

**Treatment Access, TRIPS and Trip-ups
XVI International AIDS Conference
August 17, 2006**

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GREGG GONSALVES: So welcome to our session on treatment access trips and trip-ups. I think we have Christine Steadling [misspelled?] from Vanilla [misspelled?] to thank for the title of this session. We'll deal with that later. [LAUGHTER]

Our first presenter today, we'll get straight to it, this way we can have a lot of conversation and discussion at the end. We're going to give each presenter about 10 minutes to maximize time for discussion. We won't be so harsh on you if you go over a little bit, but let's try to save time for discussion at the end.

I'm Gregg Gonsalves with the AIDS and Rights Alliance for Southern Africa. And this is Asia Russell of Health GAP, and one of the co-moderators of the session.

And our first speaker is Jonathan Berger, who is the senior researcher and head of policy and research at the AIDS Law Project in South Africa which works in close collaboration with the treatment action campaign. He'll be speaking on "HIV/AIDS and South Africa's War on Science."

JONATHAN BERGER: Okay, do we have a presentation? We do. Thanks. South Africa's health minister has asserted that [inaudible] any distance of self from AIDS denialist Dr. Matthias Rath, a German national, if it can be demonstrated

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that the vitamin supplements that he is prescribing are poisonous for people living with HIV.

Despite overwhelming evidence of the harm that Dr. Rath is causing - Rath is the lovely gentleman on the very right-hand side of the slide - the prescribing and dispensing of unregistered medicines, the conduction of unauthorized and unethical clinical trials, the minister has continued to refuse to use her powers, the secretary powers that she has, to stop his dangerous campaign. Instead, she continues to lead a calculated and coordinated war on science and on those who use and rely on it in responding to the HIV epidemic.

In today's presentation, I want to touch on three issues. Firstly, a few introductory points clarifying the abstract that I presented, because I am departing somewhat from the abstract that has been published and really going into the scope of this presentation.

Secondly, as part of the introduction, deal with what I consider the four pillars of the war on science. And as you will see, I don't think that the war on science only is comprised of the AIDS denialism. It's an essential part of the war, but certainly there are many other aspects involved.

I want to look at the relationship between those four pillars, and then if time permits, I will go into looking at some of the examples in each of three of the four pillars that I've identified. I probably will touch on one or two.

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I'll most likely get cut off towards the end. And then some concluding remarks on a way forward.

The abstract class of [inaudible] speaks about a study of the steps that South African civil society has taken to ensure that the state protects the public from Rath's local activities.

And it also speaks about a consideration of the context in which Rath's campaign has flourished, as well as the relationship between the state's constitutional obligations in respect to access to health care and evidence-based medicine.

What I've come to realize during this conference is that such noble ideals can't actually be dealt with in 15 minutes. And as we learned a few minutes ago, we've actually got 10 minutes.

So you're not going to be getting [inaudible] of the Rath wars in South Africa. If you want that you can go to the treat induction campaign website, www.tac.org.za, and it's all there very nicely.

I'm not going to deal with academic arguments with constitutional jurisprudence. That will come later when the matters get to court.

Instead, I'm going to focus on the broader context and try to try and understand how an environment has been created where quacks, charlatans, and crooks like Matthias

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Rath and a bunch of others are actually able to sell their unregistered products and to cause the harm that they currently causing.

I've always believed that the problem is not people like Rath. The problem is those who allow the activities to continue. The abstract speaks about a state-sponsored campaign of promoting untested remedies coupled with an attack on evidence-based medicine.

I thought somewhat about this and certainly thought in relation to more recent events and I think it's a lot more complex than that. I've identified at least two further issues that inform the context.

And I think there's quite a significant amount of nuance in respect of all of those that I've already identified. And I think, really, there are four pillars of the war. And I won't go into much detail on any of them.

Firstly, it's the failure of President Mbeki expressly, clearly and decisively to deal with the aftermath of his flirtation with and his embrace of AIDS denialism. Whether or not he still is an AIDS denialist we won't know, we don't know. We believe he is, but certainly the harm that has been caused by much of what he has said, and that is very well documented, he has not stepped up to the table to atone for that.

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Secondly, the second pillar is a state's responsive campaign of promoting untested medicines. It's about misrepresenting, distorting evidence, raising legitimate concerns about the pharmaceutical industry but in a very underhand manner, and really by appealing to sensitivities about culture, tradition and colonialisms assault and traditional knowledge systems.

A number of legitimate aspects to it, but the manner in which it is done and the agenda which is pursued by appealing to legitimate concerns is of concern.

Thirdly, by allowing for breaches of the [inaudible] in particular. Here I'm talking about the Medicines Act, in terms of the medicines, the registration and the use of meds, and prescription medicines is regulated as well as the conducting of clinical trials.

And then finally, what I call a relentless lawmaking agenda which seeks to expand the powers of the executive by reducing Parliament's Portfolio Committee on Health to a rather stamping body with [inaudible] oversight authority, by undermining the independence of regulatory authorities under the guise of transformation, and by centralizing control in the hands of the minister by investing with unguided, overly broad, and frequently inappropriate discretionary powers.

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And while I'm reading this, I think perhaps many of these things might well apply to the country that lies just across the border to the south.

[APPLAUSE]

These four pillars really underpin South Africa's epidemic of pseudo signs and are overlapping and mutually reinforcing. On their own they're dangerous enough, but when they work together, that's really where they're often knocking short of a full-frontal attack on science.

I'm not going to deal with President Mbeki's denialism today because that is very well documented. I can't think of a single official publication, speech or reported comment that has sought expressly to distance the president from his earlier position.

Instead what we have in the words of Zapiro, the most famous cartoonist in South Africa and maybe beyond, is we have a comprehensive rollout of obfuscation. That is what we get. We never get clear, concise, accurate messaging from government.

It is always about, it's not what we said. We said this, we said that, we revised. We don't actually know what is the position? What does the president believe? Does HIV cause AIDS? Do antiretrovirals work? We don't get any of that in any of the official media, and that is what is missing.

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But I'm not going to dwell on that today. Enough has been said about that, any more which would really just belabor the point.

The second pillar really is about evidence on traditional medicines. And I want to give one example here. And that is that the provincial launch in February of 2004 of what's known as the National Reference Center for African Traditional Medicines. This was the Western Cape Provincial launch where the minister was steadfast in committing her department to mobilize resources from all quarters to ensure that traditional medicines and the practice thereof enjoyed, for the first time in our history, the full recognition and support they've always deserved.

She quoted from a publication from the National Reference Center, and what she said, she spoke about the importance of traditional medicines in the treatment and management of life-threatening diseases. And the paper speaks about that, the paper from which she quoted.

But it then goes on to say a whole range of things which, not by accident, were excluded from the minister's address on that particular day. And in particular, it said as follows: No adequate scientific evidence has been documented in these specific areas. It then went on to say the following: The popularity of herbal medicines has led to increasing concerns about the safety, quality and efficacy.

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In many countries, the herbal medicines market is poorly regulated and products may be neither registered nor controlled, national surveillance systems to monitor and evaluate adverse events are rare.

Though there has been an increase on scientific studies on herbal medicines, such studies are seldom designed to produce reliable data on safety, quality and efficacy.

And then the paper goes on to talk about a particular study from George McCurry [misspelled?] Hospital, which is near Pretoria, which raises even further concerns about traditional medicines and further areas for investigation.

