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World CAB

Community Advisory Board

Focus on International Drug Pricing

5-7 February 2004, San Francisco

We have given our lives to our governments, to our doctors and to the pharmaceutical companies. People with HIV must take back their lives and say, this is my life and I will run it. You are my doctor and I am ready to work with you, but I am not working for you, we'll work together. I have this disease and I'm going to manage it. So don't just tell me I'm taking two white pills. I must know what drugs I am taking and what they are doing.

Rolake Nwagwu, Nigeria

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We have given our lives to our governments, to our doctors and to the pharmaceutical companies. People with HIV must take back their lives and say, this is my life and I will run it. You are my doctor and I am ready to work with you, but I am not working for you, we'll work together. I have this disease and I'm going to manage it. So don't just tell me I'm taking two white pills. I must know what drugs I am taking and what they are doing.

ROLAKE NWAGWU, NIGERIA

During the past year and a half, people living with HIV/AIDS (PLWHA) and HIV community advocates from around the world have begun meeting to plan how they can advance treatment literacy and increase PLWHA input into decisions by the commercial, research, educational and care programmes that affect them. In Europe and the U.S., community advisory boards (CABs) have long been an important vehicle for representing the needs of PLWHA to drug companies, researchers and government regulators.

In February of 2004, for the first time, a World CAB was convened to enable PLWHA from the developing world to voice their concerns about drug pricing and research practices in their regions to senior executives of the multinational pharmaceutical industry. Twenty-seven individuals from 21 countries gathered in San Francisco, California in advance of the annual Retrovirus Conference, the year's most important scientific conference on HIV, to meet with officials responsible for global marketing and pricing policies at Roche, GlaxoSmith Kline, and Boehringer Ingelheim. The meeting took place over three days and the participants discussed issues first as a group and then with each of the companies separately.

The participants, from Africa, South America, Eastern Europe, South and Southeast Asia, Europe and North America, are active in treatment advocacy and literacy efforts in their own countries; many had first met during the first International Treatment Preparedness Summit, held in Cape Town in March, 2003. This report contains an edited digest of the discussions in San Francisco.

Participants

AUGUSTINE CHELLA, ZAMBIA

Speaking as an African, I think treatment is life. Without treatment there is no life. I'm coming from a society where the impact of HIV is visible. In Zambia, where I'm from, we see 39 years of independence and development eroded because of HIV and AIDS. We see its impact on our economy, its impact on our industry, its impact on our educational sector, where since 1999, my country lost 1,600 teachers and we have only been able to train 1,000 teachers. This is a disaster and the government accepts that we have a crisis before us, but the question is treatment. Is treatment readily available in Zambia? No, it's not. We have set a target to treat 10,000 Zambians by 2006, but up to now only 900 Zambians are on treatment. We have a population of two million people living with HIV and about 600,000 of those need treatment immediately.

SUBHA RAGHAVAN, INDIA

In India we are very proud of our generic drug manufacturers for manufacturing all of the potential regimens — but they don't make them accessible to our own people. We export to the developing world, through the Clinton Foundation, at a much cheaper price than we give our own. We pay one dollar a day or more whereas we are giving it to the Clinton Foundation for 140 dollars per year. So we have this distinction of manufacturing every drug under this umbrella, yet they are not available at affordable prices to our own.

Pricing

Roche

Christopher Murray, Director, Pharma International

ROCHE: All of our policies regarding access to our drugs come from Roche headquarters in Basel. I have responsibility for these international issues within the company. The Roche pricing policy for protease inhibitors is that Least Developed Countries (LDC) receive a no-profit price from Roche Basel. Currently, the Roche no-profit price is better than that of generic versions of nelfinavir. Roche also offers a clear pricing policy for direct supplies of Invirase and Viracept on ex-factory sales to low-income and lower-middle-income countries as classified by the World Bank.

SUBHA: What does no-profit mean?

ROCHE: No-profit means no marketing or R&D costs are covered. It only covers what it costs to get the drug into a finished pack; no financing or inventory costs. There are no royalties paid to Pfizer, who owns the patents on nelfinavir. Effectively, the no-profit price includes a contribution from Roche. These prices are for direct sales from Basel. We only quote a price in Swiss francs due to exchange rate fluctuations and zero margin. We don't differentiate between public and private sectors. We don't differentiate between any NGO (non-governmental organisation). We will only re-price based on changes in economy of scale or reduction of demand.

GREGG: But many of these lower- and middle-income countries still can't afford your drugs.

ROCHE: You may not like the classifications, but this gives us transparency in how we set our prices. I must be rigid because otherwise we will have to negotiate with every country separately.

RICHARD: The price jumps from $880 in LDC to nearly $2,900 in lower-middle-income countries. This says a lot about the profit to be gained in those countries.

ROCHE: Our transparency policy is not to negotiate country to country. The prices we have today are derived from people in your countries saying exactly how much they need.

GREGG: How did you make the decision on who gets the no-profit price?

ROCHE: Kofi Anan asked the pharmaceutical companies to offer the lowest possible price in the Least Developed Countries, and we did.

LOBNA: Can't you offer the no-profit price in countries not on the LDC list where there is a great need but no resources?

World Bank Classification of Economies

The World Bank divides economies on the basis of gross national income (GNI) per capita.

The 2002 groups are:

Low Income	Average income under $735 per person per year	64 countries
Lower Middle Income	Between $736 and $2,935 per person per year	54 countries
Upper Middle Income	Between $2936 and $9,075 per person per year	34 countries
High Income	Over $9,076 per person per year	56 countries

Roche's World Pricing Structure for Viracept

Least Developed Countries and sub-Saharan Africa	$ 887/year
Low Income and Lower Middle Income Countries	$2,927/year
Upper Middle Income and High Income Countries	Full price

ROCHE: No. We are not going to have the no-profit price for regions other than the LDC countries. The lower and middle income countries still receive a reduced price from the European price. We offer an equitable pricing structure.

MARK: You can't say your prices are equitable even though they are uniform, because people can't afford them. We're saying they are not fair, period.

ROCHE: There are huge variations in income levels within and among developing countries. The classification includes oil-rich states and states with a strong industrial base. High-income, non-OECD countries are classed as developing. They pay the middle price of $2900. Upper-middle-income countries pay the regular price. And all of these countries have different prices in-country depending on distribution costs.

