIDS research that is so greatly needed is unrealistic.

But there's a more basic question. Does the industry really have an interest in developing drugs for which there is great need, but from which one can derive little profit? Well, the answer is no. Despite the fact that tropical diseases were the main killers of the world's peoples only 13 of 1,233 new drugs that reached the market between 1975 and 1997 were approved specifically for tropical diseases. There was simply no market to support R&D in this area. In the same way that for big pharma the millions of people suffering from HIV/AIDS in Africa, South Asia and Southeast Asia simply pale in comparison as a market for rich people's diseases in the north. Profits determine corporate R&D not human needs. [APPLAUSE]

My point is that R&D for HIV drugs and other essential medicines is no longer efficient within a corporate context. Big pharma is more interested in protecting its 20% margin, provided by monopolistic pricing based on patents, than in producing drugs for

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people with little purchasing power, like those suffering from HIV/AIDS in the developing. Big pharma worries that if it loosens its tough stand on intellectual property rights, on HIV/AIDS drugs this will lead to a collapse of its whole system of monopoly pricing. Now I have no problem with giving big pharma of 20 or 30 years of strict patents rights to Viagra and other chemical toys to enable 70 year old white men and women to have another fling. But essential drugs to save million and millions lives, that is another matter. TRIPPS simply cannot handle the simple distinction between essential life-saving drugs and frivolous drugs like Viagra, which is why we need to replace to TRIPPS. And corporate research and development, protected by the TRIPPS Agreement simply is an obsolete framework when it comes to essential drugs.

We need a new R&D framework, maybe coordinated, in which there are many actors including government, government institutes and civil society organizations. This new Manhattan Project can be funded from a global fund, such as that proposed a few years ago, by Dr. Sawat [misspelled?]. One that could be supported by a tax that would amount to 1% of global drugs sales of 450 billion dollars today, or 4.5 billion, which will be a big fund.

But in conclusion, let me return to the matter of executive pay. Increasingly, more and more resources that would otherwise go to corporate R&D are being funneled into pay packages for the top layers of the pharmaceutical industry. Here you see the pay packages

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for some top CEOs. But the champion in terms of executive pay, is non other than the CEO of Pfizer.

MALE: What the fuck?

WALDEN BELLO: 28 million dollars as annual pay package plus unexercised stock options of 30 million dollars. Now, I can safely say that most of is in this room, would not make in ten lifetimes would this gentleman makes in one year. Now we know why corporate R&D costs so much. [APPLAUSE] But what I really wanted to say is that these are the very same people who have begrudged the millions and millions of people infected with HIV the radical price reductions their lives. This is the height of inhumanity.

[APPLAUSE] Let me end today by saying that what we need badly are new Madame Curies, new Louis Pastuers, new Jonas Salks, not Hank McKinnells. Thank you very much.

[APPLAUSE]

BRIAN BRINK: Our next speaker is Harvey Bale [misspelled?] he is the Director General of the International Federation of Pharmaceutical Manufacturers Associations, essentially representing the interests of research based pharmaceutical manufacturers. Harvey.

HARVEY BALE: Thank you very much Brian. I have a few slides and I hope to be provocative but I will not nearly be as provocative as Dr. Bello just a few minutes ago. And I found a number of distortions in his remarks, but I just want to point to one

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that I think is important for an AIDS conference to understand. Dr. McKinnell mentioned the very first AIDS product that came out, AZT. And Dr. Bello alleged that that drug was invented by the government. It is true that the compound was financed by the U.S. government and discovered under a U.S. grant. But it was discovered as a cancer drug, as a failed cancer drug. This is very typical of many drugs that simply fail in their first discovery and use. And it was the Barros-Wellcome [misspelled?] company that developed that drug and spent hundreds of millions of dollars in doing so that made it the effective AIDS treatment for patients. So I hope sir, that in your future presentations you might make a note of the reality of that drug development process. And I think that question that we have here today, and again I will be provocative, and I hope that in just in a few short slides point to some of the economic and trade issues, and compliment some of the other remarks. I just want to say that as part of this discussion, the question that is raised, "Are Intellectual Property Rights a Barrier to Increase Access to Anti-Retrovirals?" is somewhat of a circular question. Because the other part of this question, you have to understand that without those intellectual property rights, we wouldn't be debating accessibility to ARVs. And we have to understand that internal contradiction in the debate that is going on about access to anti-retrovirals and drugs for opportunistic infections.