None of this was raised in the address by the minister, and only what she spoke about was a glowing report of traditional medicines without any of caveats that her own department and the Medical Research Council and the Council for Scientific and Industrial Research had come up with.

I do not believe it's by accident. I think it was certainly by design. See, I have seven, six, five seconds left so Gregg has graciously given two more minutes.

The second area really is about facilitating [inaudible] Medicines Act. And there is a written paper that I've prepared that talks about this in some more detail. So I won't go in to much detail. But what happened is that quite recently, a shipment of medicines as defined by the Medicines Act, vitamins that are peddled by Matthias Rath, arrived in

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Cape Town and the Port [inaudible] officials would not allow the shipments to enter the country because, in their opinion, numerous regulations and provisions of the Medicines Act had been violated.

To cut a long story short, direct intervention by the director general resulted in those medicines being released. The official explanation was unconvincing. In private, the director general has told colleagues of mine that his intervention was based on legal opinions, both internally and externally. I'm not sure which [inaudible] he's consulting, but certainly they don't have the same understanding of the law as many of us working in the field do. But be that as it may, whether there was a basis for intervention or not the Medicines Control Council thought it was necessary for them to intervene and to investigate the matter.

And yet they were instructed once again by the director general, hands off. So it's quite clear, as far as I'm concerned, that there has been direct intervention, that he has been abusing his powers to stop anyone who seeks to take action against Matthias Rath.

What makes it even more disconcerting is that the very medicines, the pull that were being let into the country, are the ones that are the subject of litigation between the Treatment Action Campaign and the South African

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Medical Association and Matthias Rath and the minister and many others.

And while that case is going through the court and whether or not those medicines should be registered, whether they can be distributed in the way in they're being distributed, while those very issues are being debated and being adjudicated by our courts, it really is irresponsible and perhaps even criminal for any official to intervene in a way which supports the peddling of those medicines.

I won't go into any detail on this almost final slide other than to say we have seen an arrange of pieces of legislation whether it is the Nursing Act, the Health Professions Act, the Medicines Act, how over the years government has been very consistent in amending legislation to ensure that power is taken away from independent [inaudible] councils and given to the executive.

Their powers are reduced. The role of the minister gets exaggerated. Discretionary powers get given. Detail for the exercise of those powers is removed from the act putting the regulations outside of Parliamentary approval.

It's a very dangerous move, moves that are taking place and certainly when seen in the context of the denialism and the attempts to facilitate breaches of other pieces of legislation by granting greater discretionary powers which

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are unregulated to the executive. We're really seeing all of these areas coming together in quite a significant way.

I will sum up right now. The theme of this conference is "Time to Deliver." This presupposes a strong connection between evidence and policy. But in a country like South Africa, where science is both rapidly advancing and coming under increasing attack, the disconnect between the two places effective service delivery under threat.

If we are serious about ensuring universal access to comprehensive prevention, treatment, care and support services, one cannot sit back and watch as the benefits of scientific development are effectively withheld from those in need.

There has been much silence at this conference about many of these issues. Mark Haywood, in his plenary speech this morning, spoke about that. We've heard much about the immorality of the Bush administration and what we've heard is correct. The Bush administration's policies are neither exchanged on the Global Gag Rule, on emergency contraception, who knows what they're going to do with the HPV vaccine, whether it's going to be made available to young teenagers or to younger than teenagers.

That's all correct. But, as Mark said, there's a silence on African leaders and one has to ask why. Just because the evils are being committed by people who we think

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should be the nice guys, doesn't make those evils any less evil. Thank you.

[APPLAUSE]

GREGG GONSALVES: Thank you, Jonathan. And if people go over their 10 minutes to 15 minutes that's fine, but after 15 minutes, you're in big trouble.

Our next speaker is Gabriela Costa Chaves. She's a pharmacist and has a master's on public health from the Sergio Aruca National School of Public Health at the Oswaldo Cruz Foundation in Brazil. And she'll be talking about "Measuring Public Health: Sensitive Degrees of IPR Legislation in the Context of the WTO TRIPS Agreement."

GABRIELA CHAVES: Good afternoon. And I think the first slide will be a little bit easy for you, but it's just to have a line of thinking. So this is the contents of the presentation. This was part of my master's degree. The study we developed in Brazil since 2002 when we started a project regarding TRIPS and [inaudible]. So the contents of the presentation is, very briefly, is in second contents of the TRIPS agreement, public health-sensitive legislation and contents validation, constructive validation, and final considerations.

So as all we know, after the TRIPS Agreement, all countries would have to grant pardons to pharmaceutical [inaudible] in process which can be barrier to access to

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medicines because pharmaceutical companies can establish high price for at least 20 years, which delays the commercialization of generic medicines.

One of the recommendations proposed by the WTO, the World Health Organization, one of the strategies sustained to improve countries are affordability of patent medicines, are the use of the WTO TRIPS Agreements.

So Carlos Cojeya [misspelled?], he says that allegedly public health sensitive in this [inaudible] legislation is that one which incorporates all implicit and explicit TRIPS flexibilities, which enable governments to officially take action in the public health sector.

So our question is which flexibilities were really included in the Latin American-Caribbean countries? So the first study we developed was in this issue, which was published in 2004 in the *Bulletin of the World Health Organization*.

Continuing this study, we tried to develop a framework to analyze patent legislation in a public health perspective. We aimed to show countries' patent legislation in a comparable way. The development of the framework involved the following steps, literature review to identify all TRIPS flexibility-related to access to medicines, the constant validation of this framework through expressed consensus which we used the [inaudible] method, the testing

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of framework with the countries' legislation from Latin American and the Caribbean in construct validation.

So as the first step we identify these six flexibilities, and I would like to highlight that the first one, that's transition period, we have also [inaudible] declaration, which established for least developed countries to not grant passing to pharmaceuticals in June 2016.

And the last one, flexibility, we considered as being one implicit flexibility from article H from TRIPS agreement, which is the minister of health participation in the analysis of pharmaceutical in the patent claims. This is in Brazilian legislation.

Now, I will explain the validation of this framework. The constant validation of the framework consists of very [inaudible] that the instruments incorporate all aspects related to the concept, which is implied in the study which consists of public health patent legislation.

We identified 11 experts to define scores to each provision according to its importance to access to medicines policies. They were also free to propose new legal provisions to the framework and we developed two rounds of questionnaires with them. We had the participation of only seven experts.

I would also like to highlight that they included three TRIPS [inaudible] provision in the framework. In other

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words, IPR legislation would only be [inaudible] discord if it did not include these provisions. This is the framework we got in the end.

For each provision, we had some scores. The TRIPS [inaudible] provision, if the legislation had it, it would be scored as zeros. Okay, so the legislation only had these scores if the TRIPS [inaudible] provisions were not there.

I selected the following countries: Argentina from South American, Argentina, Brazil, Indian communities which is included Bolivia, Columbia, Peru, and Venezuela, Paraguay and Uruguay.

Central America and the Caribbean, we selected Barbados, Belize, Costa Rica, Guatemala, Honduras, Panama, Nicaragua, Dominican Republic, and Trinidad [inaudible]. And for North America, Mexico.

These are the legislation we collected from wide poll collection of law, NITAA collection of law in Internet. I would also like to highlight that as we were searching for [inaudible] in the legislation, I also found for Argentina, Guatemala, a legislation regarding confidentiality.

So this framework, we tried to express the health sensitive degree of [inaudible] legislation in such a way that we could find ways to compare. As you can see in this graph, we can see that any country could improve their legislation in order to be, all countries should improve

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their patent legislation in order to be more health sensitive.