There are additional costs for freight, import duty taxes and distribution to be added. For example, the no-profit price ex-Basel is 90.90 Swiss francs, which becomes 125 Swiss francs in South Africa. That's 38% higher:

Clearing, freight and insurance adds 2.5%
Local packaging and quality control adds 6%
Local warehousing adds 4.5%
Distribution adds 8%

So the local cash price is net plus 21%. Then the government adds a 14% VAT (value added tax), which equals a 38% increase.

LEI: We are puzzled by the huge differential between your prices and generic prices.

ROCHE: The nelfinavir sold in Botswana is the same as sold anywhere else. Our suppliers optimise their existing resources. But there is not a huge difference in price between ours and generic nelfinavir.

CHRIS: Would increased volume lower the cost?

ROCHE: You would need substantial volume increases to get small reductions in price.

LEI: Are you looking at options to manufacture in countries where costs are lower?

ROCHE: The manufacturing model is to have the machines running 24-hours a day making the same product. Moving the site of production doesn't change the cost.

CHRIS: We've heard multinational pharmaceutical companies say before that this is our rock bottom price. Then generics come in at 1% of that and the companies say: "Now we can reduce the price."

ROCHE: If Ranbaxy can make nelfinavir for $600, then you should buy it from them.

OLIVE: Can those of you here from Africa afford nelfinavir?

ROCHE: It is not our job to arrange funding. It's not our role to buy our own products. It's the government's role. In South Africa the problem is political apathy. When the government is only spending $5 to $10 a year per capita on health, the situation is their responsibility, not Roche's.

DELME CUPIDO, NAMIBIA

The situation for access to treatment in Namibia is better than in some countries. In the last year or so, I think as a response to advocacy that we and a lot of other groups have been doing and because of the 20 percent infection rate, government has more or less come to its senses and has rolled out ARV in six sites across the country. The uptake in the ARV programmes is still problematic because there's been almost no treatment literacy work done, so a lot of people are not aware that treatment is available at public hospitals.

CHRIS GREEN, INDONESIA

For us the access effort started around 1996. Access to information brings an ability to have some control over one's own life. The price for treatment has come down now to about 50 dollars a month. Several years ago we formed a buyer's club to purchase drugs from Aurobindo in India. Now, a local company is manufacturing ARVs and will soon make a combination pill. At the moment they are making nevirapine and a version of Combivir, which is available at 50 dollars a month — and that should be coming down. The government has promised a 15 dollar subsidy, but it hasn't appeared yet. They say around 1,300 are currently getting it. Fewer than 5000 are identified as HIV positive in Indonesia, but the current estimate is about 200,000 with HIV.

ROLAKE NWAGWU, NIGERIA

Two years ago we had no ARV access whatsoever. The very few drugs we had were from the big pharmaceutical companies, from Glaxo and Roche, and it was just too expensive. In 1998 I paid about 500 dollars a month for my drugs. And that was unacceptable. Two years ago our government announced the roll out of the ARV programme and they said they had drugs for 10,000 adults and 5,000 children in 25 centers. The government is paying. These are generic drugs, mainly from Cipla and Ranbaxy: lamivudine, stavudine and nevirapine as individual drugs. The government buys the drugs for about 30 dollars a month and gives them out for about seven dollars a month. There is a waiting list to get in. When this programme started, if you went to the

The Global Fund

The Global Fund to Fight AIDS, Tuberculosis and Malaria was created in 2002 to dramatically increase resources to fight three of the world's most devastating diseases, and to direct those resources to areas of greatest need.

With Global Fund resources, more than 500,000 people are projected to receive HIV antiretroviral treatment over five years. This represents a near tripling of coverage in poor countries (including a more than six-fold increase in Africa). All HIV grants include prevention, much of which is focused on school-aged children and youth.

In the past two years, $1.26 billion in Global Fund grants for HIV have been approved.

But only about 12% of approved grants have been disbursed.

HIV clinic it was like death row. The HIV clinic was next to antenatal, which was noisy because you have pregnant women and women with babies; there's festivity there. Next door was the HIV clinic and it was still, because people had no hope. A year later it became much better because all those who came in sick could see people who used to be like them who now had so much hope. So people wanted to get on this program. Ameftmeer the quota was filled people were still desperate to get on.

ANASTASIA KAMLYK, BELARUS

Most of the people in my country who need it do not have access to treatment. Most of the countries in my region do not have many of the drugs registered. In most countries, AIDS is not a priority for government. Only in Russia and Ukraine have we seen the Global Fund money. Some other countries don't have that many official cases of AIDS so the pharmaceutical companies aren't interested in them. It is not a huge market.

HANNA: But most of the people who need your drugs are poor, so even if they live in a middle income country, they have no access.

ROCHE: We don't have differential pricing within a country. There are people in rich countries who can not afford the drugs. We will not reduce the price any further.

GERMAN: If you know that the Global Fund will be providing the money for a lower or middle income country, will this change your policy on who can get the no-profit price?

ROCHE: No. We will work within the 3 by 5 plan to increase the volume, but that won't change the no-profit status of the price. It is not possible to negotiate for a better price in the middle income countries. We are willing to be priced out of the market in those countries when generics come in.

SUBHA: Can we discuss lowering the $880 price in least developed countries?

ROCHE: No.

MAURO: The most promising untapped market is in the developing world. Why are you giving up on this market?

ROCHE: There is no profit for us.

SUBHA: I want you to leave us with a different message. You have to give us something to help us get going with your drug.

ROCHE: I can't give you anything more. The fact that our drugs are not affordable in some parts of the world is not Roche's responsibility. I can't give you a warm glow when I leave the room.

LEI: Take back a message that your non-negotiated stance is unacceptable. This is not a product that people can live without. You have come into a room full of HIV-positive people and said: "If you can not afford this drug, it's not our problem." This is unacceptable. You are saying go home and drop dead. Companies must face a historical judgment. Your company will be held accountable.

Boehringer Ingelheim

Larry Phillips, Head of International Marketing for HIV and Virology

Doug Mayers, International Therapeutic Area Head

BOEHRINGER: There's quite a learning curve going on in our company about providing access to our drugs in the developing world. For us, in terms of price reductions, there are two ways to go about it. One way is you can donate drugs, which we don't think is a solution. The other way is to grant

voluntary licenses to generic drug makers and create competition in the market. We think the best idea is to have as many people producing nevirapine as possible at the local level. True price reduction will never come from one company; it has to come from competition.

Of course, we have to make sure a company we license has the obligation and the capacity to actually produce the drug. We will then grant a voluntary license, but they have to produce the drug and produce a quality drug.

ANASTASIA: Is the generic nevirapine the same as your Viramune?

