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**XVII International AIDS Conference
Universal Access/Universal Crises/Universal Prices
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JAYA SHREEDHAR, M.D.: Would you like to move up to the front so that we have a good discussion later on? I agree it is a much better atmosphere.

Good morning and welcome to the symposium "Universal Access/Universal Crises/Universal Prices. My name is Jaya Shreedhar. I am a medical doctor by training and a journalist by profession. I have had the privilege of covering the HIV epidemic in India for the last several years.

This session holds special significance for India, which is the largest producers of antiretroviral drugs in the world, and we also export more than 50-percent of what is produced to other countries. This became possible thanks to the historical decision by the government of India in 1970 to only respect process patents and not product patents. All this was set to change after India became [inaudible] TRIPS Agreement and now we are bound to respect process patents as well.

India is particularly at the center of this debate because whether we realize the dream of achieving universal access or not will depend on whether we win the battle against the restrictions placed on access to second-line drugs.

Without any further ado, it is my pleasure to introduce the distinguished speakers on my panel. We have with us Dr. Kevin De Cock, Director of the WHO Department of HIV/AIDS, who

oversees all of WHO's work on HIV and AIDS. He is particularly focused on initiatives to assist developing countries and scaling up treatment, prevention, care and support. He is going to share his thoughts on scaling up universal access to ART, in particular the challenges, vis-à-vis drug pricing and, of particular interest, access to second-line regimens.

We also have with us Dr. Mariangela Simao, Director of Brazil's program against HIV/AIDS, who is going to share with us the lessons that Brazil has learned in its long battle with drug pricing policies and the challenges they bring.

Please join me in welcoming Ellen T'Hoen, Coordinator of the Globalization Project of the Campaign for Access to Essential Medicines of the Medicins Sans Frontieres. She is going to unravel the story of why and how patents have taken precedence over access to essential medicines and what to do about it.

It is also my pleasure to present to you Dr. Agnes Binagwaho, the Executive Secretary of Rwanda's National AIDS Control Commission. She is a member of the country coordinating mechanism of the Global Fund for AIDS, TB and Malaria, chairs the Steering Committee of PEPFAR, and is a visiting Professor at Harvard. She has also published more than 100 papers on women and children. Agnes is going to share her thoughts on the way integration of HIV in all sectors in

Rwanda is being used as a tool to achieve the target of universal access.

The last speaker on our panel will be Richard Elliot, Deputy Director of the Canadian HIV/AIDS Legal Network and the Founding Member of the Global Treatment Access Group, who is going to highlight Canada's attempt to implement flexibility in the TRIPS Agreement and share with us whether these attempts were successful and whether the flexibilities in TRIPS indeed allow for access to essential HIV medicines.

I would request each speaker to stick to their allotted time of 10 minutes so that we will have at least 30 minutes for discussion afterward. There have been many times that there is not much time for discussion after the session. And now I call upon Dr. Kevin De Cock [applause].

KEVIN DE COCK, M.D.: Jaya, thank you very much. Colleagues and friends, thank you to the organizers for inviting me. Jaya, please stop me if I have gone on for a bit too long, because my text is probably a little bit too long.

Actually, if I could start with an anecdote, I had a flashback of 1974 when I was a first-year medical student going to an amazing concert by the great blues singer Memphis Slim. There were just about 20 people in the room in a room bigger than this and we were all asked to come to the front. He had a sort of personal concert for us. So, if you do want to move to the front, as our moderator said, please do so.

All right, in this brief presentation, I am going to review data on treatment access, interventions for HIV/TB, PMTCT, I am going to comment on HIV testing, and I will make some comments about drug pricing, but I am going to have to refer to the report that is shown on that slide. This is available from WHO. It is available at this meeting in the Media Center and from the WHO and UNAIDS stand. It is a very important report.

I think this is probably the slide of the conference. You have seen it time and again. There were 3 million people in low and middle-income countries accessing and maintained on ART by the end of 2007, almost three-quarters of which are in Sub-Saharan Africa. The next greatest number, shown in Pink, is in Asia, and then in dark blue in Latin America and the Caribbean. With an estimated 9.7 people considered in need of therapy, global coverage was estimated at 31-percent. This issue of coverage is actually much difficult. The denominator is actually more difficult than it superficially seems.

These data from 2007 represent an additional 1 million people compared with the year before, with a 54-percent increase in Africa alone. Access among women is at least as good as it is for men, and it is often higher. Of the recipients of therapy, 97-percent were on recommended first-line regimens and the prices of these have continued to fall, as indicated from the left to the right in these histograms.

The details do not matter. The histograms represent prices for different combinations over time. You can see that for most of these WHO-recommended regimens, prices have fallen substantially. The most widely used regimen, Stavudine (D4T), lamivudine (3TC) and nevirapine, is now available at less \$100 per year, but we heard about the issues of Stavudine in the plenary, and I will come back to that.

By the end of 2007, some 200,000 children were on ART, 80-percent in Africa—90-percent of children with HIV are in Africa—and this represents an increase of over 50-percent compared to 2006 and by an increase of about 150-percent compared to 2005. Now, because of re-considerations of treatment and changing need and so on, we are very reluctant to give an estimate of coverage because we are still trying to figure out what a meaningful denominator actually would be. WHO changed treatment recommendations for infants aged less than 12 months earlier this year, and infants less than 12 months should now receive ART upon demonstration of infection, rather than waiting for specific clinical or immunological criteria.

However, we obviously have very far to go, recognizing that in 2007 only 80-percent of HIV-exposed infants were assessed virologically for diagnosis. And since a third of infected children die by the age of 1 year, one-half by 2 years, I think a scale up has probably benefitted particularly

older children, though we do not have good insight into that. Much remains to be done for the youngest who face the greatest mortality risk.

Concerning tuberculosis, WHO has a 12-point policy defining key health sector HIV/TB collaborative activities. I will not list what they are, but, again, the histograms show significant improvement, but still a very long way to go. By 2006, as shown in the light blue histogram, 35-percent of TB patients in 11 African countries, which make up over half the world's HIV/TB burden were tested for HIV. An estimated 78-percent of TB patients diagnosed at HIV-infected received cotrimoxazole and 41-percent of such patients were enrolled into ART, again representing a greater than two-fold increase and these are data from 2006 compared with 2005.

However, there is certainly a lot to do. We in the HIV community must focus on what we refer to as the Three I's. That is intensified case finding, isoniazid preventive therapy, tuberculosis infection control, and then we need to measure this as well.

For the first time, we included PMTCT in this universal access report, good collaboration with UNICEF, with whom we share this responsibility. There is some data on primary prevention of infection in young women and family planning access also. Concerning access to interrupt transmission from women to their infants, some 18-percent—just concentrate on the

left-hand side of the diagram for the moment. In Africa, the uptake of HIV testing amongst pregnant women was only 18-percent. It has crept up slowly, as you can see. It is actually 18-percent globally as well, but in some Sub-Saharan African countries, especially those with the highest burden, it is much, much higher. For example, testing of all pregnant women in Zambia reached 65-percent.