To me the issue is not whether there should be, but rather

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how to manage IP rights. In this sense I sympathize with a number of the points that Jonathon Berger had made earlier, although I might disagree on some his conclusions, I think he raises a number of the right questions. IP rights do exist to foster necessary innovations to cures and vaccines, but we do face the problem of inequalities in income making both patented and generic drugs inaccessible. We have to remember that the World Health Organization has identified that one-third of the world's population do not have access to any quality drugs, but these drugs are largely off patent. Including anti-malarials, tuberculosis, measles vaccines, respiratory infection medicines et cetera. What we have today, and I think what we will have in the future, is a mixed system of intellectual property protected products and generics. We will have anti-retrovirals and innovative companies are generally not applying for patent protections in sub-Saharan Africa, with South Africa as an exception, and I note here that the India company Sipla [misspelled?] has sought a patent and obtained a patent in South Africa for its tri-immune combination products. We also have examples of patent rights being locally licensed, particularly in South Africa, by innovative companies. And I understand just today that MSD is licensing it is Effevevan [misspelled?] drug to a local company Timbalane [misspelled?] which is jointly owned by Ran-Baxi [misspelled?] and Adcock [misspelled?] in South Africa.

Companies are offering differential pricing and donations

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and these pricing offers are frequently below those prices offered by any generic producers and almost always below at least some of the prices of some of the generic producer's products from India and elsewhere.

And finally, developing country companies are increasingly using the patent system themselves. They're evolving their own research agendas and developing products that are good for the first world and the third world, cardiovascular and diabetes drugs for example. So, it's becoming a globalized system indeed.

So we have an alternative scenario, I think, ahead. I think we can see a quasi-global mixed IP right system, with a mixed presence of generics and patented drugs and vaccines and we will also have a system, I think, if stick with it that is in aid in fighting counterfeit medicines, which I don't believe has been emphasized enough as a danger to expanded access of ARVs. We see in countries like Nigeria, the Southeast Asian region, as well as other regions, Latin America, Brazil, the extent of counterfeit medicines is becoming a public health menace. It is not so much a commercial threat for the pharmaceutical industry, as it is a public health threat. In some countries and some officials in Nigeria for example have said that counterfeit drugs are as a danger a public health threat as is AIDS.

Now the other model, which I think Professor Bello prefers, is no IP rights, everything becomes generic, some kind of a public

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drug development model, a Manhattan Project which I think we can say for discussion is totally inappropriate to drug discovery and development. And this situation we see actually today in some countries. Now in many of the countries of the developing world we see branded generics. It's not just as Brian Brinks said earlier, it's not just a question of branded versus generics, it's what kind of generics do you have? Many companies have branded generics, we have monopolistically priced generics based on a brand. Generic companies have marketing sales forces that market generics. And in that case of course, given that the R&D, is zero the ratio of marketing to R&D is infinite. In other countries like India you don't have branded generics so much but in the case of India where no patents exist you have more pharmaceutical companies something on the order of 22,000 pharmaceutical companies in India, you have more pharmaceutical companies than you have patients being treated for AIDS. Which is on the order of 13,000s, whereas you have 22,000 pharmaceutical companies. So a generic world is simply not a world, which I think we want to live. The IP is not a threat, but an opportunity. It's essential to the development of new ARVs and the AIDS vaccines that are in the pipeline today. Lack of access to ARVs is serious and it's also serious for many other drugs that need to be tackled, it's a global issue. But the real challenge comes from the fact that the lack of IP would be a far greater threat to public health and the problem of access to affordable high-quality medicines

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would be worse, not better.

Addressing HIV/AIDS everybody, I think, understands is multi-faceted and many people have addressed the point of political commitment, getting more money for the global fund, capacity building, et cetera. I just want to point out this last item, which is trade policy. We're talking about trade policy today. The issue of high tariffs and domestic taxes and the elimination of anti-dumping matters which is kind of a tariffs plus game, whereby if the product is too cheap governments, and governments have done this because drugs have been too cheap coming in across the border, have applied extra tariffs. A tariffs plus system to make drugs far more expensive to their patients than they would otherwise be. And I think these are the issues that we have to tackle and I hope we tackle the trade policies issue as well as these other issues that are of course far more important. Thank you very much.

[APPLAUSE]

BRIAN BRINK: Now the community program was keen that this meeting involved participation, we started a bit late and we had the interventions but I think we can, with your indulgence, we can have twenty minutes of discussion. But I'd like to ask everybody to keep their contributions to a minimum, 1 to 2 minutes only and in order to save time will you queue up behind microphone number 3? And I'd like to encourage people who aren't used to speaking, especially Thai people in the audience and I may help with translation. I understand

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that the interpreters will have to take a break at 12:00, so we'll have to carry on without them.