BOEHRINGER: There are some differences between the generics and drugs from the developed world, but those mostly have to do with registration issues and not necessarily with potency.

GREGG: Would you also grant voluntary licenses to middle income countries?

BOEHRINGER: Eligibility for our donation programme is based on lower and middle income status as classified by the World Bank. But in a country where it is obvious that the people can't afford to pay for their therapy, then we are willing to consider voluntary licenses.

Within the industry, everyone is worried about the diversion of generic drugs back into the markets where they make their money. Everyone is concerned with diversion and re-importation, and if it is handled irresponsibly, it damages the process. We don't think it is an insurmountable problem, though. But I think a lot of local legislation is needed. These people are crooks. Voluntary licensing can't be done without some guarantees in the market.

There are also tricky issues with the FDA about voluntary licenses. One has to do with safety. We have a safety reporting obligation, but we can't make the generic companies report their safety.

GERMAN: Your company is interested in granting voluntary licenses. Which countries have you done that with? Are you also interested in doing technology transfer to those countries so they can learn to make the drugs?

BOEHRINGER: Technology transfer varies from company to company. When we deal with Ranbaxy, they already have a version of the drug, so it's no problem. We are in active negotiations in South Africa; we are looking in Eastern Europe; we have licensed the Indian companies; and there is a possibility to find one in Asia and one in South America.

ANASTASIA: In Eastern Europe, I don't believe you can't find a producer in our region.

BOEHRINGER: Eastern Europe has not gotten the attention it deserves because the immediate concern was Sub-Saharan Africa. You have to sell the idea of making HIV drugs to generic makers. Some don't want to get into HIV because it is such a hassle.

BEN: If BI's HCV protease inhibitor makes it to market, will you have voluntary licenses in countries with large HCV prevalence like Egypt?

BOEHRINGER: People like the voluntary license with nevirapine because it is such an easy drug to make. With other drugs it won't be so easy.

CHRIS: What royalties do you expect?

BOEHRINGER: MSF calls for 3%, which is what we ask for. We ask the company to put it into local HIV programmes as part of the contract. But we can't enforce it. If they don't do it we can't pull the license.

DELME: The 3% donation can't be enforced?

BOEHRINGER: You could try to enforce it, but I don't know how you could. What if you give a voluntary license and the company doesn't produce the drug — do you take it back?

OLIVE: I'm a suspicious person. What's in it for you? I like what you're saying but how does it translate into something we need?

LOBNA IBRAHIM, EGYPT

Access to ARVs in Egypt is extremely limited. The Ministry of Health provides nevirapine for mother-to-child prevention for free. Even though, the Ministry of Health and its National AIDS Programme are doing a wonderful job in addressing HIV/AIDS, the high incidence of HCV and other communicable diseases in Egypt, along with the low reported incidence of HIV/AIDS make access to treatment a low public priority at the moment. Also, the drug prices offered by pharmaceutical companies are too high to attract government support. But generally, people receive palliative care and treatment for opportunistic infections in the fever hospitals or through the National AIDS programme of the Ministry of Health, mainly for free. And many people go home for their end-stage disease — if they have a family to accept them, which is often the case.

Even for people who could afford ARV treatment, there is a limit because Egypt falls under the lower-middle income classification of the World Bank and does not qualify for reduced prices like those available in the Least Developed Countries (LDCs) or Sub-Saharan African countries. This means the average price of treatment — if you can find it in stock — costs you around 1,000 dollars a month. Egypt has an average GNI per capita of 1,470 dollars according to World Bank figures of 2002.

The 3 by 5 Plan

On World AIDS Day 2003, the World Health Organization (WHO) and UNAIDS released a detailed and concrete plan to reach the 3 by 5 target of providing antiretroviral treatment to three million people living with AIDS in developing countries and those in transition by the end of 2005. This is a vital step towards the ultimate goal of providing universal access to AIDS treatment to all those who need it.

What will 3 by 5 do?

To reach the 3 by 5 target, WHO and UNAIDS will focus on five critical areas:

- Simplified, standardised tools to deliver antiretroviral therapy.
- A new service to ensure an effective, reliable supply of medicines and diagnostics.
- Rapid identification, dissemination and application of new knowledge and successful strategies.
- Urgent, sustained support for countries.
- Global leadership, strong partnership and advocacy.

PAISAN SUWANNAWONG, THAILAND

We went to India to bring drugs to Thailand even though it was illegal. We set up a system of buyer's clubs and we found some doctors to write prescriptions for ARVs but many doctors didn't want to do that. At one point the customs stopped us, so we talked to the Thai FDA to figure out how they could allow us to import drugs. So the FDA is now okay with it, but they keep it quiet. About 60 people are getting drugs this way. We started in one province and now there are six. This has been working for several years and we go every few months. Still, you have to have the money to get pay for them. Of course now we can also buy drugs from GPO (Thailand's state-run Government Pharmaceutical Organisation).

JAMES KAMAU, KENYA

MSF (Médicins Sans Frontières) are doing treatment and right now they are reaching nearly 1,000 people. They are a fantastic example of how to roll out ARV (antiretrovirals) in a resource-poor setting. They are using the triple therapy combination in a single pill, Triomune. It's working out to be much cheaper but the demand is too great. They have successfully shown that it can work. Compliance is 90 percent, which is fantastic. It's because of the way the do it. Before they start you on drugs you go several times for training. After they give you the medication, they follow-up, and they follow-up on opportunistic infections. Having been in the field, they are able to detect the problems much faster. PWAs are involved in their teams; they are in fact the counselors and the people

BOEHRINGER: Nothing is in it for us. It's philosophical in a sense: There is both a business and an ethical component to pharma. We have a high standard of health care in the North; but our industry doesn't sell cookies. We want to make a profit and we know health is a human right. You can think of all the reasons for why you can't deal with these problems, or you can try to deal with them. It's the belief of the people on my team that the industry must take responsibility for what is going on. But the governments have to take responsibility too.

We found you can't just give drug away; you have to go out and market it to governments. Within your ability as a company you have to approach governments, WHO and NGOs. Then you need to get the people in your company behind you and try to make it work.

RICHARD: In Jamaica, there is no patent on nevirapine and a company called Lasco is distributing Cipla's Triomune at an inflated price.

BOEHRINGER: The problem in Jamaica can best be addressed by competition. Where people are poor, there is no way to make it perfect. The pharmacist adds a markup because he wants to eat too.

ANASTASIA: In Ukraine the price of one package of your drug is 100 Euros, in Belarus it is 280 Euros. What is the difference?