Now, if you look at Africa, under ideal circumstances this whole map would be colored light. The pink shows the highest coverage rates of PMTCT services, 80-percent, and then brown is 50- to 80-percent. Global coverage for antiretroviral prophylaxis amongst pregnant women was estimated at 33-percent. Just 20 countries, all in Africa, with the exception of India, account for 90-percent of pregnant women with HIV and 12 of these are in southeastern Africa, so there is a particular need for this map to look pink in southern Africa. We are not there yet, although the little pink island above South Africa is Botswana, which truly has shown leadership.

Here you see the percentage of HIV-positive pregnant women receiving prophylaxis in the 10 countries with the highest estimated number of pregnant women living with HIV. Coverage in South Africa was 57-percent. In Kenya it was 69-percent. But rates remain low in several very large countries, such as Nigeria, Ethiopia and the DRC. Still, between 2004 and

2007 in southeaster Africa, the most affected area, coverage increased four-fold.

These proportional bars add up to 100-percent. They show the frequency of different regimens used in 2007. The essential message is that almost 50-percent of women were still receiving single-dose Navelbine. And an area of great concern is the very low proportion of pregnant women who were receiving combination therapy for their own health, or even to be assessed for it when they needed it.

There are some important conclusions concerning mother-to-child transmission prevention scale up here. We need to do better with linkages between family planning and care services for women. Preventing pregnancy is safer and more effective than using drugs to prevent transmission. We need to do much, much better with women who need ART for their own health, who transmit disproportionately anyway. It is critical to focus on these women to prolong their own lives, preserve their families and prevent orphanhood.

We are going to be under increasing pressure to review ART regimens for pregnant women with HIV from research findings, as well as advocacy and arguments of practicality. The issue is whether we should be using triple therapy for all pregnant women, irrespective of CD4 count, and what to do throughout the breast-feeding period. We are actually

arranging a consultation on this later this year, but it is going to dominate discussion more and more.

So, your work, our collective work and implementation has made a huge difference. It is captured in the statistics that I just described, but we do have some major challenges for universal access. I have mentioned knowledge of HIV serous status, increased early mortality from late diagnosis and actually very worrying, long-term retention of patients is not as good as everywhere or as hoped or believed.

There is increasing pressure to eliminate Stavudine and adopt tenofovir, as well as to initiate treatment at higher CD4 counts, although we must recognize that actually, in reality, whatever the recommendations, most people are accessing treatment at counts well below 200. I think Gregg Gonsalves very clearly in the plenary discussed some of the constraints around this.

I think a huge issue, perhaps one of the most important events in public health in recent time is the emergence of MDR and XDR tuberculosis in association with HIV infection. There is a whole discussion about access to those kinds of drugs, the second-line drugs for MDR and XDR tuberculosis.

Let me just finish with a quote which I think is very apt, a quote and then the moderator—madame, if you allow some quick highlights on second-line therapy from this report. How much data do you need to make policy decisions? The British

statistician, the late Bradford Hill said, "All scientific evidence is incomplete, whether it be observational or experimental. All scientific work is liable to be upset or modified by advancing knowledge. That does not confer upon us a freedom to ignore the knowledge we already have or to postpone the action that it appears to demand at a given time." And I think that nicely captures some of the difficult questions we face.

I will finish with some observations from the report on second-line therapy. In a survey that ended up being of 30 countries, representing about 63-percent of the 2 million people on therapy at the end of 2006, 97-percent, the very great majority, were receiving first-line regimens and most of them were adherent to WHO recommendations. As far as second-line regimens are concerned, only 3-percent of adults were on these and they were very diverse. The single most common one included abacavir, didanosine and ritonavir-boosted lopinavir and accounted for about 15-percent of patients. So, there are many different second-line regimens in use. The data in children are not very different.

As far as pricing is concerned, we are not doing well. The median cost of the most commonly used second-line regimen, which is didanosine, abacavir and ritonavir-boosted lopinavir, was \$1,214. Compare that with less than \$100 for the first-line regimen. There are huge differences in price across

different countries. For example, South Africa pays \$1,600 per person, per year for that regimen and El Salvador pays almost \$3,500.

With those comments, let me finish and hand it back to the chair. Thank you for your attention. A final comment—I think the challenges are enormous, but, at the same time, if we look back at what has been achieved, I think we should just be courageous, keep going, and keep reevaluating. Thank you [applause].

JAYA SHREEDHAR, M.D.: Thank you, Kevin, for again holding up that specter, the emerging specter of heavy expenditure on second lines that is looming. We really need to address it now. Now I will call about Dr. Mariangela Simao from Brazil, who is going to talk about the challenges in Brazil to scale up.

MARIANGELA SIMAO: Good morning to all. Although we are in Mexico, I am going to speak in English because the only language I am really proficient in is Portuguese and unfortunately not everybody would understand.

There is a very big outlook on the epidemiological situation in Brazil. On the left-hand side you see the cities with at least one AIDS case from 1990 to 1995 and now we have 85-percent of all cities in Brazil with at least one case of AIDS. Our prevalence is 0.6, but we have for the first five years around 32 new cases a year in Brazil.

We are talking about pricing and access, and I would like to say that Brazil has had a free universal policy in place since 1996. I would like to stress that it is free universal access because it is free of extra charge for patients. Everybody pays taxes and this comes from the budget for the Ministry of Health, which buys all the ARTs in Brazil, so we are really the only buyer. Our budget has been increased for 2008. It is around \$640 million. By the December of this year, we will have 190,000 on ART. We do have national guidelines and patients are treated through the national health system.

These are the drugs that distributed in Brazil. The ones that are in red are locally produced. We do have two new drugs for multi-payer patients. We introduced T-20 in 2005 and this year we introduced darunavir as an option for multi-payer patients. For 190,000 patients, we have around 3,000 patients that are multi-payer.

I would like to say that I think in Brazil we are as close as possible to universal access. According to our data, which is different from the way WHO and UNAIDS calculates coverage, based on our internal data in Brazil, we have about 95-percent covered for ARTs. Our price, Kevin, is quite different from what you mentioned. We are a low-prevalence country, a concentrated epidemic, so we do not access the prices that are on the access programs for African countries,

for example. Our first-line and second-line regimens are slightly different, our definitions are slightly different. I am sorry that I forgot to put abacavir on the first slide, so it is missing abacavir. We now have in Brazil 25-percent of all patients using second-line drugs. This average cost excludes darunavir and T-20. When you see that, there is a huge gap in cost from first line to second line. I would like to say that this is one of the major challenges that Latin America has right now because Latin America does not access cheaper prices like Africa and today Latin America has a high coverage of first-line treatment.

So, what we would like to bring for reflection and for discussion later on in the debate is that the sustainability of free and universal access is related to fair prices. What is a fair price? That is a good question for us to reflect upon. The first, most common price determinant in our country today is intellectual property rights, and theoretically they are based on innovation. I like to say theoretically because sometimes you have patients being asked for second line or for drugs that are being used for a long time. And also, we do not really-by international agreements and regulations, patents are held for 20 years. How long does it take to really pay for innovation and who pays for innovation? How do you separate why the real cost of innovation is from all the propaganda marketing that pharmaceutical companies are doing, even in this

space with bags and nice pens and so on? We are all paying for that [applause]. So, it is really a black box. How do you open that box to discuss what is a fair price? An IP, in theory, promotes innovation, but ends up in monopolies and in no competition at the country levels, so it hampers access to cheaper and generic drugs.