JOPAL NOWATI: [Misspelled?] I'm Jopal Nowati [misspelled?] I'm a professor of economics in France and I'm responsible of the French Agency for AIDS Research Program, Economic Program. I would like to make two comments. Economics clearly tells you that in some circumstances patent protection isn't necessary to guarantee a rate of return for private investors, but I think the debate a lot more balanced if we add real data on the real R&D costs. Which is very difficult to get. So, I will make a suggestion, it would be in the great interest of the industry if you agreed that an independent task force of economists that could be added by a Nobel Prize of economist, does work on what are the real R&D costs of drugs in various sectors. And that you open your data files, in order to make the debate more clear. That would be a great progress in the sense of a more a balanced [inaudible]. [APPLAUSE] And I volunteer for that, and INRS will volunteer to participate in that.

Second comment, we did an extensive analysis of real transactions that has been published in a book which is available on the France booth and also partly published in Major Medicine in December, that shows a few things about the relationship between determinants and prices. Clearly when there is patent protection in a country, it is everything equal, that has an effect of increasing prices of all drugs and secondly clear that its competition, market

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competition, which has been the major factor for decreasing prices. So the question is not generic versus patent. The question is to really build real markets, real competitive markets, and the problem is that quite paradoxically some of the forces, including the U.S. government, that should anchor these market mechanisms seems sometimes -

BRAIN BRINK: Could you wind up please?

JOPAL NOWATI: [Misspelled?] to step beyond. Thank you.

[APPLAUSE]

BRIAN BRINK: Thanks. Please introduce yourself.

BARUN MITRA: [Misspelled?] I'm Barun Mitra [misspelled?]

from NGO in New Delhi, India and although there are no Indians on the panel but India was mentioned a couple of times. I would like to ask, particularly in view of the topic of session, that in India patients rights traditionally have been extremely weak. Thousands of pharmaceutical companies, yet for a few thousand I think about 1% of the total AIDS population in India are actually receiving any kind of treatment, while we are taking of Indian generic manufacturers trying to export foreign markets. I mean, I cannot understand how is it that a country that has such an enormous industry can't produce drugs for its own people. [APPLAUSE] And this issue therefore to me goes much beyond patent, because I would like to point out since Professor Bello mentioned Viagra, that two of India's major pharmaceutical companies were much more aggressive in marketing the generic India

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version of Viagra than many of the other life-saving drugs. So it seems to me the corporate interest, whether it's domestic, need not necessarily follow the interest of the patients. And therefore the final point that I'd like to submit is in countries like India where, in most developing countries, where the basic delivery mechanism for any kinds drugs is so weak, how is it that all of us or many of us here seem to think that just by having those drugs we are going to make the drugs available to the people or access for all?

BRIAN BRINK: Wind up please.

BARUN MITRA: [Misspelled?] Access for all, I think can not happen, unless the infrastructure issue of delivery is looked upon and which happens [APPLAUSE] to be completely in the government's hands in most of our countries. Thank you.

BRIAN BRINK: Next speaker please.

RICHARD ELLIOTT: Richard Elliott from the Canadian HIV/AIDS Legal Network. I have a comment and a question. The comment is that we've unfortunately seen too often that those who are advocates for treatment access have been painted as somehow simplistic in their analysis of this problem. And I've think that we've seen that again here today. We've seen this rather [inaudible] to cast treatment advocates as somehow rabid socialists and the suggestion that capitalism will heal. When I think the treatment activists have always said from the very beginning that we know patents are only part of the problem and that addressing the patent

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barrier is a necessary but not sufficient solution. I think it was quite indicative of that that Jonathon Berger in his remarks quite expressly said that our concerns in not patents per se, but that governments actually have the appropriate ability and power to pursue competing public policy objectives in the design of their public policy. The conflation is also seen in the notion that it's IP or no IP, when in fact we can see regimes that unbundled that concept of IP rights and say that this is a package of rights and we can have certain kinds of protection of rights vis-à-vis intellectual property while at the same time allowing for that public policy space for governments. And greater use of compulsory licensing with payment of royalties to patent holder. There is a balance that can be better struck there, it's not a simplistic either/or, and in that regard I think what we saw in the comments from Mr. McKinnell an attempt to use that simplistic characterization in an attempt to divide those who are activists for treatment and those who are activists for prevention technology such as vaccines and microbicides.

BRIAN BRINK: Thank you. Can you wind up please?

RICHARD ELLIOTT: Therefore it's important that as advocates for health and the human rights of people with HIV that prevention advocates and treatment advocates come together and develop joint positions about the appropriate public policy approach to stimulating innovation but also insuring access to those products.

The question to Mr. McKinnell is we've seen recently that

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in the U.S. context all of the sudden the patent companies are stepping forward to say "Now we'll produce fixed dose combinations or co-packaging of our products." It seems to me that they've only done that because generic companies the fixed dose combination products. To me again it suggests that competition is in fact what will crompt the response from patent holders and I wonder if you can give us any explanation, Mr. McKinnell, as to why the companies that hold these patents on these products, knowing as we have for some time that fixed dosed combinations are needed, have not actually acted before that threat of competition from the generic sector actually emerged.