They didn't make for use of [inaudible] declaration. Panama, for example, does not have compulsory license in [inaudible] legislation. If we take Columbia out of Indian Community, there is also a decree which includes that exclusivity.

The concert validation, it was another part of our study. It's necessary when there's no external validity criterion that allows for comparison. It's so that objective is to verify whether the instrument is able measure what it's supposed to measure.

So what did you do? With countries which adhered to two, three trade agreements, North America free trade agreement and the Dominican Republic Central American free trade agreements. So for example, Mexico, Mexico if when not adhered to NAFTA, they would be almost 60-percent health sensitive according to this framework. [APPLAUSE]

And when adhered to NAFTA, it is less than 50-percent. When you look to countries which adhered to GR customs, this graph can show how less health sensitive they will be. So as final considerations I just would like to say that the framework makes possible a form of measuring [inaudible] legislation in terms of its compliance to Access to Medicines policy.

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But it must be improved in order to better express if using public health TRIPS [inaudible] flexibility by each country is actually feasible. The framework has a potential application for monitoring countries like the legislation across time. Especially those which are negotiating FTAs.

[Inaudible] the issue, it's in part to consider TRIPS amendment as well as the pre-grant position used by India, [inaudible], the public civil suits to [inaudible] license by AIDS [inaudible] in Brazil the government used in Malaysia and all other experience I've heard from Canada, Thailand, and South Africa during this conference.

The framework is just a way to show the structure but does not reflect if it's being used to improve access to patent medicines in countries. I would like to thank all experts that participated in the validation of the framework, the National School of Public Health where I could develop my Masters, and the support from WTO and French Minister of Foreign Affairs. Thank you.

[APPLAUSE]

ASIA RUSSELL: Thank you. Our next speaker is Chan Park. And Chan is from the Lawyers Collective HIV unit in Bangalore, India, working primarily for the affordable medicines and treatment campaign. Before joining the Lawyers Collective, Chan practiced as an intellectual property litigator for four years in the United States.

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And Chan will be speaking today on "Taking the Fight to their Realm: The Role of Patent Oppositions in the Struggle for Access to Medicines."

CHAN PARK: Good afternoon, everyone. Today I'm going to be talking a little bit about the patent opposition work that we're doing in India, but before I begin, I would just like to acknowledge and give thanks to all the tireless support provided by MSF Access Campaign particularly, Lenam [misspelled?] and Gainey [misspelled?] from the access in India. [APPLAUSE] Without their work, a lot of this work would not have possible. So I'd just like to thank them.

I'm generally accustomed to talking about patent oppositions before an audience that sees the value of patent oppositions as self-evident. I realize that this may not be entirely such an audience, so before I get into the meat of the presentation, I just want to say a few words addressing the typical pro forma argument put forth. Something to the effect that the patent system is absolutely essential to promote research and development to develop newer and better drugs.

I just have two things to say to this before I move on. The first is there is something seriously wrong with the incentives created by the patent system when we have three or four drugs for erectile dysfunction on the market and we

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still don't have a cure for sleeping sickness or other diseases that affect primarily the global south. [APPLAUSE]

Second, whatever the benefits of the patent system, the fact that there are millions of people today who don't have access to essential medicines, life-saving medicines simply the prices are too high is unacceptable. And there are many causes for this problem, but patents are a big problem and they need to be broken by any means necessary. [APPLAUSE] Moving on.

So why do we oppose patents? Well, the first, most obvious reason is to ensure access to affordable ARVs and other essential medicines as has been stated *ad nauseum* throughout the conference. The prices of first-line ARVs have witnessed a historic decrease over the last five years from around \$10,000 per person per year to the current prices of about \$130 per person per year.

The continued availability of even some of these first-line medicines, and it's especially the second- and third-line medicines, is under jeopardy because of the implementation of TRIPS throughout the world, and particularly in India.

The second, less obvious reason why we oppose patents is that it gives us, civil society, an opportunity to shape how the patent law is implemented and interpreted in India. It's a brand-new law.

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And if you actually look at TRIPS, it defines a lot of things but it doesn't define what novelty is and it doesn't define what obviousness is to standard criteria for patentability, but it leaves it open for individual countries to actually interpret and implement.

It gives us, civil society, an opportunity to advocate strongly an interpretation of these standards and other basic criteria to advocate for an implementation of an IP protection scheme that's consistent with protecting public health.

Okay, so to give you little bit more about the Indian concepts: Again, as most you probably know, Indian generic pharmaceutical companies are the largest producer of affordable ARVs and other essential medicines throughout the developing world.

Just last year, India introduced a TRIPS-compliant 20-year product patent regime that for the first time provided patent protection to pharmaceutical products. Before that, India did not recognize product patent protection for pharmaceutical products, thus allowing the Indian generic pharmaceutical industry to become what it is today.

The law, the Patent Amendment Act of 2005, was enacted amidst a political firestorm but, fortunately, there

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was unprecedented mobilization of local and international civil society in opposing the amendment.

And although civil society wasn't entirely successful in blocking the amendment altogether, we were able to win some key concessions that have proven to be critical in our subsequent patent opposition work.

So some of these provisions include section 3D, which states that a new form of a known substance which doesn't actually make the drug more effective cannot be patented. This may seem obvious, but it actually is a unique provision to Indian patent law. And again, a new indication or a new use of an already known substance is not patentable.

Again, it sounds like common sense, but India is the only country that specifically prohibits the patenting of such substances in the statute.

And section 25 gives the right for both pre- and post-grant oppositions. And both these provisions were actually key in the cancer patient's aid associations landmark victory in January of this year against the vertices patent application for the critical cancer drug Gleevec.

As a result of the victory, the prices for Gleevec went down tenfold from about \$2,500 per person per month to about \$200 per person per month. So that was a landmark victory and it showed us the potential power and the

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effectiveness of patent oppositions and improving access to medicines.

So the first ARV opposition that was filed in India was against GlaxoSmithKline's Combivir, which is a fixed-dose combination of AVT and 3TC. As many of you know, it's one of the most widely fixed-dose combinations in the world today. And Glaxo had over \$1 billion in global sales of Combivir alone in 2004.

Needless to say, generic versions, more affordable versions manufactured by Indian manufacturers, are critical throughout the global south. For example, in MSS-sponsored programs the AVT 3TC combo, over 90-percent of it is manufactured by Indian generic manufacturers.

And if you actually look at the patent application for Combivir, you realize that it's an exceedingly silly application. It concerns the combination of two old existing drugs, AVT and 3TC, both of which are not patentable in India and combining it with something called a glident.

A glident is an inactive substance that adds no therapeutic value to the fixed-dose combination. And a glident can comprise of everyday normal substances such as silicon dioxide which is sand basically, calcium carbonate which is basically chalk, talcum powder, and a variety of other substances that pharmaceutical companies regularly use when making a medicine into a tablet form.

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The classic example of evergreening. Evergreening is an unfortunate but all-too-common practice used throughout the pharmaceutical industry where pharmaceutical manufacturers patent the original drug and then stagger trivial modification to the drugs thereafter to artificially extend an already 20-year monopoly on their drug.

So as a result the Indian network of people living with HIV/AIDS and the [inaudible] network of people living with HIV/AIDS filed an opposition against the Combivir [inaudible] in March claiming that the invention lacked novelty, was not inventive, and on section three grounds as I described to you before.