I would like to cite here the example of Peru because Peru now buys lopinavir/ritonavir from a generic company, but at a cheaper price than was offered by Abbott to Peru. But Abbott, in 2006, their total sales was about \$1 billion. That is total sales. I am not talking about profit because we do not really know what part is profit. A lot of people say that the whole cost of innovation is \$500 million. If in one year the total sales are \$1 billion, I think we should reflect that. That is 2006 when the drug had already been in place for some time.

Talking about criterion, I would like say that prevalence and level of income alone or combined are very poor criteria for Latin America and the Caribbean. We would like to propose for the pharmaceutical companies what we called fairer criteria. First of all, an equal cost per patient for all developing countries, with small differences according to gross national product per capita, or consider the level of use of the drug in the country—I am going to show some examples from Brazil—and the treatment coverage. The third and very

important point is the costs that are incurred by government from their own budgets. Sustainability and a long-term commitment must come from governments. If you are not paying a fair price, it is not sustainable because you press a health budget that has to deal with so many other chronic diseases.

I am going to speak very quickly about the case of the compulsory licensing in Brazil last year. Efavirenz was the most used imported drug for 75,000 patients. This year we have around 85,000 patients using efavirenz. The first combination in combination is AZT/3TC and 32-percent of patients use efavirenz. We are paying \$1.59 for each tablet. It has been stable since 2003. We had a long negotiation with Merck, which did not result in anything, but Merck proposed to reduce the cost from \$1.59 to \$1.56. We asked Merck for the price that Thailand was paying, which was \$0.67. Thailand was not paying that. Merck had proposed to Thailand \$0.67. What I would like to reflect here is this. You see that Merck used prevalence, but did not use, because it was not convenient, the number of patients. We had a larger number of patients and a lower prevalence. We are now buying now from a pre-qualified generic Indian company at \$0.46, including royalties paid to Merck. The estimated savings—and I put savings in quotes because I do not really like connecting saving money with health, because you actually need to spend resources more adequately, not talk about savings. In our contract in 2007, we reduced cost by \$30

million in one single year when we bought from the generic company. We are starting the national production by next year.

This is just to point out the proportion of expenditure for a year of use in 2006. The red is the imported drugs and the green ones are nationally produced drugs. I would like to point out that efavirenz used to be about 12-percent of our budget for imported drugs, and now it is 4-percent. I would also like to point out the next challenges we have.

Atazanavir, the two formulations, 150 and 200 milligrams today account for 22-percent of our budget, and tenofovir for around 15-percent. So, what we spend today—we have lopinavir and ritonavir and the other protease inhibitor that competes with atazanavir. We have 43,000 patients using lopinavir/ritonavir, but we have a growing number of patients using atazanavir and we are now paying almost \$55 million a year on it, which is 22-percent of our budget. With atazanavir, the fact that we still do not have a generic pre-qualified, but are about to have a pre-qualified generic by the end of the year, so it is a process to negotiate prices and so on.

The other challenge that we are having right now is tenofovir. You can see from the graph that the blue line is the price and the number of patients on the red line. This year we started talking to Gilead again. We have an agreement until March 2009, but there is a rapid increase. It is a first-line drug. We already have 33,000 patients using it.

The patent was deposited in Brazil in 1995, but it is not granted yet. The Ministry of Health declared it of public interest last April so that we could speed up the analyses at our Intellectual Property Office. What we are asking of Gilead-Brazil is now paying \$3.25. We are asked Gilead to pay \$1.24 like Thailand. CIPLA is not yet qualified, but it is almost there.

Just to finalize, I think we have a challenge to expand access to fair prices, reveal the present criteria for Latin America and to use the flexibilities provided by TRIPS under Doha Declaration, but to do that countries have to have support from partners. I would like to say that Brazil had two very important partners, the Clinton Foundation and the Medicins Sans Frontieres on this process. And now we have a new partner on board, WHO, because at the World Health Assembly this year the Global Strategy on Innovation for Public Health and Intellectual Property was approved, and it is not time to put it into practice.

This is a classic, just to end. I think many of you already saw it because it is a 2003 cartoon from Brazil. We always remember that we had a conference that was bridging the gap, and this is filling in the gap. The money that is there is not dollars anymore, it is Euros. This is very up-to-date and it will be, unfortunately, for a very long time. Thank you very much.

JAYA SHREEDHAR, M.D.: Thank you, Mariangela [applause]. I think her session has made a sound introduction to Ellen's session, which is coming up, which is going to tell us precisely how to get around these patents. Ellen?

ELLEN T'HOEN: Thank you very much. It is a real privilege and a real pleasure to be here. I work for Medicins San Frontieres, and we currently treat 140,027 patients, of which approximately 10,000 are children. As many of you know, we have been able to do that because the price of the recommended first-line treatment came tumbling down very rapidly and we are now able to access first-line, fixed dose combinations for about \$87 per patient per year. Without that, it would have been very, very difficult to expand our programs in the way we did. We also have to realize that that was possible because until 2005 India excluded pharmaceutical products from patenting. The scale-up that we have seen in the recent years is really because of the Indian 1970 Patents Act. Today, 80-percent of our antiretroviral are purchased in India. Only a few days ago the *Wall Street Journal*, in general not a great advocate for generic production, had an article with the headline "Generics Fuel AIDS Program."

We have to recognize that the times are changing and when talk about universal access, we also have to ask ourselves the question, universal access to what? The impact of the changed environment, with regards to pharmaceutical patenting

is quite dramatic. Though 3 million people have access, there are many people who do not have access—we have to continue to realize that—to a combination that contains D4T and increase efforts are necessary to replace those treatments with the better and the new recommended treatments. But when we do that, we see dramatic price increases. We should not fool ourselves. AIDS drug prices are on the rise. They are not on the decline. That is true for the first-line treatment and it is certainly true for second-line treatment. If you here compare the cost of offering second-line treatment to the first-line treatment, the costs are phenomenal and we are struggling with that in our project. I imagine that we are not alone in that.

Now, there are different responses to that. You see differential pricing and the price discounts by companies, but those are limited and you can see that that discounts are not enough. The slides I just showed you, those graphs, are the best-case scenarios. I have not shown you the worst-case scenarios. That is taking into account all of the discounts that are being made available today. Also, differential pricing is not a solution to patent barriers today to the development of new fixed-dose combinations and in particular, fixed-dose combinations for children, for example.

Another strategy is voluntary licensing. I put the voluntary in quotation marks because the voluntary licenses are

often in response to actions by civil societies to legal threats. For example, the successful TAC's complaint at the South African Competition Commission and the very important work that the Lawyers Collective is doing in India with the pre-grant oppositions.

We see the compulsory licensing. We just heard from Mariangela how Brazil has successfully used that. We also heard earlier in the conference about Thailand. That has had dramatic effects on the number of patients that can benefit from these drugs. We also see developing countries today use government use power. That is a particular kind of compulsory licensing where the government says, I am going to make use of that patent for my national program, for example. We also see least developed countries exclude product patents in their procurement of practices. These are all very good developments. These are all a result of the 2001 Doha Declaration on TRIPS and Public Health, which the WTO adopted. It is encouraging to see that countries use these powers.