[APPLAUSE]

BRIAN BRINK: Thank you. Next speaker please. And please be aware that there are many people behind you wanting to speak.

HANK MC KINNELL: Would you like me to comment on that?

TOBIAS LOCOU: [misspelled] Hello my name is Tobias Locou [misspelled] I'm with Doctors Without Borders, Access to Essential Medicines campaign. MSF is treating 13,000 people on ARVs in developing countries a substantial number of them are children. Mr. Bales and McKinnell you have described IP as the driving force for innovation and for research into new medicines, so I'd like you to explain to me why we are desperately waiting for diagnostic tool and ARVs in pediatric formulations. We know how difficult it is to treat children and we would like to know now Pfizer when are you going to produce the first ARV in a pediatric formulation? Thank you very

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much. [APPLAUSE]

BRIAN BRINK: The speakers will have an opportunity to come back again for 2 to 3 minutes, but first we want to encourage participation. Next speaker please.

FEMALE 1: I think this question is best directed to Harvey Bale IPMA. There's been a lot of discussion at this conference about the potential negative consequences of an FTA with Thailand and the United States. But we do have examples of FTAs with other countries like Mexico, Chile, Singapore, Israel. Have you found that these FTAs have added any benefits for the patients in those countries?

WIJAY KHONDURA: [Misspelled?] Hello. I am Dr. Wijay Khondura, I work in Los Angeles and I treat HIV patients, I am basically from India. I would like to comment this addition made by this addition made my Indian colleague. Perfect shouldn't be the enemy of the good. And in India the government is accused anyway, whether it provides HIV medication saying that there's no infrastructure and if it don't they're accused of not giving it. So I think we should start something for everything, so we can't let patients die until infrastructure is put in place. Regarding the speaker who spoke last, the arguments seemed very specious and evasive at best in trying to make a case for IP. You mentioned there were 22,000 pharmaceutical industries and they're not able to treat even 22,000 patients. And the question is, what was the point in mentioning that? Thank you.

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BRIAN BRINK: I think we only have time for the people that are now lined up. I apologize to anybody else who wants to speak but we are short of time.

JULIAN MORRIS: I'm Professor Julian Morris from the University of Buckingham and Director of International Policy Network. I have a question to Walden Bello who seemed to propose an alternative model for developing new drugs based on the United Nations taxing pharmaceutical companies. It seems to me that you're proposing something along the lines of what the Soviet Union tried to do for about 70 years, rather unsuccessfully in terms of drugs production. Do you really believe that by reducing the incentives of research based companies, transferring money to an unaccountable bureaucracy you will be more successful than say for example the attempt to produce a vaccine for malaria in the 1980s which resulted in huge amounts of money being transferred to bank accounts of the researchers? **[APPLAUSE]**

SIERRA WASHINGTON: Hello my name is Sierra Washington, I'm a Harvard Medical Student, currently I work Zambia helping to treat people with HIV. I have question for Dr. Hank McKinnell and also the last gentleman who spoke. I'm just curious as to why, if Africa, only accounts for 1.5% of the market share as one of the speakers pointed out, why then are the pharmaceutical companies against parallel import and compulsory licensing for those countries? Why is it so important for your industry, who has clearly a large profit

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margin in the north, why are you against those policies for countries that can't afford your drugs? [APPLAUSE]

JOHN PIERIE: My name is John Pierie [misspelled?] I'm the coordinator for Global Justice Zambia. I'd like to speak on behalf of the youth around in the world, because the right now are like in majority. And I believe that those in majority are the ones that are highly effected by this HIV/AIDS epidemic. My concern is about the debt crisis Africa is going through. I feel very sad that the majority youth can't access ARVs or AIDS treatment, the people in Africa who can access ARVs and AIDS treatment are those especially in government or leaders because they have the money. And those in big positions like the directors, managers, in big companies. Now, to all the big speakers in front, I'm posing this question because African governments are servicing deaths instead of servicing education for the youth or fighting HIV/AIDS. We the youth are a window of hope, not only for Africa, but the world the large. We determine the course of our nations. When we the youth lack vision the future of our nations is bleak. And when we the youth gain vision our nations will gain direction. Why should our governments be investing money in servicing deaths instead investing money in our future? Investing in the youth means that they have to protect and guarantee our health 100%, so we need to fight the debt crisis Africa is going through. If there is the IMF and the World Bank here I please am kneeling down on behalf of the youth, drop their debts so

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that we fight HIV for Africa to rise. [APPLAUSE]

BRIAN BRINK: I'm sorry but we don't have time for new people to join the queue, we're short of time. Next speaker please.