BOEHRINGER: It's probably due to the local pharmacies. Whatever the ex-factory price is, you can't be sure what the pharmacy sells it for. All we can do is recommend a price.

SVILEN: In Bulgaria we have registered nevirapine, we have the money to buy it, you have local reps there, but still we have no drug.

BOEHRINGER: I don't have an answer for you.

LOBNA: In Egypt, the free nevirapine programme works through UNICEF but only two women have used it.

BOEHRINGER: You have to market the programme and tell them it is available, but I can't force governments to use it. We say, use the prevention of mother-to-child transmission (PMTCT) donation sites to build your treatment programmes upon, since there is at least minimal infrastructure. We lobby where we can, but the NGOs need to get going too.

AUGUSTINE: You've spoken of a strong presence in South Africa, but we don't seem to see the effect in price reductions in Zambia.

BOEHRINGER: We are working in Zambia with the nurses association on education. The problem with the granting of voluntary licenses is to get the companies started. With the tenders, you say, I've got a million dollars, how much drug can you give me for that? Supply and demand regulates prices.

Then, some countries don't want you to import; they raises taxes at the border, etc. If they can tell us how much drug they want and when, then I can do more.

AUGUSTINE: What are you doing in very rural areas where the need is great?

BOEHRINGER: We've approached WHO to have them make these sites part of 3 by 5. We will give help and assistance to qualified groups but we don't want to tell people what to do.

JAMES: Can you do extended stability studies so we can have extended expiry dates, especially in the African climate?

BOEHRINGER: We can look into that.

GREGG: What's the pricing policy in middle income places without generic production?

BOEHRINGER: We look at our own processes and try to make it cheaper. We produce our drugs in a different regulatory environment and it costs more. Maybe we can farm out production, but we still have to produce to FDA standards, so it still costs more. Producing to WHO standards produces equivalent therapeutic quality, but it costs less. Viramune is produced in Ohio, which is probably not the cheapest place to make it.

GREGG: So, what is the price in those middle income countries?

BOEHRINGER: Sixty cents per day, the same as in the AAI (Accelerating Access Initiative) countries.

LOBNA: What are the criteria?

BOEHRINGER: It is the World Bank criteria, but lower-middle-income countries also get the AAI price.

LOBNA: In Egypt the problem is availability. There's no market so the companies don't register the drugs. The big distributors don't order them. There's no market for generic makers. We simply need cheaper prices.

BOEHRINGER: I don't know about the situation there. Where we've had local BI business units for a long time, they have become very independent. Like a who follow up. Quite a number of MSF patients become educators.

ROMAN DUDNIK, RUSSIA

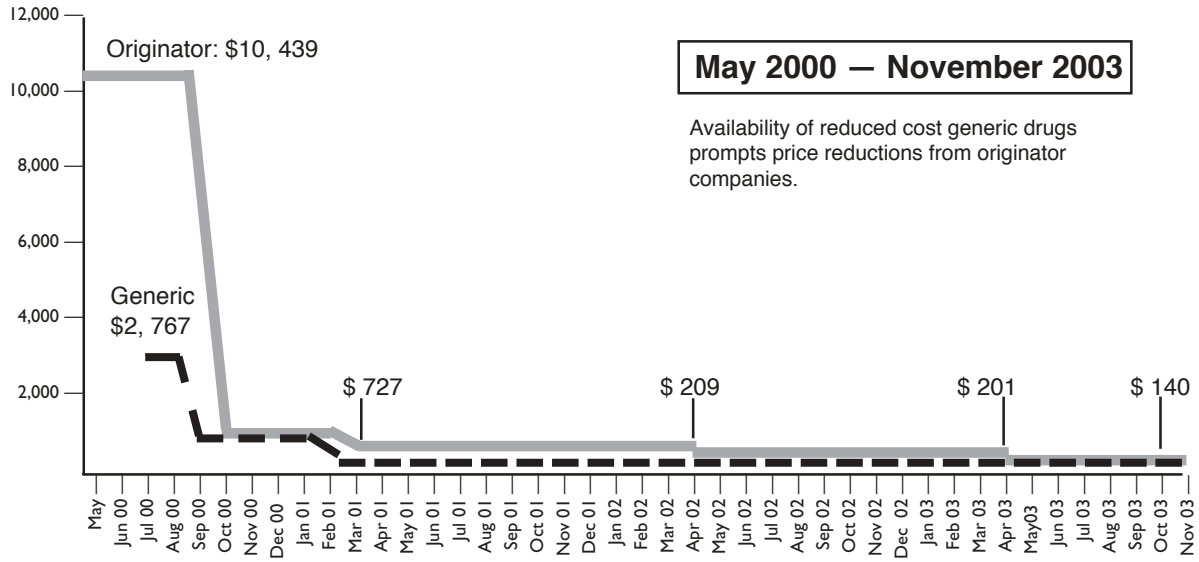
In Russia, maybe only 300 people are getting ARV treatment. There are tens of thousands of people who will need treatment eventually. I'm not optimistic because we are a huge country with a stupid government and everything takes a long time. There are no generics now, but Cipla has started the process of registration. There some good doctors, but they need additional education and information. They know something but not a lot. If you want information you have to speak English. There is no information in Russia in Russian. In Moscow someone can get care, but outside it is a completely different situation.

ROLAKE NWAGWU, NIGERIA

Ranbaxy sells their drugs to the government for about 30 dollars a month, but if you want to buy it on the open market they charge 70 dollars a month for their generics. People don't have access, they don't have money, they can't get drugs from the government; why should the price be so much higher? They blame the price on all the taxes and duties they have to pay for the higher price. They have to make these drugs easier to buy.

The effect of generic competition

A first-line antiretroviral (ARV) triple-combination: stavudine (d4T) + lamivudine (3TC) + nevirapine (NVP). Lowest world prices shown per patient per year in USD.



Source: MSF Testimony Submitted to DHHS for the Meeting of the International Subcommittee of PACHA. December 18, 2003

GERMÁN HUMBERTO RINCÓN PERFETTI, COLOMBIA

We do not gain ground when we accomplish access to medication while the International Monetary Fund and the World Bank implement neo-liberal policies that historically have lead to more poverty and hunger. It would be like gaining medication for many people but making them go without food or access to a health system. Poverty and inequality are a symptom of a greater epidemic. Let's review the poverty and HIV maps: the greater the poverty, the larger the portion of the population diagnosed; the greater the wealth the lesser the statistics.