We have also seen India, in its Patents Act, which they have to amend because of their obligations to the World Trade Organization's rules to include pharmaceutical product patenting, but there is some good news there, too. India restricts the patentability criteria to real innovations only. That gives the possibility to have successful, hopefully pre-grant oppositions related to AIDS drugs. Currently there are

15 pre-grant oppositions pending in India. So, some of these products that on the one hand we expect to be patented may actually not become patented if those groups are successful. I should say that is mostly driven by civil society groups and by AIDS treatment groups in India.

But when you do prioritize health over patent protection, you come under harsh criticism. I think Mariangela can talk about it. I think also our colleagues in Thailand can talk about it. You are called pirates by the *Wall Street Journal*, and even the initial responses by the WHO were not exactly encouraging. We have seen retaliation by companies with Abbott, for example, and its refusal to make new drugs available in Thailand while Thailand kept the compulsory licenses in place. We have seen legal action by Novartis to try to overturn those pro-health and patent laws in India. And we also see a limiting of the scope of the effectiveness of those TRIPS flexibilities that exist in certain countries and patent law through bilateral and regional trade agreements.

So, we are pretty much down to a situation of hand-to-hand combat that sort of drug-by-drug, country-by-country. The struggles are becoming much, much harder to bring those prices down. I cannot emphasize enough that we cannot count on drug prices coming down automatically. We cannot sit here and put up a graph and say, look, the prices of first-line treatment, even of the newer drugs, are coming down. They are not. They

are much more expensive and we do not have an automatic mechanism anymore, which we used to have before the WTO rules came into play, which will bring the prices down. We will not have the automatic generic competition. We need to have a more systematic approach to that. If not, we will see patent disputes break out all over the globe, certainly with so many people on treatment today and so many people still waiting to get treatment. So, that is the bad news.

Now, here is the good news. We also think that times are perhaps changing again. There is a realization that patent protection for pharmaceuticals has perhaps gone a little bit overboard. I think the Doha Declaration was the first recognition of that. You have to try to answer the question would these WTO patent rules, these global, one-size-fits-all system we have today, would that ever have come into being if at the time these treaties were negotiated the AIDS pandemic had existed? I do not think so. So, we do have an opportunity to start turning some of that back. We are very encouraged by the recent decision by the recent decision by the UNITAID Board to establish a patent pool, and they have set a process in motion to make that happen. This decision is based on some of the work that has been done in the WHO Commission on Intellectual Property, Innovation and Public Health and the recent decision that Mariangela also referred to that the recent agreement reached by the World Health Assembly on Public

Health, Intellectual Property and Innovation refers to patent rules and says we should really examine the feasibility of voluntary patent rules for upstream and downstream technologies to promote access and innovation. I think it is very good news to see UNITAID move so quickly after that decision.

Now, what is a patent pool? A patent pool is a mechanism where, in fact, the patent holders put their patent rights in a pool for others to use. Third parties, for example, generic manufacturers or researchers, for that matter, can then make use of these patents to produce generic drugs or to do follow-on research. It is kind of one-stop shopping where there is no need for a case-by-case negotiation.

In a way, with a patent pool you could mimic the situation as if the patents are not there, so the patents will no longer form a barrier, with one exception which is that you will have to pay royalties when you make use of those patents. But we think that that would only be fair.

Now, what could a patent pool do? It could, for example, help increase the production—it could help the development and also the production of the new WHO-recommended first-line regimen. We do not have sufficient suppliers for that today to bring the prices down. And you can see here the list of rights holders you would have to deal with. I should also say that the patent holders are not always companies.

They can also be research institutes or, for example, the U.S. NIH.

A patent pool can also help in the development of second-line and pediatric antiretroviral drugs. Here are some examples of what a patent pool could possibly deliver. We would like to see atazanavir, ritonavir, TDF, 3TC as once a day second line. A patent pool could help that come about. Also, new pediatric formulations—we would like to research and development on atazanavir/ritonavir boosted once a day for small children. That does not exist yet today. And, of course, those would like to develop those products do face the patent barriers to that.

Now, is the patent pool feasible? I think it is. I think there is political momentum. I already referred to the WHO Global Strategy and Plan of Action. I see a real commitment from UNITAID. There is a commitment amongst the NGOs and the treatment groups. I should particularly mention that Act of Paris [misspelled?] has played a very important role in making this happen.

The initial responses by the pharmaceutical companies have been very positive. The International Federation of Pharmaceutical Manufacturers Association called it very interesting and, believe me, that is a very positive endorsement for that group. GSK already declared that they are willing to put the license patents of products that they are

already licensing in the pool. Of course, we would want them to do a little more, but initially that is a very good response. European Generics called it interesting. This week we have heard from a number of individual companies some very encouraging responses. Gilead spoke at a session on patent pools that we organized, together with Oxfam and Knowledge Ecology International earlier this week, which also gave very helpful suggestions to make it come about.

Now, are we there? No, we are far from it. There is a lot of hard work ahead of us. It is hugely the case that the devils—I think we are going to see a lot of little devils—will be in the details of working this out. It will be in the details of the licenses, it will be in the details and in the negotiations on the remuneration, but I hope that we will be able to at the next conference talk about the angels and not the devils.

In conclusion, we have to recognize that we are operating in a changed environment in the post-TRIPS era. We have to stop pretending that it is not happening. Newer products will be patented in developing countries, including in key producing developing countries that without deliberate action will lose the role they are playing today in the provision of affordable generic medicines. Again, the prices will not come down automatically. Stop dreaming if you think that is going to happen. We need to resolve also the IP

barriers to the development of the fixed-dose combinations. We need the adapted products. We need the deliberate action. But I do feel that there is real momentum to do so.

Before I close, I would like to draw your attention to something that is going to happen at two o'clock because to increase access and to improve care and to make sure that we increase the number of people on antiretroviral treatment, but also on good antiretroviral treatment, yes, we need the drugs and we need the diagnostic tools, but we also need the healthcare workers to make that happen. I would like to invite you to join the rally at two o'clock in support of the healthcare workers. I thank you [applause].

JAYA SHREEDHAR, M.D.: Thank you very much, Ellen. That was an excellent presentation and it really calls on all of us to push the frontiers of advocacy to help us realize the dream of universal access. I would now like to call upon Dr. Agnes Binagwaho to make her presentation on how integrating HIV into all sectors is helping Rwanda to achieve universal access.

DR. AGNES BINAGWAHO: Good morning. I thank the organizers for giving me this opportunity to share with you the experience of Rwanda.

As we talk about healthcare, I want to recall that the primary thing preventing access to healthcare is poverty. I would like to share with you what in Rwanda, in the heart of Africa, we have done over the course of the past decade to roll

back barriers to prevention, to care and to treatment. First, we have assessed the situation to make an evidence-based decision. In 1994, in the post-genocide situation, it was dramatic, with a lot of desolation and [inaudible] destroyed, poverty, lack of services associated with geographic inequity, leading to lack of services to healthcare, with a population having the highest rate of illiteracy and fatality leading to demographic problems. We evaluated the first killers, which were malaria, TB, HIV, digestive and pulmonary diseases, also unsafe delivery leading to high mortality for mothers and children. And I will share with you where we stand now.

The last four years we won four years of life expectancy. For the first time, life expectancy went beyond 50 years old in Rwanda. We are at 53 years for the life expectancy. The proportions of people who need ART and received the drugs are 70-percent of all people in need. I would like to explain to you how we did this. You can still see malaria death due to two-thirds dropout.