MAYLENE WAI: Hi, my name is Maylene Wai [misspelled?] University Science in Philadelphia. My research focus is on pharmaceutical access to HIV medicine and intellectual property rights in the WTO framework. I have a question for the CEO of Pfizer. I think we all agree with you that we all need work together on this issue. And my question for you is this, what can we do to help you and others pharmaceutical companies to bring down the prices? Have you thought about international divisional labor? Have you thought about working with the companies in India, Brazil so that you can bring down the prices of production? Maybe research R&D? Do you need tax breaks from the U.S. government? Do you need other forms of incentives? What can we do together to bring down the prices? [APPLAUSE]

STEVE LOSICULAR: [misspelled?] Good morning and thank you for the opportunity. My name is Steve Losicular [misspelled?] and I'm the Vice President Strategic Trades Development for Espon Pharmacy [misspelled?] which is South Africa's largest pharmaceutical manufacturer, largely generic based. I have a comment to make, rather than a question for the panel. And the question relates to pretty much to, and I guess that's why we're all here at this conference, to share experiences to see how we can work together and

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learn together and enhance accessibility. I'd like to pick on a comment by Harvey the last speaker from IFPMA and illustrate an example of where original research based companies can work together with generic companies to find a common solution where accessibility is enhanced. It's a particular example, it pertains to my organization Espon Pharmacy [misspelled?] which pioneered anti-retrovirals on the African continent, development of anti-retrovirals. We were able to secure this by negotiating and agreeing voluntary with licensees with GS Code BMS and BI, and the context of those licensees have enabled the local development and the precipitous drop in price for anti-retrovirals. And perhaps this an illustrative example of rather than bickering around WTO and international trade law, international trade relations, [inaudible] all the other things we talk about perhaps what we should be rather doing instead of getting embroiled in all of that is focusing on people on the ground practical resolutions to problems, such as are we able to extend voluntary licenses? Are we able to secure additional voluntary licenses? So I think that's the message I'd like to put across. It's certainly been a very successful model for us. And also just to touch, and perhaps I'll assist the chair here, and to also touch on the issue around parallel imports. Why parallel imports, in my considered view aren't necessary, because they do absolutely nothing for capacity building but then enhance substantially the risk of cancer fakes, et cetera et cetera. So

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let's rather build capacity on the African continent and other developing countries so that we can together with enhancing access -

BRIAN BRINK: Can you wind up please?

STEVE LOSICULAR: [misspelled?]- also assist in the economic transformation of the developing world. I thank you for the opportunity.

NOGANO KOMO: [misspelled?] My name is Nogano Komo [misspelled?] from South Africa and I'm public health physician and I don't treat AIDS patients. I would like to know from any of the speakers, why is it that most of the difficult trials in third world countries? However when it comes to plowing back or making drugs affordable for those countries it becomes difficult? [APPLAUSE]

TIM TUCKER: My name is Tim Tucker, I head up the South African Aids Vaccine Initiative. We're a not for profit entity but we're very involved in patenting. Mainly, because we don't want to make any money out of them but because we want to make sure we're not locked out of certain technologies. The more we deal with IP, the more complex I realize the area is. It just seems to me that we need to make sure those most involved with the generation of IP in the area, which is pharmaceutical companies, are far more accountable to us. Whether Hank McKinnell 10 million, or 20 million, or 30 million a year, it's just symptomatic of the lack of accountability that the pharmaceutical industry has and I think it's symptomatic of the many ills that we've seen with pharmaceutical industries. And it's my

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sense that if we punish the pharmaceutical industry the generator of much of the innovation is going to be [inaudible]. And what we need to do within that setting is create incentives. We know that the vast majority of money plowed into R&D is for therapeutics for diseases for that affect people in the first world, not the third world. Shouldn't we be creating massive tax incentives for pharmaceutical companies to develop vaccines and new drugs for those neglected disease like TB, HIV and malaria? Shouldn't we be finding ways to make sure we can have a rational investment so that we can actually see the generators of new intellectual property focusing more on the burden of disease in the world, rather than the minority of diseases in the first world? My second point is -

BRIAN BRINK: Can you be brief please?