And also there's a patent application for Combivir, known as Combid in Thailand, currently pending. And just last week, as a sign of solidarity and show of protest against Glaxo's frivolous patent application, both Thai and Indian PLHA groups staged demonstrations in front of GSK offices in both Bangkok and Bangladesh. So a couple of photos follow. [APPLAUSE, LAUGHTER].

So just two days after the demonstrations on 9th of August, just last week, GSK issued an open letter announcing the withdrawal of this patent application in India and Thailand. I actually have the letter with me and I'm going to read a few portions to you. [APPLAUSE]

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"GSK offices in Thailand and India have recently been subject to demonstrations against GSK's patent applications for a Combid, Combivir in those countries. Prior to these demonstrations, GSK decided to withdraw its patents and patent applications directed to a specific formulation of Combid, Combivir wherever they exist.

This includes the patent applications, which were the subject of the demonstrations in India and Thailand. In June 2006, GSK instructed its agents in Thailand and India to withdraw this patent application. This means that GSK has no patent protection on Combid, Combivir in Thailand or India and is not seeking any." So, great news.

However [APPLAUSE] our offices in India actually went to the patent office and, as of yesterday, there is still no sign of any requests for withdrawal for Combivir application in India. So we call on Glaxo to withdraw its patent application in India immediately. It is a frivolous application and it will be rejected under Indian law.
[APPLAUSE].

So these are some of the other oppositions that we have filed in India. I won't have time to get into the technicalities of any of them.

The PLHA groups have filed them and represented by Lawyers Collective and the Initiative for Medicines, Access,

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and Knowledge. There are more oppositions to come. Stay tuned. [APPLAUSE]

So some of the key lessons that we can take from these patent oppositions: Patent oppositions can be a powerful tool for improving access to medicines, but their efficacy is maximized by direct action such as the protest in front of the GSK offices and coordinated media and government advocacy to build pressure on the pharmaceutical companies as well as government.

The active involvement of PLHAs and civil society as we have seen in the Patents Amendment Act during the enactment of the TRIPS Compliant Act is critical to ensuring that sufficient legal protections are included.

This is especially pertinent for least developing countries that still have 2006 [inaudible] to comply with their TRIPS requirements.

It is imperative that as and when these laws get amended that civil society stand up and demand sufficient legal protections and that governments utilize maximum TRIPS flexibilities.

And finally, building capacity among civil society groups to actually oppose these patents is both possible and absolutely necessary.

So some final recommendations before I leave you. Obviously, educate and empower PLHA groups and other civil

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society groups as to the importance of patents and TRIPS related issues. Not the most interesting of issues to talk about and people's eyes start glazing over, but people have to understand the importance of these issues on access to medicines. We need to build capacity among civil society groups throughout the world who want to oppose patents on basic patent law and basic pharmaceutical science.

And we need to build a global network of sharing technical, legal and strategic information, because there's a lot of experts out there, there's a lot of people who are good at a lot of things, but we need to coordinate better and we need to communicate better and share information better.

[APPLAUSE]

Finally, with this network, we need to support the local movements with international media advocacy to build pressure and awareness amongst the general population, amongst government, and particularly amongst the pharmaceutical companies that are applying for these patents.

And finally, everything that I've just said goes out the window if countries agree to free trade agreements with the United States. [APPLAUSE]

These agreements typically contain provisions that go far beyond what TRIPS requires. They typically broaden the scope of patentability, allow for patent term extensions, and mandate a five- to 10-year period of data exclusivity. It is

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imperative that developing country governments reject any proposals for entering into free trade agreements with the United States. So that wraps up my presentation, and I wish everyone a happy Indian Independence Day. Thank you.

[APPLAUSE]

ASIA RUSSELL: Thank you. Our next presenter is Jude Nwokike. He is the senior program associate with the Rational Pharmaceutical Management RPM Plus Program of Management Sciences for Health based in Arlington, Virginia. And he's the Namibia program manager.

JUDE NWOKIKE: Thank you very much, friends and colleagues, for having me here. I'm going to primarily be looking at if we have the drugs, and patents are no longer an issue, do we at times have problems with in-country registration processes? [APPLAUSE]

Or does [inaudible] country [inaudible] processes at times, do they pose a threat to the [inaudible] of medicines. I want to start talking about the fact that [inaudible] RPM Plus Project, is working in Namibia and Namibia has one of the exemplary countries that have taken HIV/AIDS epidemic head on. Namibia currently has been cited as another country that is frequently more than 50-percent of patients who are eligible for treatment and treating more pediatric patients and women than a whole lot of [inaudible] here in African countries.

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And Management Sciences for Health RPM Plus Project in Namibia is also recently [inaudible] a whole lot of support from the ministry. And what's primarily strengthening [inaudible] system to support this [inaudible] of [inaudible] programs.

So I'll go straight into talking about improving the ability of ARVs in Namibia by streamlining the drug-restriction process.

This is just primarily by grant information about the drug-restriction process in country in Namibia. And we have the Medicine Control Council, which is the statutory body responsible for restriction on medicine and ensuring the quality [inaudible] of medicines that are found in Namibia.

And like some of you may well know, Namibia had independence in 1990, but prior to that, most medicines that are used there are medicines that are already registered in South Africa.

In 2001, the Medicine Control Council published a notice regarding the medicine and the [inaudible] control act of 1965, therefore calling [inaudible] medicines not previously released to be actually we can attempt to release them Namibia. That was post independence. And all medicines [inaudible] in South Africa after 1990 were considered unregistered. But applicants who applied for registration were given a grace period of six months to make their

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products. And by 2004, [inaudible] applications for restriction had been received, but only 100 applications had been reviewed. And of course, it might interest you to know that the dedicated committee [inaudible] analytical committee that is charged with the responsibility of making [inaudible] that are submitted by companies to AIDS registration, and in September 2004. [APPLAUSE] And about then, the national ARV program was already started and [inaudible] about a [inaudible] generic ARVs [inaudible] from pediatric formulations were needed to be reviewed and the Namibian Medicine Control Council or the Namibian Register of Medicine contained 49 branded generic and multi-sourced ARV medicines. And there were some backlogs building up.

But [inaudible] then had to do the [inaudible] as the number of drugs that already pre-approved in South Africa [inaudible] so essential released that ban Namibian authorities alone. And of course like U.S.A., there were some backlogs building up.

But I think what is very, very interesting here is a government that had a commitment and had a motivation to ensure that in-country registration [inaudible] does not constitute an [inaudible] hindrance to the abilities of these laws.

So the government took the bull by the horn by directing that efforts should be put in place to ensure that

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this medicines quickly really start to make them available in country. But this slide is primarily trying to show you what the situation was before the streamlining activity with the government which the Medicine Control Council through the control and inspection did with the assistance from RPM clause.

As of 2004, we had [inaudible] medicines that are contained in the medicine register. And interestingly, most of the medicines there are those that are included in the antiretroviral guideline from Namibia.

And another interesting thing is that as a den, Namibia had registered [inaudible] which a [inaudible] of other countries the fact that it has not been formerly enlisted being the reason why they have not really studied.

And indeed there was a need on the side of Namibia because there was some degree of high prevalence of hepatitis and HIV co-infection. But the problem, issue I wanted to highlight here is that's a drive in leadership to ensure that this medicine was released.