First, we created the necessary institutions. Secondly, we changed our national policies, strategies and plans. We integrated HIV/AIDS and fight against HIV/AIDS into all sectors from the policies to the tools used. Having done this, we had the vision of poverty reduction measurement and the promotion of gender equity. Thirdly, we worked hard to get access to Global Fund, World Bank and PEPFAR money.

With this mobilization of funds, we have several partners and our strategy is total national ownership. As you can see, we have several partners and those are only the major partners in the field of HIV and AIDS and also health. All partners' fund allocation is decided in a committee chaired by a Rwandan official, with me as the Executive Secretary of the National AIDS Control Commission and the [inaudible] Secretary of the Ministry of Health, for example for the coordination mechanism.

This strong coordination will exemplify and harmonize planning and reporting tools using standardized formats. All plans have to be approved by the National entities before they are implemented, and all plans have to have the real total and literal bridges. These allow us to understand the real cost and to determine the real cost effectiveness of all interventions. This is very important when we have to choose what to bring in scale.

An example is that all partners—we have what we have a common basket of procurement for antiretroviral drugs. This allows us with the same money to treat 30-percent more people. Having 70-percent of people who need antiretroviral drugs on treatment would not have been possible without improving the overall health status of the population and without using AIDS money to address development issues that are the root cause of disease, as mentioned before.

We have a strategy of no vertical programs, which means an integration of the fight against HIV and AIDS in sectorial programs. This is an example of the health sector and giving antiretroviral drugs—before that we need to test for [inaudible]. That means labs for the tests. Before building or improving existing laboratories, we need to provide common basic care in sites where HIV services will be given. That means basic care for all, not only for people living with HIV/AIDS. This is integrated into the existing health facilities and this is really a prerequisite for giving antiretroviral drugs in a safe manner and with respect to the needs of the entire population.

HIV money—with that, we have implemented countrywide what we call performance-based financing and provide health insurance for the poor. In fact, HIV and AIDS money has brought an important infusion of resources that have been used to provide human resource infrastructure, materials, drugs, [inaudible], technical assistance for overall health functioning from the peripheral hospitals to the primary health facilities and to district hospitals. AIDS money has supported the central level, but also the 30 districts.

Here is to show you the increase in the health insurance at the community level. Now we have more than 75-percent of people paying from their own pocket for this insurance, and it saves them from the five major killers I

talked about in the beginning of the presentation. This health insurance costs \$2, the cost of six traditional beers. That is why for promoting that insurance we have a billboard with three bears.

This is the evolution of the use of the overall healthcare system, curative care. You can see that coming from around 25-percent of the population using curative care we are now above 60-percent. This is to show you the increase of the HIV services, PMTCT, VCT and ART services. This is to show you the increase in the people on ART. Today we have 55,000—we have a prevalence of 3-percent. This means that it is 70-percent of the people in need today.

This is to show you our policy of the decentralization. This will be in three years from now because I cannot put here the 174 sites providing ART, but the only place where there is no site here—and here is the national spark [misspelled?] and this is the national [inaudible].

How did we do this? To reach that point, we had to improve the financial access to health facilities. We did that through the community insurance. We have to reinforce the community participation in healthcare management, create the demand, and increase the quality of care. We did all this largely with HIV money.

However, we have great constraints. Like the majority of the developing countries, it is largely externally financed.

We have solved that partially by making the funds country driven and in-country, community driven with a multi-sectorial approach and a sectorial approach. To reach that concept, we need to put the civil society and all sectors on board when we design policies, strategies and plans. To create sustainable health, we need to come from a low-income country to a middle-income country. All the sectors are working hard to increase the economic capacity of the country. That means development. That means also that AIDS has to be totally integrated into our national plan with transparency on both sides, on our side and on the side of the donors.

We face other challenges. We have a shortage of human resources. Many interventions are underfunded—for example, the link between hunger and health—and there is still a challenge, even if the costs go down, of the sustainability of life treatment like ART if the global solidarity one day broke down. Another challenge is the fact that development requires long-term development partner commitment for programs. We do not have that. Thanks to PEPFAR, who signed a bill for three years, but three years is still low when we want to plan for the future.

Having challenge in Rwanda, we have also a lot of opportunities. We have clear political commitment and technical vision. We have strong government leadership and coordination. We have a vision beyond the [inaudible].

Because we want to integrate all, we have what we call the [inaudible] for the victory. We promote broad-based community and civil society participation, and we have goodwill of partners of partners and global society. We have strong programs on which to build a vision of full integration. We have also zero tolerance, zero, for corruption and lack of transparency.

In conclusion, in Rwanda, we want to go for universal access for 2012, but we still have a long way to go. Universal access goes hand-in-hand with overall country development and a full integration of the fight against HIV/AIDS in sector. It means a strong coordination with stakeholders and improvement of the health sector and to be ready to change the law and to create institutions for that. I thank you for your attention [applause].

JAYA SHREEDHAR, M.D.: Thank you very much, Agnes, for that fine presentation. I will call upon our last speaker, Richard Elliot from Canada, who is going to talk to us about to what extent the flexibilities in TRIPS allow for access to essential HIV medicines.

RICHARD ELLIOT: Thank you, madame chair. Good morning, ladies and gentlemen. I am pleased to be invited to speak about the Canadian example of trying to implement the TRIPS flexibilities because I think it is a fairly instructive example, and it is one of the few that we have so far of this

particular kind of flexibility trying to use. I am going to pick up on a few points that were alluded to in Ellen T'Hoen's speech about TRIPS and the flexibilities therein.

So, very briefly, to put this in a little bit of context, as many of the people may have known, TRIPS, the Agreement on Trade-Related Aspects of Intellectual Property Rights at the WTO globalizes one particular approach to dealing with intellectual property rules, including when it comes to pharmaceutical products and the processes for developing them. In particular, there are a couple of provisions of the TRIPS agreement that are the legal framework within which the Canadian model that I will be talking about in a moment fit. The things to note here are highlighted on the screen, including the fact that the TRIPS Agreement requires the granting of exclusive patent rights on pharmaceutical products, as in other fields of technology, but also specifically it does have a number of provisions that provide some flexibility. The two that I think are most relevant at the moment are articles 30 and 31. Article 31 is the provision that authorizes certain kinds of compulsory licensing, whether it be to a private actor or for government use. Article 30, which I will come back to at the end of my remarks, provides for limited exceptions to the exclusive patent rights that countries that have joined the WTO must grant.

Ellen, in her remarks, made reference to and our colleague from Rwanda made reference to the Doha Declaration on the TRIPS Agreement of Public Health, the two most salient features of which are to be found in paragraphs four and six. Paragraph four, I think, is an incredibly important statement of international law, and that is that the TRIPS Agreement can and should be interpreted and implemented in ways that support the efforts of WTO members and their right to protect the public health, particularly to promote access to medicines for all.

In paragraph six of that declaration it was also recognized that some countries, specifically those that have insufficient or no manufacturing capacity in the pharmaceutical sector, will have difficulty in making effective use of compulsory licensing because if they do not have within their own borders that capacity, than obviously there is not someone who can be the recipient of a compulsory license that would then be able to use it to manufacture the lower cost generic drugs.