TIM TUCKER: I can. The second point is that we have a global emergency, we have 60 million people dead or infected with HIV and yet we cannot declare global emergency so that we can get generic substitutes easily in developing countries. We just need to see that it is possible to declare global emergencies in certain area and to have certain patent in regulations overturned so that we can get access. [APPLAUSE]

DAVID GOLD: My name is David Gold I used to be the Vice President for Policy at I Abbey the International AIDS Vaccine Initiative and was responsible for designing some of the IP deals which tried develop win-win situation. Very briefly a couple of

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things. In my view the companies have clearly early on in the AIDS drug controversy made some mistakes of historic and moral perspectives, that being said and that's important to note. I worry that if we do not have investments in private sector we will be stuck with ARVs which have done a huge amount of good in the world, but let's face it they're pretty lousy drugs. We do need better drugs, we do not to figure out to direct investment that are better, usually with the wealthy countries paying the costs. The point that I also want to make is that there are new compounds, entry inhibitors, intergrase [misspelled?] we desperately need those drugs. We've got to do figure out ways and as bad as the companies have made on AIDS drugs there are a lot of pharmaceutical companies that are not investing in infectious diseases for anyone, okay. So we could fault a lot of different companies, but let's look at companies and say every company has a responsibility for investing in drugs against infectious diseases. And the second point is, when companies invest in prevention, Hank McKinnell is right, the big money in the world is not in developing treatments or technologies that prevent disease it's in treating disease. And somehow together we've got to figure out how to change that paradigm a little so there is a little bit money that can be made for companies that come up with new real innovations for preventing diseases. So I congratulate all of the panelists for sitting through this because I think that when we do exchanges these ideas you do a little bit to move the overall field

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forward. [APPLAUSE]

MAHIN NOSENAVAL: [misspelled]One of the most recent anti-retroviral to date is called a fusion inhibitor, and it's called Fusion C20, my question is - today it costs \$2,000.00 a month - an economical study showed that it is cost effective in England to treat the patient with this product. I would like to know how this product and when this product is going to be available for African patients? Mr. Havebill have you got a project about that? How are you going to make engine generate copies of the fusion inhibitors so that finally brand name pharmaceutical companies are going to lower their price down because of competition if tomorrow India is not anymore allowed to make any generic forms of AIV? Is this our future?

BRIAN BRINK: Before we bring the speakers back, I'd just like to make a small plug for a film show tonight from India called Patents versus Patients and it's showing at the Gother [misspelled?]Institute at 7:00 P.M details can be found in the community project guidebook.

GILES JI UNGPAKORN: Just before asking for the responses from the speakers, I know we're late, but I think everybody wants to get a reasonable answer their questions. We've got four speakers who are going to reply, and they're going to reply in the order; Waldo Bello first, Harvey Bale second, Jonathon Berger third, and Hank McKinnell fourth. I would like to give each of them five minutes, if the hall is available for that is the audience happy to sit for 20

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minutes and get decent answers?

BRIAN BRINK: And if we can agree on that to the speakers I'm going to interrupt you at 4.5 minutes to ask you to wind up. And Walden Bello would you like to start off, please?

WALDEN BELLO: Okay, very very quickly. I fully agree about full disclosure on the part of the drug companies so that we can really determine the R&D costs and separate what really are not really R&D costs, because there's just a lack of transparency here at this point and I would fully support the proposal from the French doctor.

Second on the question of debt. Yes, I think there should be debt forgiveness, debt moratoria, so that the money that is going debt, sometimes this costs, this is about 50 to 60% of government budgets goes into debt servicing rather than into education and medical needs within the country. Which is why we then have the problems of health delivery infrastructure difficulties. So, I think a big part of the problem is the whole question of debt and we really need to resolve this and in order to be able to move more closely on this problem. My point here was there is a lot of corporate waste going on and I think we really need to focus on this because the corporations often times say that they are spending on R&D and everything else, but then researchers have shown that up to about 40% of what is supposed to be R&D is really classifiable as corporate waste, is not really R&D but marketing costs, and executive pay. So

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I think we really need to put a critical look into this.

About my proposal, the Manhattan Project was not a Soviet project, I mean who was it - it was a gentlemen here. I was proposing this coordinated effort between the public sector, the private sector, civil society, that is the sort of emergency that needs to be made at this point. So I don't know what you're talking about that I have been proposing Soviet model. I don't know any Soviet model.

And fourth is, the point that I would just like to end with is to say that the trade related intellectual property rights framework is just obsolete. It was framed by the pharmaceutical companies, it was meant to serve their needs not the needs of people, which is why the ability to be able meet the needs on the part of the global research community is very, very much constrained by this very, very narrow pro-corporate framework. We need to be able to get out of that, we need a new framework, we need a framework that discriminates between giving adequate patent rights payment for non-essential drugs like Viagra, but to have essentially a lot of liberty, a lot of innovativeness that is promoted in essential drugs and not have to be crippled by tremendous intellectual property rights and restrictions.

So that is the sort of thing that we really need to be moving on at this point. TRIPPS is obsolete, it is anti-people. We really need to move on. Thank you.

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BRIAN BRINK: Thank you Waldo. And thank you very much for not using all the time, and to all the speakers you don't have to use all the time at your disposal. Harvey.