And another thing that I think might be very necessary to mention here for you to thoroughly understand, therefore that was put in place, is that this is a system that hired a lot of streamlined activity about how to do things. For instance, medicines get into the register. After the guideline committees for any political [inaudible] in

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this instance the technical advisor committee for the ARV management, by the time they agree on what message should be used in country, then those medicines find their way into the essential medicine list [APPLAUSE] and subsequently gets procured by the Censor Medical Staff and it becomes available in all public health sector facilities. So what was done, essentially, was to support the ministry by providing technical assistance to actually find ways of clearing these backlogs of those [inaudible].

And [inaudible] that were used was to try and grandfather certain products that were marketed in South Africa, approve medicines registered by member countries of ICH, and [inaudible] from school retreats for the former School and Analytical Committee.

I made this committee because people who have AIDS have other responsibilities. How do they find time to meet. And of course establish a medicine-registration database.

Prior to that the people who are working [inaudible] were having issues where using [inaudible] to manage the data. And of course, we looked at the database to manage the [inaudible] review process on an aligned data.

And I think one of the things that prior to the medicine or prior to [inaudible] the request for registration, one of the things that you know happens is essentially the fast-track approval from the country where

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the drug is manufactured, then there are still the pre-approval processes, the pre-politician processes that are primarily handled [inaudible] division in FDA, then the need to recognize to have a [inaudible] way for [inaudible] recognition of countries who have [inaudible].

And by the time you have done all this, it becomes questionable whether you need to have an in-country detailed and rigorous way of registering that same medicine again.

So what primarily was done was, with the support of the IPM clause, the Medicine Control Council Secretary [inaudible] interventions to streamline the restriction processes by prioritizing the review of the ARVs [inaudible] and essential medicines.

So essentially we are talking beyond ARVs. We are talking about both medicines and of course medicines for TB and malaria. Then establishing a [inaudible] process to screen for those that had already been approved by reputable and competent regulatory authorities who would [inaudible] create a medicine registration base and train nonprofessionals.

It becomes another way of looking at packages to see how to involve other people who can do basic primary things that will fit into what a person can subsequently handle.

And another thing that was done was to quickly becoming the different elements, trying to set up the

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database to determine the elements that need to be captured and to [inaudible] have a new [inaudible], have a place to keep doses because usually you need to have a register [inaudible] for certain number of years before they are destroyed. And of course to discuss by what [inaudible] processes and subsequently develop a standard of questionnaire procedure.

Again, I wanted to assist in making sure that the database was developed and support in making sure that people working in [inaudible] have experiences from a neighboring country that have a relatively robust or order medicine registration system. [APPLAUSE] And of course to train people who, particularly the nonprofessionals, who may be using the database like we mentioned.

Some of the issues that, some of the results that obtained, we did intervention to streamlining registration process, included that by 2006 1,392 medicines were registered.

And ARVs that had been registered increased by 30.6-percent. Fifteen ARVs included in mostly [inaudible] combination and pediatric formulations were registered. And since four generic areas have been reviewed [inaudible] percentage of ARV in the register by 76-percent.

I've tried to show you the last slide in a graph. And essentially what I did was to try and group the ARVs and

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have them as how many number of the same group products [inaudible] ARV products that were registered, before and after, the number of [inaudible] combinations where there were two components, two-combo or three-combo [inaudible] combination, and of course the nukes and non-nukes [inaudible] in the pediatric combination.

And I think for the pediatric combination, there was quite an interesting thing because there were a definite to have more pediatric formulations registered. [Inaudible] but this process had led to the registration of [inaudible] 15-milligram, which a little bit [inaudible] pediatric patients when trying to swallow can actually be able to use that.

And I think one of the things I got from this conference, that's very, very encouraging, is the fact that some companies like [inaudible] have been in the position to give a look, a smaller pill, solid dosage form of [inaudible] that can easily and quickly dissolve in water and is flavored and you drink it, take it.

And I think some of these are the ideas, these are some of the ways to improve access and to make sure that pediatrics do not subsequently become a victim even when we have [inaudible].

And I think [inaudible] comes really in mind is the need to even with all these efforts to have more amount of

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these medicines, even the application getting into countries and being registered.

For instance, we're talking about Truvada, Atripla [misspelled?], and all these, they're medicines that have already been approved by FDA and [inaudible].

In conclusion, we think the various assessing ARV can give a look but any level [inaudible] system and an immediate combination of policy and managerial interventions streamlined the medicine registration process. As from [inaudible] registration in [inaudible] can lead to more antiretroviral medicines being available. And [inaudible], and I think this is very critical, [inaudible] countries should monitor and develop [inaudible] school policies and presidios and try to find out what are potentially hidden obstacles that might limit access to antiretroviral medicines in their country.

And of course try to address us before [inaudible] their programs. Thank you very much.

[APPLAUSE]

ASIA RUSSELL: Thank you. Our last speaker is Daniel Rosan, who's the program director of public health at the Interfaith Center on Corporate Responsibility. He has over five years' experience in corporate accountability work and is the author of a new study, "Benchmarking AIDS" of which there are hard copies at the back of the room.

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He'll be speaking about "Benchmarking Research-Based Pharmaceutical Company Responses to AIDS, Tuberculosis and Malaria." The floor is yours.

DANIEL ROSAN: Thanks, Asia. I'd like to start out by thanking my fellow panelists and the moderators for pretty interesting presentations today. And very good work. And thanks to all of you because it's been a very long week.

And it's been a very long day. And you decided to spend the end of it by coming to hear about drug registration and electoral property protections in arcane free trade agreements.

So you're obviously gluttons for punishment and I'm going to try to give you a little more of it before we close today. The poster child for benchmarking AIDS is a young man from Mombasa, Kenya named Sudi, who in this photo is 13. And we originally put him on [APPLAUSE].

He is a very nice guy. We originally put him on the cover of our report because he's an example of how scaling up treatment access and particularly scaling up pediatric access can work in the developing worlds. As we were going to press Sudi died suddenly in a way that was very difficult.

And I feel like some of the voices that Sudi represents as young person and that his community represents as people living with HIV and people from the global south. I

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haven't heard as many of those voices as I'd expected to coming here in Toronto.

ICCR tries to be guided by those voices. I don't think we always succeed, but I think it's our intent. And I just wanted to call attention to that.

The report that I'm going to speak about is in the back and the PowerPoint that I'm giving is up on our Web site at the Interfaith Center so if I skip through slides quickly, you'll know where to get them.

ICCR is a faith-based organization but it's also an investor organization. It's essentially church pension funds with some foundations and some universities thrown in. And so we have to consider ourselves owners of the pharmaceutical companies that we're having these discussions with and that we're encouraging to make their drugs more available.

But I think it's important to also think about yourselves as owners of these companies. Not only in the way that we traditionally think about it as consumers of products or as stakeholders in this process, but as literal stock owners.

If you are member of a major Protestant or Catholic or Jewish or Islamic religious organization, then your organization probably actually owns some shares in these companies and has a literal financial stake as well as a humanitarian stake in how they're doing.

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That's what we try to bring from ICCR. So what did we do? We tried to figure out what pharmaceutical companies could do to increase access to medicines both from a humanitarian perspective and from a fiduciary perspective. We try to balance those concerns.

And then we tried to figure out what should they do and then what they're actually doing. We're basing this on some very previous research that has been done by MGOs and investor groups over the last five years.

And we're taking as a given that AIDS and neglected diseases presents a real financial risk to companies. And in particular the pharmaceutical share owners group I think proved this in their report.

It is not only about having an adequate humanitarian response as a pharmaceutical company, but failure to respond to HIV/AIDS creates actual financial impacts on shareholders. That's an important part of our advocacy work. Henderson Global Investments wrote that there's a mismatch between pharmaceutical business strategies and global health needs.