There was recognition of that problem, but there was no solution agreed at the time in 2001, but there was an agreement to come up with a solution by the end of the 2002. They missed the deadline. However, they did agree to a final text, all WTO members, in August of 2003.

Now, what is the problem? There is the insufficient manufacturing capacity of some countries to manufacture generics using compulsory licensing domestically, but when you combine that with the fact that there was a provision in TRIPS that limited the use of compulsory licensing by any WTO member to predominantly supplying your own domestic market, then it imposes a restriction on the ability of those countries that do have the manufacturing capacity to issue compulsory licenses within their own borders, under their own national law for the purposes of exporting those generic products to the countries that need to import them because they lack their own manufacturing capacity. The drugs are in one place or the ability to produce the generic drugs is in one place, and the need for them is in another place. That was the gap that needed to be bridged.

So, I mentioned that there was an agreement to come up with a "solution" to this problem in August 2003, and I have highlighted it here on the screen in red. The WTO General Council adopted a solution in the form of an interim waiver of this restriction on issuing compulsory licenses for the purpose of exporting lower cost generics. And that has provided the basis for action by a handful of countries, six or seven, to actually implement that at the domestic level.

Canada was the first country to implement a detailed legislative framework, although at the very same time Norway

adopted a very short regulation that simply replicated the language of the WTO agreement, which, to be frank, I do not think it is all that helpful. After a long civil society campaign that involved a great deal of effort by a number of people and enjoyed the support of the UN Special Envoy on HIV/AIDS in Africa at the time, Stephen Lewis. After an exchange of letters between the U.S. and Canada to overcome a similar sort of barrier that the NAFTA Agreement might have posed and through a number of political changes and ups and downs, in a period of eight months we managed to get legislation unanimously through both houses of our Parliament that would create a mechanism under Canadian law for issuing compulsory licenses for the purpose of exporting generic pharmaceutical products. The legislation was passed in 2004. It came into force a year later and following a change of government, it has now been relabeled Canada's Access to Medicines Regime. I know here on the screen is the government's website provides more detail about the regime, but I am going to give you some of that detail now, although probably in a little more critical way than the government website does.

So, this particular Access to Medicines Regime, does it work or does it not? First of all, a WTO member country that wants to import medicines must notify the TRIPS Council, or, in the case of a country that does not belong to the WTO, must

notify the Canadian government directly that it wishes to use the WTO mechanism and the Canadian legislation implementing it for the purposes of importing generic medicine. It has to state or already have been determined to be a country that lacks manufacturing capacity and if there is a patent in place on that particular product that it is interested in its country, than it needs to indicate that it has or will be taking steps to issue a compulsory license.

Now, here is where we get to a problem with the Canadian Regime and that is that, frankly, the process is backward, but the process is backward partly because of the WTO decision on which it is based it worded or structured. What has to happen is that a generic producer in Canada and a developing country purchases essentially need to strike a tentative deal with a determination of a specific drug, a specific quantity that the country anticipates purchasing from that generic manufacturer with a specific price and a certain time frame. It is only when that information is actually already notified to the WTO or to the government of Canada and provided to the companies that hold the patents on those drugs in Canada, in an attempt to negotiate a voluntary license, that this process can actually get underway. So, the generic manufacturer, in these conversations with a potential purchaser, is somewhat hamstrung because they do not actually have in hand at that point the legal authorization to supply

the product that they are potentially agreeing to supply to the country. So, you can imagine that from the country's perspective that makes the whole enterprise somewhat less attractive.

Assuming there is a product that generic drug company wants to export and there is a client that wants to purchase it, the product must go through Health Canada's Therapeutic Product Director, which is the equivalent of the U.S. FDA, for review. It is the drug regulatory authority. Interestingly, this process is only required for drugs that are exported if they are exported under Canada's Access to Medicines Regime. That is, if they are exported under a compulsory license. That provision was added to the law, even though the law in Canada up to that point had been that you can export drugs outside of the Canadian market without going through the approval process. But all of a sudden when we were talking about compulsory licensing for export, this particular provision was added. Now, to its credit, Health Canada, the regulatory authority, did commit to a fast track process for any such medicines, and I think that they have been true to their word on that. They have moved things along reasonably quickly, as far as drug regulatory authorities go.

There was also an issue about how do we do a scientific review of this particular product if there is no existing comparator product already approved for the Canadian market?

The review that the drug regulatory authority will do will be to apply the same standards as if the product were to be destined for the Canadian market for consumption by Canadians, which, in principle, is as it should be, but, as I will point out later, it poses some potential problems, particularly if there is not already a product approved for sale on the Canadian market against which you can show bioequivalence and therefore get through the review process that much faster. And in particular, that would be the case for a number of fixed-dose combination products because, of course, because of the patents that are held by different companies on the individual products, there are relatively few fixed-dose combination products that have been approved for sale in the Canadian market because different companies hold the patents. There are just two or three where it is the same company that holds the patent, such as Combivir, for example. They also have to look at the features that differentiate the product that is going to be exported under the compulsory license from the product, the same brand-name product that is going to be sold in the Canadian market. That is an anti-diversional measure.

So, assuming that there is this tentative between a generic manufacturer in Canada and a developing country purchases, the generic manufacturer then needs to go to the patentee in Canada, the company or companies that hold the patent, especially if we are talking about fixed-dose

combination products, and dispose to them that they have a tentative deal with X country for Y quantity of this particular drug and would the patent holder please give them a voluntary license of reasonable commercial terms and conditions, which is a requirement of the TRIPS Agreement? One of the good things about the Canadian legislation is that it actually limits the amount of time that you have to try to negotiate, and it says you have to try to negotiate for 30 days and if you do not succeed, then after that, as a generic manufacturer, you can apply to the Commissioner of Patents for compulsory license. And other good feature about the Canadian legislation is that if the statutory conditions have been satisfied, then the Commissioner of Patents shall issue the compulsory license to the applicant. There is no discretion on the commissioner's part at that point, which is an important feature because it limits the opportunities for litigation to try to slow down the process.

One of the other good features about the Canadian Regime—and really, I think, the best example so far at this point of the handful of countries that have done this—is that it actually has in the regulations that go with the legislation itself a very clear formula for what the royalty payable will be in any given instance. It removes uncertainty, which was, as we heard from the generic industry, a major concern throughout. They were concerned that if the royalties were

left unspecified then that was going to open the door to all sorts of litigating in the courts, especially in this particularly litigious industry, between brand names and generics that would draw out the process and would constitute additional hassle and additional cost to try and get through the process, and would really just turn everyone off of trying to use it.

There is a sliding scale that is set out in the regulations that is based on the importing country's ranking on the Human Development Index as a rough proxy for the level of ability to pay. There is a maximum 4-percent cap on any royalty payable, but that is for the country with the highest Human Development Index ranking, which obviously would be a developed country like Norway, for example, which would not be eligible to import. So, most of the time we are talking about countries paying 2.5-percent, or considerably lower, royalties if they were to use this system.