AUGUSTINE CHELLA, ZAMBIA

In Zambia we have home-based care. But many families not able to take care of their sick and the public health system is overwhelmed. We have nine general hospitals that are able to administer ARVs but out of the nine, only two are able to do CD4 and viral loads.

The 900 people in Zambia on treatment are receiving treatment in both public and government clinics. In the government, there are only three big hospitals offering treatment. And when we talk about the 900, I'd say that 70 percent of that is from government and 30 percent is private sector.

DELME CUPIDO, NAMIBIA

The Government has taken up the drug donation offer made by Boehringer. They are using brand name drugs at the moment through the donation programmes, which is problematic because I'm not sure now sustainable that is. The Government has said to us the intention is to roll out treatment across the country, to expand it to the 13 regions and at the end of it they are hoping to roll out to something like 35 sites across the country. They are doing a progressive realisation type of plan; you get the donation then you are able to treat so many people. We are going to get funds from the Global Fund which can then finance the roll-out to other sites. We are on the cusp of getting treatment for a quite a number of people. When that's going to happen, who knows?

lot of companies, we let the local guys run the local businesses. Getting them to approach HIV from a different standpoint has not been all that easy. In the middle income countries prices are often negotiated on a case-by-case basis.

SUBHA: Can you cite a good example of case-by-case negotiations?

BOEHRINGER: The CARICOM (Caribbean Community and Common Market) countries approached us as a group and asked for our lowest price, which is what they got. When you apply for registration in Africa, sometimes you can do it in a block for several countries. It would be good if that process were streamlined for HIV.

RICHARD: I have your prices from the CARICOM negotiations and from your Central American AAI negotiations. I see big disparities between countries in the daily price of nevirapine. The CARICOM price is 60 cents per day, but in very lower-middle-income countries like Nicaragua and El Salvador, your price is $1.66 a day. These are countries where no generics are registered so they must buy from BI.

BOEHRINGER: Those countries are controlled by our business unit in Mexico. The Caribbean is controlled by the Canadian BI office. It is a big internal battle within the company. Any company has a lot of politics; and we have a lot of people who came up through the pharmaceutical industry.

RICHARD: So, here's my headline: "Mexican BI Executives Triple the Price of Nevirapine for Central American People with AIDS." Is that correct?

BOEHRINGER: I don't think that headline reflects the intention.

RICHARD: The AAI, UNAIDS and Peter Piot asked the companies to negotiate in good faith with the regions, yet I know that Central America is paying 2.7 times as much as the Caribbean countries, even though they have lower socio-economic status. So if Canadian BI and Mexican BI are not controlled by German BI, we need to know about it.

SUBHA: Could we hear some solutions on how we could follow up on this?

BOEHRINGER: Are these countries eligible for the lowest price, which is 60 cents a day? Yes they are. Can I make that happen? Yes I can. And I will. You can help me make this happen by working locally with the representatives. Just please be certain that the prices you quote are BI ex-factory prices and not distributor or pharmacy prices.

But, yes. I can go to the countries that meet the requirements for 60 cents per day and make that happen.

GREGG: Any country?

BOEHRINGER: If any country fits the criteria we can do it.

GlaxoSmithKline

Didier Lapierre Vice President, CDMA, HIV, Europe

Edde Loeliger, Director, Clinical Development

Mounir Ait-Khaled, Manager, Clinical Development

GLAXO: In October, 2003, the no-profit price of Combivir (lamivudine/zidovudine) was 65 cents per day and Epivir (lamivudine) was 19 cents per day. Our no-profit price is not an ex-factory price, it includes shipping, etc. No-profit pricing is available in 63 LDC countries and in Sub-Saharan Africa. This covers 67% of the HIV-positive population. We have a wide range of customer groups: the public, NGOs, aid agencies, international purchase funds, employee programmes, etc. We also sell to projects fully funded by the Global Fund, which includes around 40 additional countries with more developed economies, such as Honduras and the Ukraine.

HANNA: There is a different policy between the Government price and the Global Fund price?

GLAXO: Yes.

RICHARD: Your policy is to offer the lowest price if a programme is purchasing from the Global Fund, but in a neighbouring country, the price can be twice as high. In Colombia's Social Security system, it is doubled again. This policy in Latin America makes for absurd differences between countries with similar human development indexes.

GLAXO: Our strategy is to negotiate a commercial deal with the authorities. The price they get is based on the political will.

RICHARD: It is based on the stupidity of authorities ... or under-the-table payments.

GLAXO: If the government has the right priorities, it can be a win–win situation. But it is still a commercial deal. The company wants to run a business. It is the responsibility of the government to get the best deal from GSK.

LOBNA: Thank you for making no-profit drugs available. But in this room we have people from Africa who use generics… the patented drugs are not a factor in their lives.

GLAXO: The generic companies can make the drugs at that price, but we can't. Although we can continue to improve our industrial processes and lower our prices.

MAURO: How can the generics make the same drugs at a lower price?

GLAXO: I'm told that they can squeeze the price of their production. Our production lines may be older.

LEI: How can you further reduce the no-profit price?

GLAXO: We squeezed our suppliers and took back production internally that had been contracted out. The manufacturing lead time has been reduced by up to 60 percent, and future reductions are possible as efficiencies are gained and economies of scale come into play.

MAURO: The generic makers are for-profit companies. If you can make the drug at a price that competes with the generics, you can make money. Those are for-profit prices. Why can't you compete?

GLAXO: We don't plan to locate our factories in the developing world, for one thing.

GERMAN: In Colombia you only reduced the price of your products after generics came in.

GLAXO: You see this anywhere generics come in. We cut prices to keep a part of the market. It is a commercial practice. That decision is made locally.

LOBNA: But nobody is using your drug in the least developed countries. You put the price a little bit lower knowing that no one will use the drug because it is still too expensive. Then you have high prices for the middle income countries where people can't afford them either. How can you talk about governments not meeting their responsibility? What about the people in middle income countries who can afford the drugs and are dying because they are not available?

GLAXO: Middle income countries can apply for Global Fund money.

GROUP: (laughter)

GREGG: Middle income countries have prices that are out of reach of the people who need them. We need to see rationalisation of prices for middle income countries.

RICHARD: Most middle income countries don't have Global Fund money. It may be your policy to negotiate prices with those governments but it makes

Svilen Konov, Bulgaria

In Bulgaria, the only medications we can use are the originator's products. There are no generics. Unfortunately there is only one centre where HIV-positive people are treated and the centre has only two doctors. With the money from the Global Fund, the national coordinator on HIV/AIDS claims that the system will be decentralised, but so far we see no measures taken in that direction. Doctors outside of that centre have no experience and no real knowledge about treatments. Even a rich person would have a hard time getting special care. If you are knowledgeable you can ask for a better combination, but you can not get anything exceptional.