HARVEY BALE: Thank you and I had a number of questions here, so I think Professor Bello leads me on answering the question that I received about some of these free trade agreements that have been negotiated in recent years and in the past. Actually perhaps TRIPPS is becoming somewhat obsolete but I think it's becoming obsolete in the rather opposite directions. Because I think if you look back beginning in the 1980's with Korea and a number of Southeast Asian countries moving through developing countries like Russia, Mexico, China, Taiwan, Chile, Jordan, Israel, Singapore, all of the major countries that aspire to be a manufacturing and bio-science center are adopting not TRIPPS. Absolutley TRIPPS is the floor, these countries are adopting a much more strong system of encouraging R&D. Why? Of course they care about their patients and their sick people. They just do not see IP as the issue. The issue is one of mobilization of societal resources, prioritization of health care and this does get to the debt issue. And I also support debt cancellation, but let's not let countries re-established a new debt level with new borrowings to buy weapons. We have prioritize health care, it is true, but just canceling the debt isn't going to solve a thing if governments go about their spending patterns and buy weapons from the country that I come from. I think we need to spend

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the money on health. So I think the issue of TRIPPS is perhaps is obsolescences, but I think it's because it hasn't yet been tried by some countries like India.

And that gets me to India, why did I mention that there are 22,000 to 24,000, actually nobody knows in India how many pharmaceutical companies there are because there's not a central registration process that's a durable one. And yet only 13,000 patients are being served in India with ARVs and it's simply to point out that we have a system here which I fear the most. Which is no IP system, no innovation within India among the majority of companies, except a good number of smaller companies like Rann_Baxy [misspelled?] Dr. Ready's laboratory who are shifting because of the TRIPPS and the TRIPPS plus model to an R&D system. So they're making the change. But unfortunately the majority of companies in India are not yet making that change. And unfortunately too many of those companies are also selling counterfeit anti-malarials in Africa. And it's a problem.

The issue of pediatric formulations was raised representative by the MSF, I think is the serious issue, I don't know if Hank can help me out on this because I know in the U.S. they've had pediatric legislation, there have been very serious liability issues in doing tests on children, fear of lawsuits, so I think this could be part of the problem, but I'd look into it more and I appreciate the question and I appreciate the problem.

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Fusion. Yeah Fusion is very expensive it's treating very few patients. I suspect that as the volume increases that those prices will come down, but that's my estimate as an outsider. The problem I think, however if you want to India today to copy Fusion they can do it. But it's a damn difficult drug to copy and in fact the engineers and the scientists at Roshe thought that they would never actually have a commercially available drug. It was thought not to be able to be made in commercial quantities but they overcame that it's a very expensive product. I think I should stop. [APPLAUSE]

BRIAN BRINK: Thank you very much Harvey. Jonathon.

JONATHON: Thank you. I'm going to really conclude on three issues which incorporate a number of the questions and concerns that have been raised. I think the first point is that we must not cloud the issue, this is not a question about the quality of drugs we have drug regulatory authorities that deal with those problems, IP is not in which the way we regulate the quality of drugs. I agree that drug quality is important to deal with but not through the system of intellectual property. The other issue which we should not cloud the debate that we're having today are the other barriers which limit access treatment. Yes we know that developing countries are not enough, yes we know that government of India is not doing enough, we know that the government South Africa is not doing enough, but that does not take away from the issue of intellectual property and how exclusive rights in intellectual property have been abused in a

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manner which limits access.

My second point about openness and accountability and I really support the points that were made both by Dr. Tim Tucker and sorry I didn't get the name of the first speaker from France, and I fully support the call for an independent investigation into research and development costs. This is something that we tried in South Africa last year we pushed the case through our competition commission looking specifically at the issue of true costs of research and development and we did not get to a hearing because the pharmaceutical industry was willing to negotiate on good terms to avoid having these issue debate in public. We were faced with a problem we had to insure access immediately to drugs and that is why we settled but we lost out on opportunity to thrash out what are the real costs of research and development and I would strongly support for an independent investigation in this regard.

And my final point is that we need to talk the truth. We need to recognize the history of the whole campaign for access to medicines. Yes it's correct that we are now seeing licensing agreements. I wouldn't call them voluntary licenses I would call them forced licenses. MSD is moving ahead licensing Timberlame [misspelled?] because it is scared of action that might very well come from my organization and others. GSK [misspelled?] and Barona Engliehime [misspelled?] because of the pressure that they were placed under and I think it's important the point that Stevrus Nickalau

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[misspelled?] from Aspen raises about the licensing agreements that they entered into. Number one there's a context to that, it would not have happened without the global campaign, it would not have happened without the incredible pressure that was placed on the pharmaceutical industry. And second what Mr. Nickalau fails to mention is that the initial agreement were on conditions that were quite unfavorable and were quite impossible to implement correctly it was only as a result of the case that we took to our competition commission where the terms and conditions of those agreements were revised so that we now have licenses and reasonable terms and conditions. So to conclude I think it's important that we deal with these issues in an open, accountable manner and we speak the truth, we cannot forget where we're coming from, we mustn't remain in the past, but we have to recognize the context. And the context is one in which the pharmaceutical industry whether brand name, whether generic, patent whichever industry one's looking at, they will only act openly and accountable when we as civil society make them do so. Thank you [APPLAUSE]

BRIAN BRINKS: Thank you very much Jonathon and finally Hank.