If you jump through these hoops and you get a compulsory license at a generic manufacturer, it is a license that is limited to authorizing you to export only that particular quantity of drug that you had disposed before based on your discussions with the purchasing country and only for that specific country. It also is subject to a maximum two-year term. This was a little invention that the Canadian government dreamed up all on its own, which is not to be found

anywhere in any WTO instrument as a requirement, which was thrown in just for good measure. We have said that that should be abolished. And then there are a number of minor administrative sort of details about posting things to websites once you are actually doing shipping and so on.

So, there are a number of limitations to this regime, which I think we should understand in order to be able to answer that question of whether or this attempt to use TRIPS flexibilities works. For one, there is a schedule that has been added to the legislation that limits the products that are subject to compulsory licensing for export. In order to add to that list, it takes the decision of two ministers and the federal cabinet, so the cabinet plays a role as a gatekeeper for developing countries' access to different medicines using this particular regime. In our view, that should be abolished and it should simply apply to any pharmaceutical product.

If you are a non-least developed country and you do not belong to the WTO, the legislation, again, unnecessarily creates some additional hurdles for you if you want to be eligible to import generic drugs made under a compulsory license in Canada, including having to declare a national emergency or similar circumstance, and you also have to make a pledge not permit "commercial use," a term which is not defined anywhere and depending on how its interpreted, and it has not

been interpreted yet, could actually limit the ability to distribute through private pharmacies, for example.

So, what is the fundamental problem? The fundamental problem is that the process has it backward, that you need to actually have a tentative deal lined up before you get a compulsory license. What we have suggested is that, in fact, you could resolve this chicken or egg problem by imposing what is called a one-license solution. Instead of requiring separate licenses for each and every drug order for each individual country, you should, in fact, grant one compulsory license up front to the generic manufacturer that would authorize the production for export of that particular drug to any of the developing countries that are covered by the legislation, which is most of them, simply with the condition that you periodically disclose the contracts that you then negotiate with various purchasers and pay the applicable royalty based on the calculation that is set out already in the legislation. Get rid of things like the arbitrary to your time limit.

I just want to finish by pointing to the one success that we have had so far, and it is the only success anywhere in the world of using this particular WTO-agreed flexibility. Last year Rwanda became the first country to notify the WTO that it was going to attempt to use this mechanism via the Canadian Regime. Voluntary license negotiations were

unsuccessful and in the end a compulsory license was issued last year and an international tendering process took place. The Canadian generic manufacturer that had developed this one particular fixed-dose combination of AZT/3TC/nevirapine was successful in that competitive process, and they have offered a price that is now cheaper for this particular fixed-dose combination than any other price so far publically reported from any other generic manufacturer, so the cost would not be down to \$146 U.S. Dollars per patient, per year. It is expected that that first delivery will happen in September or October of this year. I will stop there [applause].

JAYA SHREEDHAR, M.D.: Thank you, Richard. Thank you to our other speakers who have helped us to navigate an incredibly complex area of legal challenges to universal scale up of ARVs within the very, very short time that we had. We have about 14 to 15 minutes left for questions, so the floor is now open. Our request is that you restrict your question to just one or two and keep them down to about 40 seconds so that there will be enough time for discussion. Please identify yourself and tell us who you are addressing your question to. Thank you. I think a mic is reaching you. Can you stand up and identify yourself? Yes, please, can we have the question?

MICHAEL HUBBLE: Yes, this is Michael Hubble from Bering Engleheim [misspelled?]. It is not a question, but just some addition to what Richard has said. According to the

company policy, we had offered Aspen a Non-Asset Declaration, which means it is a royalty-free declaration, one-sided, going to all WHO pre-qualified companies. They then can produce the product and distribute it in low-income countries with no royalties, regardless of any patent. This is the policy that we follow, which comes also close to what Ellen said, in a way a pooling of patents. Unfortunately, this was rejected and then Aspen issued a compulsory license, as has been said.

Thank you.

JAYA SHREEDHAR, M.D.: Make sure that the mics are on.

RICHARD ELLIOT: Just to clarify, I think you meant to refer to Abatix, not to Aspen, in your comment. And we were not privy, obviously, to the details of the negotiations between Abatix and the various patentees in Canada, one of which was of Boehringer Ingelheim, the other would have been GlaxoSmithKline. Because this was a fixed-dose combination, they needed to get a voluntary license from all of the patentees that held the relevant patents of the different medicines, but thank you for that clarification.

JAYA SHREEDHAR, M.D.: Yes, sir?

MALE SPEAKER: My name is [inaudible]. I came from Haiti. I do have three short questions for the doctor coming from Rwanda. I am delighted to hear about your experience, but by question is how much money does the Rwandan government spend

by itself? And the insurance paid by the population is symbolic? Thank you.

DR. AGNES BINAGWAHO: We all know that there is no developing country which fights the diseases, HIV, TB, malaria and some others without the global solidarity. What we try to do in Rwanda is to put all those external supports into the budget, as a budget support. This allows us to direct money where we need to direct it. Now in the health system, for now, the Rwandan government did not reach the commitment, like many countries, but I think those commitments should be reviewed because I do not know on which criteria they have said that 40-percent of the budget should be put into health when we have to build schools, roads, hospitals, et cetera. We reach now somehow 11-percent. I cannot tell you what goes directly into HIV or something like that because, as you have already seen, we have an integrated approach. There are no health workers who work just for HIV, per se. For the health insurance, it is not really symbolic. It is two dollars a year for the basic care, knowing that TB is fully sponsored by the government and partners, as well as antiretroviral drugs and some malaria drugs. Insurance, if you add one dollar a year, you get the capacity to be transferred to the regular hospital and the population pays only 25-percent of the cost of health. It is not totally free. You give two dollars per year per capita in your house per family, so that means this insurance is

individual, even for children, not for family. For one more dollar, they have access to refer for transfer. But for the poor, we have almost 800,000 people who are paid for partly by the government, partly by a project funded by the Global Fund.

JAYA SHREEDHAR, M.D.: Thank you. We have a question to my left. Please, sir, go ahead.

ROBERT CLUTSMAN: Thank you. I am Robert Clutsman [misspelled?] from Columbia University. I am wondering about use of exceptions to the TRIPS Agreement for other medications or for other tests, even for diseases beyond HIV or TB. Diabetes, for instance, is a problem in many countries. I am wondering if there have been attempts to apply a notion of sort of public health importance or urgency to other diseases for which maybe exception could be made to patenting.

DR. AGNES BINAGWAHO: I think we should. The global solidarity of HIV/AIDS was made by activists all over the world. That is why the world's attention was captured for HIV and all of this happened. HIV is a catalyst for many things. I have shown you how it is a catalyst for development in my country, but it is a catalyst for changing the law and the rules. So, I think if the world stands up for hypertension, for diabetes, for cancer, why not? But I think we should stand up for that. It will not come on its own [applause].

FEMALE SPEAKER: If I may add to that, legally there are no obstacles to using these flexibilities in any area, for

any disease, or for any product. The WTO rules are absolutely crystal clear about that. I would invite all of you to sometimes spend a minute reading the Doha Declaration on TRIPS and Public Health, because there is an enormous amount of misinformation about that around, information of the nature that you can only use it for AIDS, you can only use it in emergency, you can only use it if the sky is blue or green-whatever. That is not true. You can actually apply these mechanisms very widely. What is also interesting is to look at the history of compulsory licensing. European countries and the United States, in the past when they were faced with increased prices because of patent protection they have on a routine basis used compulsory license and government-used measures to import cheaper generics. It is very interesting to study, for example, what happened in the early '60s in the United States. They imported most of their antibiotics from Europe because they were so much cheaper, despite the fact that those products were patented in the United States. That was common practice. That was part and parcel of government procurement policies. I think those are mechanisms that we can learn a lot from today in the procurement of medicines in developing countries. It is really important that we understand the rules and do not let ourselves be limited by perceived limitations, by barriers that actually do not exist.