Chris Green, Indonesia

There was a very empowered lady from the eastern part of Indonesia, in Papua. She joined our second national meeting of people with AIDS and went back very fired-up to do something for her peers in Papua. She started speaking out openly and she became quite well known, but unfortunately a few months later she fell sick and died. We promised ourselves that we weren't going to let that happen again, so we started an antiretroviral fund to support people like her, activists who were playing a really crucial role in the response. The first one to get ARV was a friend in Jakarta who was near death. We got her onto drugs and a week later she was out of the hospital. Now she is our coordinator of peer support development and travels around the country meeting with people and helping them set up support groups. Since then we've probably put about a half dozen onto therapy.

Now she speaks in front of the legislature and government and tells her story. We meet with legislators and try to get them to vote money at the local and provincial levels, and that's been successful enough to get as many as 100 people onto therapy in the last six month.

KARYN KAPLAN, THAILAND

Because of the Global Fund grant, the government announced a plan to scale-up from 2,000 to 70,000 by 2005. At a cost of about 30 dollars per month, GPOvir (3-in-1 nevirapine, lamivudine, stavudine) is available for 80 percent of the people who can tolerate it. They are planning comprehensive care centres where a person with HIV coming in will immediately meet and be counseled by another person with HIV. Their entire treatment support will come from another person with HIV and this is a key component of the plan. They are already seeing that adherence is better with support that includes equal involvement of PLWAs.

LOBNA IBRAHIM, EGYPT

Even if someone has money from their profession or has savings, once they get sick and stop working, it goes away. Furthermore, you can't easily find a doctor who knows enough about ARVs because they have no experience and no training on ARV administration since the drugs are not available. Then, there is only one big pharmacy in Cairo known to have these drugs, and they have mainly lamivudine, mainly used to treat hepatitis B; so it is available in a different dosage and too expensive and useless unless at least stavudine and nevirapine and/or efavirenz are available. Even then it is not always in stock. So there is no assurance that if you can start ARV that it will be available next month. You can go to a pharmaceutical company that produces ARVs and has an office in Cairo and you can make a special order, but PWAs are usually scared of disclosing their identity, so people are reluctant to do that, or don't even know that they could.

Obviously the giant generic manufacturers are not attracted to the Egyptian market with its low HIV/AIDS prevalence, making the hassle of registering generics for ARVs not worth it. So even if you have the money, you're stuck.

no sense. Does it matter where the money comes from; if it is from Global Fund or from the state assembly?

GLAXO: The middle income countries are not a homogenous group, there are wide disparities in wealth and disease burden.

Russia	$1690 gross national income (GNI)
Ukraine	$ 690
Poland	$4230
Argentina	$7460
Bolivia	$ 900

But in Brazil, with the political will, they have treatment.

SVILEN: Why is the price of Combivir lower in Spain than in Bulgaria? Do you take GNI into account when you set prices in middle income countries?

GLAXO: I can't comment on the specific cases. Each country in Europe will negotiate its own prices. Prices in Germany are higher than in Greece, generally, but it is a negotiation with each country.

DELME: You speak of commercial logic, but the developing world doesn't represent such a large part of your market share. So you should abandon commercial logic in these situations.

GLAXO: Should we do that for all of our products? For malaria, etc? It's going to be very difficult to put this burden on the pharmaceutical industry. We have to also follow the priorities of the government. In Viet Nam the government said, we don't want ARV, we want antibiotics.

ROLAKE: It's about making drugs available to those who need them. Your no-profit prices have dropped and dropped again, so obviously the no-profit prices were not truly no-profit.

GREGG: You need to set a rational pricing policy for middle income countries. You are charging what the market will bear.

Intellectual Property

Roche

MAURO: What is Roche's policy on patents?

ROCHE: Roche is a very active negotiator on patents in countries where there should be patents. In some developing countries, though, patents are questionable. It is Roche's policy to not file patents on any medications, including new or investigational HIV drugs, in Least Developed Countries and in sub-Saharan countries. Furthermore, Roche will not act against patent infringement in those countries.

The Least Developed Countries are free to import generic versions of drugs covered by Roche patents. But nelfinavir is Pfizer's drug and they own the patents, which they purchased from Agouron. We are licensed to allow us to manufacture and sell nelfinavir. We're discussing with Pfizer what their policy will be in regards to protecting or defending those patents in countries where Roche would not.

The lack of patent protection doesn't make the drugs available. Most drugs on WHO's Essential Drugs List are off patent, but are still not available. Most anti-malarial drugs not patent protected, but are still not universally affordable.

We've developed 20 compounds on the WHO Essential Drugs List. We're active in infectious diseases and malaria. But we won't give our products away. I travel frequently into Africa and see the effect of this disease. We have no cure and we still need research.

But who will pay for the R&D? It will be the developed countries. Patent protections are needed to assure future development of new medicines. The generic companies need us to survive so we can innovate new drugs for them to copy.

MAURO: Is this innovation really benefiting the world? Or just the paying markets?

ROCHE: We don't know when we start research if it will be a high cost or a low cost medicine.

DELME: You say you are not going to enforce your patent rights in the least developed countries. But there is a question about Roche's lobbying in trade agreements. What is Roche's position on those trade agreements that place an onerous burden on countries that need the drugs?

ROCHE: The Paragraph 6 provisions of the Doha agreement should not be misused for commercial or industrial purposes. The generic companies are using it as a commercial opportunity.

DELME: Companies need incentives. Patents give that. But these agreements are being sidestepped.

GERMAN: For example, the U.S. government gave my country money for "The Columbia Plan" but we had to agree to protect the market from generics for five years through the provisions of data protection.

ROCHE: There is a belief that data is not intellectual property, but we think there should be data protection.

DELME: Is Roche saying it will abide by TRIPS and Doha, or will Roche continue to lobby for stronger intellectual property (IP) protections?

ROCHE: We don't file patents for most of the countries. We focus our activities in countries where there is commercial opportunity.

GREGG: It would help to be explicit about if Roche is pushing for TRIPS plus agreements.