HANK MC KINNELL: I'll make four points. The first is there was one thing in Professor Bello's that I like. It was the extremely pay raise he gave me. I'm extremely well paid, that's true. I think today I'm earning it.

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The second issue relates to a comment, from I think it was a questioner from Canada around a distinction between prevention and treatment activists. I guess the point I was trying to make, is both are extremely, that is the way forward. And secondly on the issue of activists to support Jonathon's point, healthy activism has actually been a positive thing. It caused the FDA to speed up drug approvals in the 1980s. It caused the world in the 1990s to recognize that we had to something about this pandemic. And that actually to leads to, I think, one of the most important comments that was made.

Which is the African market only represents 1.5% of the world pharmaceutical market, why do we care? Well we do we care because there's 28 million people HIV positive in this part of the world and that is a recipe for disaster both for sub-Saharan and for America and for the rest of the world. So we do care. But the response I think is worth noting. In response to that recognition, which I agree Jonathon came in large measure because of activism, anti-retroviral very dramatically. In our own case, it caused us to look at what we could do, and we really concluded that for the population most in need, earning less than \$2.00 a day there was no price at which our drugs would be affordable. So with the drugs most important AIDS patients from Pfizer which is Diflucan and Antifungal, we started in South Africa three years ago with the Diflucan partnership, made the drug available free of charge, have since the

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beginning of that program trained 18,000 health care professionals. Diflucan is now available in 915 clinics across Africa and we've distributed 4 million doses. So in spite of all the stories about how difficult this is to do, we can do it.

On fixed doses and pricing. I don't think this story has fully played out yet, the conventional wisdom amongst the companies producing those anti-retroviral in the United States and the U.K. has been and conventional wisdom is quite often wrong, but the conventional wisdom was they could not combine them. And have a combination that would be both stable and bio-available. And the reason has to do with the PH environment needed by differing drugs and in the usual triple combination you can't put things together that require a high PH level for stability with products that require a low PH. That has been companies in India that have claimed to have done that. The American companies would question that. So we need to see data to prove that.

Similarly on the issue of pricing American companies, European companies as well haven't been able to talk to each other about price because of anti-trust constraints. But every company has agreed a price somewhere between cost, no-profit and in the case of Pfizer and few others free. The net all of that is an ant-retroviral price two patients of about \$50.00 a month, \$600.00 a year. Claims of prices of \$300.00 a year or \$140.00 a year certainly have been made. I know of nobody buying drugs at those prices, products that

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meet modern standards of stability and bio-equivalence. I'm saying the conventional wisdom here may be wrong, but there is another side to this story, which I think will play out over the next months and maybe a year.

The final comment was one of the final questioners who made the statement that companies have made mistakes. I agree with that, we have. But so has everybody else, so have governments, so have international agencies. We have decades of experience with HIV/AIDS that demonstrate clearly that local governments have not been able to accomplish much. International agencies have not been able to accomplish much. Private companies like ours have not yet been able to accomplish much. What we've demonstrated several times now with the Diflucan partnership and with an Efferdon Tricoma [misspelled?], which is not the subject of this conference, the discovery is by working together we can achieve remarkable results. So my plea is for partnerships with local governments, local communities, communities of people living with HIV, pharmaceutical companies, UN agencies, anybody who is willing to participate that I think is the way forward. [APPLAUSE]

BRIAN BRINK: Thank you everyone for participating in this session. I think it's very important that we at least talk and it's very important that we find solutions. I think there was still far too much about what the problems are and not enough about what the solutions are, I think towards the end of the session started getting

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on to how to think about the future, how to think about the long time. A private sector perspective from us as customers, we want to purchase value. Value means we want quality and we want good prices. We want reliability of supply. We want competition in the marketplace because that what hones the private sector and gets better value all the time. We also want choice, we want choice today and we want choice tomorrow. And tomorrow is the thing that I think really concerns all of us because the drugs that we do have today, are not going to last and we're going to need the new products in the future. And I think the answers going to come in finding the partnerships and doing the talking and negotiating the agreements particularly in developing countries so that we have long terms solutions of this epidemic. Thank you everyone for participating and thank you to the speakers and to my co-chair.

[END RECORDING]