The question is, how does the industry address that mismatch? Jim Kim, in the previous session, said that the pharmaceutical industry is always six months or a year behind. They do the right thing, they just do it too late.

[APPLAUSE]

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And they always do it after substantial and very skilled civil society pressure and pressure from the faith community. The question is whether or not the industry can do things on time. Can move forward in ways that respond to the needs on the ground and also to the needs of their investors. [APPLAUSE]

So what do they need to do? Well, it's not really rocket science, right? They need to make pharmaceutical available to people and they need to invent new pharmaceutical products that meet people's needs. Things like microbicides.

Microbicide research is being scaled up this year and it's been scaled up last year. Frankly it should have been scaled up in the mid-'90s when the need was already apparent, but the industry came to the party a decade too late.

So we looked at some companies and we tried to figure out what they're doing on HIV/AIDS. And we didn't look at the industry as a whole. We looked at specific companies. We said, what's Abbott doing, what's Bristol Myers doing and how can they do better?

The findings that we came to are not going to be a surprise to people. The pharmaceutical companies are not providing consistent leadership. It isn't a total failure.

There aren't companies that are companies that are completely abdicating their responsibility in every area.

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But every company is abdicating their responsibility in one or two areas or three or four or, in some cases, five or six.

They don't really know how to deal with access to medicines issues beyond Africa. And I think it's an arguable point as to whether or not adequately dealing with it in sub-Saharan Africa.

That tends to vary from company to company. And most pharmaceutical companies, especially American pharmaceutical companies as distinct from their European counterparts, are not bringing their core R&G skills to bear.

So let's take a look at some specific issues and how the companies are moving. On fixed-dose combinations, the most important story here is Abbott, the maker and the exclusive provider of ritonavir.

Ritonavir is a clinically very important drug because it makes at least a half a dozen other products adequate for use. And yet the only fixed-dose combination containing ritonavir contains the other drug controlled and invented by Abbott which would be lopinavir.

Ritonavir could be of great use if it was combined for example with atazanavir from Bristol-Myers Squibb. And so now that Giliad and Bristol-Myers have demonstrated that you can in fact collaborate across companies, you can overcome the antitrust issues and other sorts of things, it's

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unclear to us as to why other companies aren't taking advantage of the situation.

We also see a clear distinction between the European companies who are at the top and the American companies who are at the bottom on neglected diseases. I don't particularly know why this is.

A reporter suggested to me on Monday that it had something to do with colonialism. But the fact is, American companies are simply not doing research on disease of poverty.

They're not responding to the market failure that since poor people can't afford to buy the drugs they need, those drugs are not invented, which was so eloquently pointed out to us by my colleague Chan earlier on the panel.

For neglected diseases we see a similar problem. Not a single company was even able to reach our best practice on pediatric needs and children's formulations.

No company is truly making child-friendly delivery systems. Things like small-dose tablets or sprinkles that could be mixed with apple sauce or yogurt or baby food.

Everybody seems to continue to believe that syrups, which are expensive and difficult to transport and taste absolutely terrible, are the way to go. Again, we don't understand this from an investment value perspective. Pediatric formulations are an absolute nightmare from a

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public relations perspective as well as the obvious humanitarian concern. And yet we don't see pharmaceutical companies meeting best practice in the area.

Let's move on to pricing because I think it's a very interesting story. What we're finding is that companies have embraced differential pricing. And what I mean by that is not that prices are affordable.

I think this has been very eloquently spoken of throughout the conference. But rather that pharmaceutical companies have seen in differential pricing and opportunity to respond to the pandemic in narrow fashion that doesn't threaten the broader discussion about intellectual property.

What we sought was differential pricing systems that worked for both low income and middle income countries. And it's here that the companies are falling short. The difference between Merck and the companies below Merck are that Merck has a predictable and transparent price for middle income countries.

I'll leave aside for a moment to question as to whether or not it's a good price. I think there's a lot of people who'd argue it's not a good price and there's probably some people who would say it is. But the fact is, you can read what it is and it's up on their website.

Other companies have not matched this issue. They continue to treat African markets fundamentally differently

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from non-African markets. I think as the pandemic spreads that's going to become increasingly untenable.

I want to now turn very briefly to the question of TRIPS because I think it's been given a lot of appropriate attention in this session. TRIPS is driven by politics and particularly by U.S. politics.

And U.S. politics for those of you who are not intimately familiar with it, which you should be thankful for, is driven by money. And money is provided by the pharmaceutical lobby. So this is very clear line.

Trade associations provide money to politicians who then push for TRIPS plus protection. If we want to address TRIPS plus, we have to look at the root causes, which is the trade associations that are funding this political engagement.

The only company that has shown any leadership on this at all is Giliad which is simply taking the approach of refusing to join pharmaceutical trade associations at the national and international level. A choice which I think well serves both their investors and humanitarians.

So I want to move now to each company. Again, I don't want to go through company by company but I want to talk specifically about Merck because they're an interesting story of inconsistency. Merck has shown a great deal of leadership on philanthropy. Their Botswana program has

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received a lot of attention here, it received a lot of attention in Bangkok. And they've shown some limited leadership in some other areas.

But the kinds of things that were really need from Merck around licensing and around pediatric formulation, they've been very hesitant to engage in. So the story of a company like Merck is not a completely negative story. Indeed it's a story of particular leadership in Botswana.

But it's not a story that's serving the needs of all of the stakeholders that have a share in a Merck. Both literal financial shares and moral and ethical and consumer shares, as patients, as people leaving with HIV, as activists, as people of faith.

This is a story that we saw again and again across the 15 companies. That the pressure from civil society and the internal leadership from some managers who care a great deal about HIV/AIDS has created some movement in some areas. But there's no consistent leadership. There's no willingness to engage across the entire spectrum of policies that companies should be putting in place.

So the next question is where is do we go from here. I'll tell you that the Interfaith Center - Again, these are all the companies, feel free to sort through them at your leisure, ask me questions about them - the Interfaith Center takes this work and turns it into a living document. We

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engage these companies. We've actually engaged two of them just in the last week. We've met with six of them in the last six months.

We are putting this out into the public domain so that corporate managers, other shareholders, and other activists and civil society members and people of faith can do similar engagement, can have some tools to move forward.

But this can't be the end of the story. We need a similar look at the diagnostic manufacturers, particularly on pediatric diagnostics, an issue which I think doesn't get enough attention when we talk about treating children with HIV and AIDS.

And we need to track this behavior year on year. This report is a moment in time. And it's a complicated story. But in order to figure out whether or not the industry is really responding we need to keep on them and have them continue to keep on each other year on and year out.

Ultimately we know that governments, generic companies, the faith community have a lot of work to do in delivering on access to essential medicines. But that doesn't excuse the role of the pharmaceutical industry. They too have a promise to keep. Thank you.

[APPLAUSE]

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GREGG GONSALVES: So actually, we have quite a bit of time for questions and answers so it people will come up to the mics, and try to keep your questions brief and please identify yourself and your institution before you ask your question. But again, no big statements. Try to keep your comments brief.

Let's take three questions and then we'll have the panel take them. And if you have a specific person, please direct it to that specific presenter.

NATALIA CAP: Thank you. Natalia Cap of Trans Atlantic [inaudible] against AIDS, Moscow. Thank you so much for a very interesting presentations. And this is probably a second or third session that I attended that addressed TRIPS and pricing and access.