James Kamau, Kenya

I had my own doctor who was treating me for opportunistic infections, but I was one of the few lucky people to get a doctor who was interested in issues of HIV. After that was when I became an activist. Since then we've been pushing as much as we can. We pushed for the licensing and importation of generic medicines. MSF brought in Triomune even before it was licensed and they had no qualms about it. They brought it in and said, here it is.

Subha Raghavan, India

Very simply put, there has been a tremendous amount of excitement and announcements in the last couple of months. Number one being, when Clinton went into the negotiations in October we put pressure on the government to do some negotiations for us within the country. As a result they have met with the pharmaceutical industry and the industry has agreed to cut the prices, but these have yet to seen reflected in market prices.

Also, the government recently announced they will provide free treatment for 100,000 people. But we haven't seen the blueprint, we have yet to see where the money will come from, we haven't seen the community involvement piece of the plan and everything is up in the air. They just held consultations in the last few days and we're waiting to see the blueprint and what their plans are, whether they're going to apply for the fourth cycle of the Global Fund. Even if the government goes ahead with treatment for 100,000, that still leaves 300,000 to 400,000 people who will require treatment immediately. Out of 4.5 million, the calculation is that 10 percent are at advanced stages.

Rolake Nwagwu, Nigeria

We put the cart before the horse; we had the drugs before the education. So people started medication not understanding what these drugs were. So people started thinking it was a cure and after a while a few people stopped. But adherence has been good and most people have had no side effects. But for the few people who did, it was a problem because there was one single regimen with no backup and no second-line. So if you have a reaction to nevirapine you have to go

buy some equivalent that is out there, which is not on the government programme. We need a subsidised second-line regimen as well.

CHRIS GREEN, INDONESIA

There was a meeting a couple of years back, at the Indonesian Drug and Food Administration, where we discussed how we were going to improve access to antiretrovirals. It was a workshop and the first day we spent producing a plan. The second day they invited representatives from the multinational drug companies and said, okay, here's the plan, what are you going to do to support it? The director of the Drug and Food Administration said, "You've got seven days to give me your offers, and I want real discounts: fifty percent is the absolute minimum discount that I would be expecting to hear." The companies said we can't possibly respond in seven days. And he said, well, if you can't do it in seven days, then I'm going to approve import from India. So he approved import from India. But that doesn't mean that the government funds it.

SUBHA RAGAVAN, INDIA

I was traveling with a WHO doctor and I wanted ask him for something that I could use to make an impression on the doctors I see in India. He said when he was seeing patients in Senegal, one of the patients was on his death bed and he said, "Doctor, I wish I was born in India so I wouldn't have to die." How ironic it is that only 50,000 out of 4.5 million people access treatment at this time and the rest of them are left to die because they cannot afford the same medications we manufacture and export to the whole world.

AUGUSTIN CHELLA, ZAMBIA

There is a need to really engage the community in the process because issues of equity arise where supply is not readily available for everybody. Only the ones who are able to afford it are getting treatment education. So that's one area that really needs our voices. As a community we really need to be involved in what is happening in the implementation of the programmes from the beginning to the end. PWAs are not yet involved in clinics to do counseling but we are moving in that direction.

ROCHE: I need to get a position on that from the company. I'm not an expert on trade negotiations.

Boehringer Ingelheim

GERMAN: Roche said they won't enforce patents in certain countries.

BOEHRINGER: We see patents as a privilege not to be abused. They may bring return in one country, but if you use them to deny people therapy, then that's an abuse. We support the patent system but we grant voluntary licenses to anyone who wants one.

DELME: In Morocco modifications to the TRIPS agreement are being negotiated to extend patent life to 50 years. This will kill the generic industry. Is your company lobbying with U.S. government to advance that agenda? If you are using your influence at an international level, then you are playing a double game.

BOEHRINGER: We are a German company. We don't have influence with the U.S. Government. Generics have been on the market in Germany for years. My stance is that patents are a good thing, but they are a privilege. I don't think our company would lobby for any law that would deny less developed countries access. We are a family owned company, so we don't have the shareholder pressure that others do.

GlaxoSmithKline

GERMAN: We need to talk about patents. Roche told us they are not interested in filing for patents in poor countries.

GLAXO: For the moment, GSK has decided to release patents in the sub-Saharan region. In other regions, we have to protect ourselves.

DELME: Currently the U.S. government is negotiating bilateral trade agreements that will undermine other trade agreements. They intend to extend patent protection to over 50 years in Morocco. Data exclusivity is another threatening demand that would kill the generic industry. These threaten access and will result in more deaths. What is your company doing around these agreements? If you are pushing for these agreements, then you should stop.

LEI: We heard from Roche that they will not compete with generics, and you've said the same. But they said they won't challenge patent rights in developing world. When you pursue patent rights, you obstruct access. You should think about what happened with corporations that cooperated with apartheid or with the Nazis. By not helping – by obstructing — you are liable to the judgment of history.

GLAXO: I think GSK has done much to develop the product; it is our commitment to develop HIV drugs. I want to improve our policy. We have made a significant step by suspending patent rights. It is hard to hear that you think we can be compared to these criminals.

RICHARD: In Guatemala people were dying in Roosevelt Hospital – only yards from your office – and drugs were expiring on the shelves of your office while people died. They were being denied the pills they needed to live. For many reasons, there is an argument that this is a systematic extermination of a class of people.

Packaging and Formulation

Roche

LEI: The difference between U.S. drug companies and your passive acceptance of generics is fascinating. What can you do for us in addition to pricing in terms of licensing agreements and co-packaging?

ROCHE: With nelfinavir, we have less flexibility because we don't own the patents; they are owned by Pfizer.

SUBHA: Are you open to allowing your drugs to be combined with other drugs in blister packs so people can have complete regimens that are easy to prescribe and use?

ROCHE: We are not prepared to have our product packaged together with drugs not qualified by us. We have been involved with Ranbaxy with a molecule for malaria, however.

SVILEN: In 2000, the Bulgarian government bought Invirase – and about 150 people received only Invirase, which is an inadequate treatment.

ROCHE: We don't have a specific way to follow up and see if the drugs are used correctly.

LEI: Have you talked to Abbott about making a version of Invirase co-formulated with ritonavir?

ROCHE: There are problems with co-formulating Invirase with ritonavir – by the time we did the necessary clinical trials, there will be new drugs. There are also IP and liability problems with co-formulating.

Boehringer Ingelheim

GREGG: Is BI open to providing drug for fixed-dose combinations (FDCs) or blister packs?