JAYA SHREEDHAR, M.D.: We have a question there. We will have time for just this one question and a question from one of our panelists, and then I am afraid we will have to close. Sir?

PAUL GROSS: Hello, my name is Paul Gross from the University of British Columbia, Canada. My question is for Richard Elliot. I wanted to start off by saying thank you. As a proud Canadian, I think your work has been outstanding in this field. It is a very important channel for access to global treatment, and I just wanted to thank you on behalf of all Canadians for taking the lead in this field [applause] and as someone who protested in front of GlaxoSmithKline in the fall of 2003. My question is regarding what Canada is doing to amend these important limitations to the regime?

RICHARD ELLIOT: Nothing. We actually have been discussing with the government or putting proposals to the government for probably almost two years now because we have been pointing out that it actually took four years, to the month, since the law was enacted for it to be used the first time, and it only got used because there was some sustained work by various NGOs and a commitment by Abatix in response to a request that originally came from MSF to develop this one fixed-dose combination product. They did it basically as a gesture of good faith, and fortunately there was an intervention later on by the Clinton HIV/AIDS Initiative, vis-

à-vis Rwanda, that helped get things moving there. That is not a sustainable way to turn on the tap of access to affordable medicines, and the number of disincentives in the regime as it stands now, some of which were added by Canada unnecessarily and some of which really just reflect the underlying WTO decision from 2003, have been identified time and again to the Canadian government as problems. Last year we held an international expert consultation, actually, that included people in charge of doing drug procurement from various developing countries. We discussed all of the different features of the Access to Medicines Regime in Canada. The general reaction then and in the months before was of people scratching their heads and saying, why would you design a system that is so complex when it is so unnecessary and what you need is something simple and quick?

So, what we did was we identified a number of reforms, including this fundamental one about changing the process so that you just get one license at the beginning and it covers all countries and you do not have to re-negotiate every single time and all of that. A few months ago, in December, the government of Canada completed a review of the legislation, which was mandated by law when it was originally passed, and concluded—and we are here at the 3.5-year mark since the law was passed with nothing yet moving—that it was premature to amend the legislation. Dr. De Cock, in his opening remarks,

alluded to the fact that we do not actually have the freedom to ignore the knowledge that we have now in shaping public policy. I think after 3.5 years of the Canadian legislation not being used and no other country's legislation that is similar being used, we can reasonably come to the conclusion that there is something rotten in the fundamental mechanism and that we need to fix the fundamental mechanism. We need to re-think the August 30, 2003 WTO decision to put in place a streamlined process like the one that we have described. So far, our government has shown no willingness to do that, but I think they are really off-base with Canadians who have consistently said, we want to help here and this is something concrete that our country can do. So, I think they are going to lose some points with the Canadian public for that and we will see where we can take it in the months ahead, but more demonstrations will help. Thank you [applause].

JAYA SHREEDHAR, M.D.: We are almost done. We are going to just wind up with a comment from Dr. [interposing].

KEVIN DE COCK, M.D.: I wonder if I ask the panel a question, whoever wants to reply. In this whole discussion, should we be worried about drug development? I think Roche a few weeks ago announced that it was actually halting its development and research program for antiretrovirals. Certainly in the HIV vaccine field, one could imagine that quite a few companies will be reconsidering their options. In

the context of the discussion that we have just had, what are the implications? I know it is a complicated question.

ELLEN T'HOEN: Yes, Kevin, I am very glad you raised that because that is often the response we are getting when we say, those prices need to come down. The companies then say, then there will not be any research and development. There is no denying that research and development is costly and that it needs to be paid for. The question is whether it should exclusively be paid for by charging high prices and particularly by charging high prices to poor people? If you have a research and development system that is primarily financed through prices, you get two things: Your research and development agenda is driven by where the market opportunities are and secondly that excludes a lot of needs. If that was not the case, I think we would also see in AIDS a different research and development agenda. Secondly, you get high prices that lead to exclusion of large number of people.

Now, we have been proposing—and we are very happy that that concept is included in the WHO Global Strategy and Plan of Action—that we need to move to a situation where you separate paying for the cost of the R&D from the price of the end product. You need to create a market and you need to create incentives for the research and development, but not exclusively through charging high drug prices and certainly not through charging high drug prices to poor people [applause].

MARIANGELA SIMAO: If I can complement what Ellen said from a very concrete experience in Brazil—I think, Kevin, when we issued the compulsory license I was in Geneva and we talked a little bit about it. Actually, people living with AIDS are still a big market for companies and we are talking about commercial interests. We are facing a disease that does have a cure and where vaccine progression is very slow, so we still have a long way to go. I think that companies try to bring a myth that when you use the flexibilities of TRIPS and so on or the Doha Declaration, you are going to stop research and so on. Actually, the ways to use the flexibilities are very complex, like Ellen said. It is very hard to do a compulsory license. We did that and we suffered a lot of pressure in Brazil.

I would like to mention a concrete example. Although we had the compulsory license last year in Brazil for efavirenz, which was owned by [inaudible], we had the registration of raltegravir this year, so we still have a very big market for Merck, so I do not think that really scared the drug companies from developing new drugs or from searching for markets in developing countries where people are sick and need to get treatment.

MARIANGELA SIMAO: As it is complex that is true. Another fact is that it is true that for HIV the majority of the suffering is the poor areas of the world. I am not so optimistic and I am a little bit pessimistic, especially when

my friend a couple of months ago said that there would be no more generalized [inaudible], except in Africa. That is why people like me are here to advocate and to pay attention. They should not stop because the people who are going to use it probably have no money to pay. We should find another way to compensate research, because it is true also that people who lead pharmaceutical firms do it to get money. So it is a matter of global solidarity and advocacy.

There is something I would like to stand up against. HIV vaccines did not fail. How many years did it take to do a smallpox vaccine? It was more than 40 years and now this horrible disease has disappeared. How many years did it take to develop a polio vaccine? It took more than 40 years and here we are only at 33 years of research. And so in the way we advocate we should also be careful the way we are wording things. There is no HIV or malaria vaccine for now. Nobody talks about the failure of malaria vaccine and they are still researching it. Why this focus on HIV?

JAYA SHREEDHAR, M.D.: Thank you. We have had an excellent discussion over the last 1.5 hours. If there is one single message I am personally taking back from this session to India, it is that I understand now the need to really push the frontiers of advocacy. This is an incredibly complex issue that calls not just for simple activism, but informed activism that requires help across the board, particularly from helpful

lawyers. I would like to place on record here and pay tribute to the work of the Lawyers Collective in India which has really pioneered for us and gotten us to prevent evergreening [misspelled?]. But it is not going to stop here. We need to keep up our efforts, keep up the advocacy, and work with people like the Lawyers Collective and committed people from all around the world to realize our dream of universal access. Thank you very much for your attention [applause].

[END RECORDING]