And what has been very interesting to me is that at these panels, there's no representative of a pharma company. Why does this happen? Are they not invited or do they not accept invitations?

Because it seems that we're talking a lot about pricing right now when if we're talking about really ensuring access to treatment, we should be talking about things much broader than that including delivery and infrastructures that would be able to implement it. And pricing is just like one element of that equation.

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And everything is clear in TRIPS et cetera, but if we want to look towards a more systemic and long-term solution it's probably not in constant opposition but in some consensus as to how we're going move forward with [inaudible].

GREGG GONSALVES: Let's take our next two questions and then we'll let our panels respond.

DR. MORRIS: Dr. Morris, [inaudible] Pharmacist in the United States. I appreciated about what Mr. Park had to say about pharmaceutical companies and ways in which they extend patent lines. And certainly in 2005, more than 90-percent of the medicines which were patented were for treating conditions for which there were already less expensive medicines already available and so they offered no real benefit.

I'd like the panelists to comment on the fact that research and development is normally cited for the reasons for why there's a high cost for medicines. However, I don't hear much discussion being made around the fact that much of that research and development is made in joint collaboration with publicly funded institutions in the United States as well as the fact that the United States government offers subsidies and tax relief for research and development especially in special populations like pediatrics. So if you can comment on that, I would like to hear.

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GREGG GONSALVES: Another question.

FEMALE SPEAKER: [Inaudible], South Africa. I'd like to Jonathan Berger, we've heard AIDS activists and human rights campaigners from other countries campaigning really against drug companies and talking about double pricing. But in South Africa, there's a second leg of activism and that is against our government.

I would like to ask from him, if that leg didn't exist, how would the energy be differently spent. How much of it goes towards policy and how much of it towards drug companies? Thanks. [APPLAUSE]

GREGG GONSALVES: Who would like to take a stab at the first question? The first question about where's big pharma on the panel.

DANIEL ROSAN: Why there's no pharmaceutical representative here, I suppose they didn't submit an abstract. I don't really know how these things work. [LAUGHTER]

But I will say that we sent our report to the pharmaceutical industry, both in draft form and then in final form, and the responses that we got were quite interesting. One pharmaceutical company sent back an e-mail that said, "Dear Dan, this work looks great. Glad to see that you're pushing us a bit. Good luck."

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Another pharmaceutical company sent me 20 pages of single-spaced, double-sided comments on all the things that we supposedly got wrong. So I think that the industries not monolithic and different companies have different attitudes.

I would say that I don't think that anybody who kept hands on pharmaceuticals or who engage with the industry believes that health infrastructure and political leadership and adequate funding are not essential elements in scaling up treatment access.

I certainly believe that all of those things are essential. But the pharmaceutical industry is simply also essential and so we choose to spend our time on an element that we can have impact on. [APPLAUSE]

Our colleagues in other parts of the community spend time on those other issues as I think Jonathan's presentation made reference to.

GREGG GONSALVES: The second question, does anybody want to pick up on the R&D priorities trend?

CHAN PARK: That's actually a very good question. Just to clarify the issues, there's two separate but related issues of evergreening which is one problem and the whole problem of me-too drugs which is another problem. They're both problems.

Evergreening relates to subsequent modifications to an already existing drug. So, for example, in the case of

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Combivir, you have two separate drugs that have already been patented. One of the patents have already expired. Now GSK's trying to get a brand new 20-year monopoly on the fixed-dose combination by adding an inactive ingredient.

That's a problem that's way too pervasive. The patent application's pending in the mailbox. In India there's 10 years worth of patent applications piled up in India, from 1995 to 2005. estimates vary but somewhere around 9- to 11,000 patent applications for pharmaceutical products.

During that same time period only about 300, 297 new chemical entities were developed by pharmaceutical companies. So that gives you some idea of the extent and scope of evergreening that the pharmaceutical is engaging.

The separate issue is the whole phenomenon of me-too drugs. A company invents a blockbuster drug and then all the other pharmaceutical companies jump in by developing their own versions. So the whole erectile dysfunction thing that I alluded to is a good example of that.

And that also is a problem because it diverts resources away and it undermines the argument that research and development is absolutely necessary to develop new and better drugs. I mean, they are using these research and development funds to develop drugs that don't actually add any new therapeutic value over what's already in the market.

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You also address an issue relating to the fact that many of these new technologies are developed in universities and funded by the government and that's absolutely true. And there is a growing movement within the United States and in the developed world of university students for instance, demanding that their universities, when they license their technologies to pharmaceutical companies demand that their patents not be enforced or be licensed at a very low price or to little income and least developed countries.

As far as the government-funded research is concerned, there's something called a march-in right. If a patent is funded in part through the National Institute of Health in the United States, the United States actually retains the right to march in and use that patent for public-related purposes.

So there needs to be a growing movement for the people in the United States to demand to their congress people that they utilize these march-in rights to actually improve access for medicines to people and to develop it [inaudible].

JUDE NWOKIKE: My comments to that might be essentially to suggest that we should look out for other ways of funding R&D. I think the patents method to allow companies to use that to recoup expenditure into recession

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the development of new medicines, it doesn't seem to be working.

I attended the session where the [inaudible] said a couple of years back, nobody believed that journals could give out their publications free. But it's happening now.

[Inaudible] and I said look, from a [inaudible] you give this message out free to resource and media settings and somebody said it's not possible and he said why not? So I think it's maybe you might not be looking out for the model where nobody pays.

But we might be looking out for a model, particularly for disease of great importance, life threatening conditions that are not really attracting as much research in developing countries. [Inaudible] that we might need to urgently find other ways of funding research and development. Thank you.

GREGG GONSALVES: So Jonathan, do you want to take that last question?

JONATHAN BERGER: Sure. Thanks for that question. I was wondering and I'd been wondering for some time how my presentation actually connected to the other four. And I think you've identified the connection.

I think certainly much of our time in South Africa is spend fighting the denialism, fighting the slow pace of implementation of the ARV treatment program, whether it's in prisons, whether it's in the public sector, more broadly.

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And it has meant that a focus on the pharmaceutical industry has slipped away. Not because we have managed to resolve all the problems of access in South Africa in respect to pricing, in respect to sustainability of supply, but because we've been very busy on a range and other fronts.

I think to add to that, not only has government taken our focus away from the drug companies by making us deal with the denialism and the slow pace of implementation, but it itself has failed to take action against those very companies.

It has allowed them to get away with refusing to license companies. It has allowed to get away with high prices and things like that.

For the record, we're hoping that within the next few months we are going to finalize a complaint that we've been working on against both Merck and Abbott. We're going back to the competition commission and this time we'll be looking at the issue of sustainability of supply.

To date Abbott has refused to license any company in South Africa to manufacture or import [inaudible] and Merck has granted a single license to Aspen Pharmacare on efavirenz and no other licenses have been granted.

And probably most disconcerting is in relation to Atripla. We've heard the Giliad are either not patented or the patents are not enforced in South Africa. Aspen is going

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to be manufacturing them, but Aspen's license as far as I understand, will not extend to Atripla. So Merck is going to hold onto that itself.

And that certainly, that combination of efavirenz, tenofovir, and [inaudible], we're hoping is going to be the [inaudible] our first line regimen in the future. So there's a lot of work that needs to be done and perhaps if we got a new Health Minister, we got a new President, we actually got some real work done on those other fronts, we could actually get back and start dealing with some of the scoundrels who've been hiding under the radar screens for far too long.

GREGG GONSALVES: So let's take three more questions, starting with two people there and then we'll go to the back mic.

BROOK BAKER: My name is Brook Baker. I'm in Health GAP. It's a comment with a question. One of the great benefits of this particular panel presentation is it's brought the issues of problems and registration of medicines, the ability to market medicines to the front because we so often focus on intellectual property patent problems.

When we hear about problems in fast-track registration, we hear about drug companies that refuse to register their products in smaller and foreign markets and we also hear about U.S. government pursuit of higher data exclusivity market protections for registration data.

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So I wonder if the panel could comment on the importance of registration related issues and the need of activists to turn their attention to those issues.

LAUREN SMITH: Hi, I'm Lauren Smith from the Student Global AIDS Campaign in Universities Aligned for Essential Medicines. And you guys have talked a lot about the problem with the existing frameworks and TRIPS which people seem to be aware of in this room at least.

But I was hoping some of you could maybe comment on alternative frameworks or mechanisms you've thought about or worked on for fostering R&D on neglected diseases that would create incentives for distributing and developing drugs that would treat the people who're looking get access to medicines.

ASIA RUSSELL: Thanks, mic number two?

JACKSON HUGHES: Hi, Jackson Hughes from Emory University in the U.S. Someone mentioned the problem of foreign trade groups acting legislation through political donations and I was wondering if anyone had any information on money flowing in opposition to this, or any kind of significant money flowing in opposition to this from any angle. Thanks.

ASIA RUSSELL: Jude, do you want to take the first question about drug legislation?

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JUDE NWOKIKE: Thank you very much. The first question if I understood that correctly is talking about registration, bring up issues about registration 34 and impotence of restriction-related issues. And indeed I think that's part of the [inaudible] strength to highlight.

Not just the global registration from the big pharma in the countries where they reside like GlaxoSmithKline in the U.K. and Pfizer in the U.S. But in-country restriction, there are issues about them that could actually being [inaudible] liability of [inaudible] in those respective countries.

But I think the question really was related more on how effort activists could focus attention in trying to actually advocacy for registration induced smaller countries, where big pharma doesn't think it's such profits [inaudible].

Indeed that is very, very true and we're seeing a hurdle of those issues in sub-Saharan African and smaller countries like Namibia. What's going on is that it's not a huge market. It's not economically interesting or juicy for them to come and register those medicines.

But then you need to understand also that some of these companies have got distributors in some of those countries that are quite small and it's the responsibility of those distributors when they attain [inaudible] to apply.

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And even prior to apply for those tenders, to try and register those medicines in country.

What does it require? It does require doses [inaudible] identify the [inaudible] the requirements that countries medicine restriction council wants and collect them from the parent company that [inaudible] and submit them to drug [inaudible] authority who reviews it and if there are questions try to send the questions back to the parent company that tries to address this.

We cannot use that as an excuse because maybe Pfizer doesn't want to or because maybe Giliad is not coming to register [inaudible] in Namibia then fold up our hands. No.

We have to first and foremost like I mentioned earlier, there is a need for these medicines to find their ways in the guideline so the guideline committee sit down and identify this is a product that is critical for our country, we want to have it, it is beneficial, and do all the cost effectiveness, analysis, and [inaudible] in relation to the [inaudible] in country.

And by time it is in the guideline then it becomes the duty of the medicine restriction authority to quickly [inaudible] for [inaudible] products or [inaudible] in country to [inaudible] products. And that's why registration of course it gets into the [inaudible] and it gets to be procured by the public held system in country.

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So I think there are ways to get about this. I'm not saying that the activists should not really play essential role here, but even the public health system have a [inaudible]. Thank you.

ASIA RUSSELL: Jonathan?

JONATHAN BERGER: Just a few points on that. South Africa, the issue of registration is also quite a crucial problem. I'll give you an example. The 600-milligram version of efavirenz took over two years to be registered even though the 200-milligram tablet was already registered. In contrast, Tamiflu was registered in two weeks. See where the political priorities lie.

Two things I think we need to look at, one the global steering committee recommendations in the process leading up to UNGAS [inaudible].

[APPLAUSE]

And three the recommendation that any product that had been [inaudible] qualified or FDA-approved or tentatively approved the use of their product should be permitted in countries. Law should be amended to allow for that pending registration. So I think that's something we really do need to fight for. To amend our laws to allow for that.

And then secondly, the issue of a regional registration. And every country having its own

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registrational authority is really not a sustainable way to go. Regional registration, domestic enforcements.

ASIA RUSSELL: Thanks. There were two more questions from the university coalition on access for central medicines and one on counter-flows of money against big pharma investments. I don't know if there's anything that the panel wants to say about either of those things. We take the last question and then maybe just do a quick 30-second wrap up if that's okay with people. Okay, so the question at mic number two.

DIANA MENDOZA: Hi, I am Diana Mendoza, journalist from Mexico. And I'd like to know what strategies could and should middle income countries be applying in order to have better access to medicine.

Today, the minister of South Mexico was proudly announcing that Mexico has reduced the treatment price per person per year to \$5,000, which I think is higher than what European countries and Canada are paying. Thank you.

ASIA RUSSELL: Thanks. So if panelists want to respond to either of the last three questions. And then we'll just close.

GABRIELA CHAVES: Okay, I just would like to say
[APPLAUSE]

Just to answer the question about neglected disease very briefly. I think there is initiative for neglected-

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disease initiative. It's the public/private partnership that's trying to fill some gaps from the experimental to get the medicines to the shelf. So I think this is one alternative for R&D.

ASIA RUSSELL: Anyone else, quickly?

DANIEL ROSAN: Just to add to that. Two alternative brain works, not necessarily mutually exclusive of each other come to mind. One alternative approach that's getting a lot of discussion these days is the prize fund approach where government or a private agency names a specific disease and says if you find a treatment for this then you win this prize.

That does away with the perverse incentives created by the patent system where everyone's trying to get their own patents and exclude other people from getting it. Whoever wins the prizes gets the cash reward but the technology thereby created becomes public domain.

Another approach that also comes to mind is what our dear friend Bill Gates was talking about which is him privately funding a lot of the research. And he requires as a condition of the research that all participants in the research actually share the technologies that are being developed.

So those are two alternative approaches. I'm sure there are many more, but my closing point basically is that

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there are many things that are currently wrong with the current patent system protection.

[APPLAUSE]

And things need to change if we're going to ensure access to medicines for all.

ASIA RUSSELL: Thanks. I think we're just on time to close the session and thanks, everyone for -

Okay, we are at the end of the session [inaudible] you have 30 seconds [inaudible]

JONATHAN BERGER: Yes, just very quickly. There was also a proposal that came out of the Brookings Institute about two years ago that would've simply tied U.S. patents to patents in least developed countries, i.e. if you get a patent in a least developed country your U.S. patent goes away. And it would be a very simple act of congress.

Not that this Congress would do it, but it wouldn't require a big international framework, they would just say if you want a U.S. market then you can't patent in LBCs, which is a very elegant way to do it.

In terms of any contravening flow of money versus the pharmaceutical trade associations it's simply not there. And I would just close by saying in addition to the moral and ethical power that civil society has very effectively bought on these issues.

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I think there's also a great deal of financial power. And that's the intersection of which we try to work. And I think that there's a lot of opportunities there that haven't been tapped.

ASIA RUSSELL: Thanks, everyone, for a great session. If you have any other questions for the panelists, please feel free to approach us.

[APPLAUSE]

[END RECORDING]