BOEHRINGER: FDCs are part of the answer but not completely. It turns into a regulatory nightmare. You need a study with endpoints to prove equivalency. At a meeting in Geneva we decided they would be interesting, but it didn't move forward. I don't know how to make it happen, given the anti-trust laws. Some companies can do it better than we can, and they should. We can look at blister packs.

CHRIS: We are concerned about the lead-in dose.

BOEHRINGER: So are we. We've heard that Cipla will develop a blister strip for lead-in dosage.

GREGG: Several years ago we talked to BI about single dose syringe.

BOEHRINGER: It's undergoing stability testing. It's only stable two months in a syringe. We are looking at an alternative method of doing a single dose. We are thinking about UniJect. It has a lot of positive features. But we don't know if it will actually deliver the correct dose. We don't know about stability yet. But if you do it the traditional FDA way, it will take years. It's actually easier to let it go out into a grey zone where we provide technical support but don't support the product. The syringe is available right now. And it's okay for two months.

We do have our own support groups of people living with HIV who are on treatment but those are small groups of people. It wasn't easy to have them, we had to lobby with decision makers as they implemented treatment programmes, we needed to add credibility to what they were saying by having people who are visibly HIV-positive put on treatment.

James Kamau, Kenya

We do a lot of group therapy in one of my organisations I'm involved with. They come together for support. Every other weekend we have group therapy where a certain topic is discussed and people share their experiences. We advise on nutrition and symptoms. You find that within the group, they find a solution. You find they encourage each other. Our churches are not engaging in AIDS, other than talking. The church movement would be a fantastic base, so the Church needs to be educated fully on these issues. They need to actually get involved.

Delme Cupido, Namibia

There was a young woman called Emma Tuahepa who was probably the first person to make her status known publicly and nationally in Namibia. She is now the head of a PWA group which is trying to establish itself nationally. I think through her example a lot of other people have also started joining. The have a lot of members but there are vey few members who are open about their status. She has spoken publicly of her status and now a number of other people have also started to do this as well. But if you consider that we have probably in the region of a quarter of a million people infected, the number of people who are open about their status is extremely small.

KARYN KAPLAN, THAILAND

In our region, with the exception of Thailand, activism comes after ARV access. In Thailand it was different, there were PWAs who organised for access and won access and built a movement. But in a lot of these other countries, like Laos, like Viet Nam, it's been the other way around. When people from Thailand share their experiences in treatment advocacy and peer education with people from Laos and Viet Nam there has been an amazing response. A lot of the international NGOs told us that they had never seen the HIV-positive people they work with be so inspired until they had the Thai people with HIV come and share what they had done. So, even though NGOs hold workshops, it's not quite the same as people with HIV in Laos hearing, seeing, with their own eyes, their counterparts – really it's more like brothers and sisters in Laos, because the language and culture is so similar – there's nothing that has inspired them more than that. And that's what we hope to build on, to remember that it's not just the North that has to teach the South, but that the South has much to teach the South and their neighbours, and it's just so much more appropriate.

GlaxoSmithKline

CHRIS: We're concerned about co-formulation and co-packaging. A single pill improves outcomes substantially. Unfortunately, Trizivir is now considered suboptimal therapy. Will you allow co-packaging so we could have blister packs that assist in adherence? We also need to see more trials about paediatric formulations and affordable prices for those too.

GLAXO: Fixed-dose combinations have been discussed with other companies and those discussions are ongoing. Paediatric formulations exist for all of our products, although they might not be right for all situations and may not be registered everywhere.

SVILEN: In Moldova, patients were treated with Trizivir alone.

GLAXO: Trizivir is not considered sub-optimal when it is indicated.

GREGG: On its own, Trizivir is not recommended first-line therapy in the U.S. or WHO guidelines.

Paragraph 6

"We recognise that under WTO (World Trade Organization) rules no country should be prevented from taking measures for the protection of human, animal or plant life or health, or of the environment at the levels it considers appropriate, subject to the requirement that they are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail, or a disguised restriction on international trade, and are otherwise in accordance with the provisions of the WTO Agreements."

From Paragraph 6, Doha World Trade Organization Ministerial Declaration, 2001

Research

Roche

ROLAKE: I was part of a Roche trial in 1999. I had to pay to be in the trial. I never heard any results and I never signed anything. There was no continuation of the drugs at the end of six months.

ROCHE: One of the reasons we put our ethical policies into place is because we don't want this to happen. But we have not sponsored trials in West Africa in 15 years.

MARK: How do you assure that your ethical standards are followed when you provide drugs but don't sponsor a trial?

ROCHE: We depend on our partners. For example, Roche has worked with HIV-NAT in Thailand since 1996.

KARYN: HIV-NAT does not require a community advisory board and often trial documents are only available in English. The rationale in Thailand is that you should be grateful for what you are given.

ROCHE: We are doing a study of Fuzeon in Thailand in 24 patients. Fuzeon is in the process of being registered there.

MAURO: The Helsinki Declaration states that it is not ethical to test a drug in a population that will not benefit from it. How can this population benefit from Fuzeon?

ROCHE: Are you saying that Fuzeon should not be made available?

MAURO: No, I'm saying you should make sure it is available on an affordable basis.

GREGG: It is not ethical to say these people are good enough to get data from but they are not worth making the drug available to.

GERMAN: According to the ethical standards of Roche, after finishing the clinical trial of Fuzeon, are you providing Fuzeon for life to that person? Or are you only doing trials in the developing world because people won't complain there.

ROCHE: I think you should involve people from Thailand in this discussion.

MAURO: I don't know how a person can give informed consent if there is no alternative.

CHRIS: What about Phase IV trials to look for long-term side effects?

ROCHE: We are finding slightly different side effect profiles in our African experience. PharmAccess International is preparing a report on this.

ROLAKE: I want to know who you meet with in Africa – I mean people living with HIV.

ROCHE: The only place in Africa where we have an office is in South Africa. I have dialogues with PLWHA from my office in Basel.

JOHN: In Australia you already consult with PLWHA groups. This is an effective model. You should practice it everywhere.

MAURO: You should use this CAB and other community groups and ask for advice.

Boehringer Ingelheim

GERMAN: What studies has your company done in the developing world? Will the results be given to patients?

BOEHRINGER: We've done PMTCT studies, with data out by end of the year. We are re-treating mothers with nevirapine in South Africa to see if we

AUGUSTIN CHELLA, NAMIBIA

What is critical is the family in Zambia. We have close family circles. You can not involve an individual without the family. If you have a person living with HIV supported by the family, then you are assured of a good treatment outcome.

SUBHA RAGAVAN, INDIA

There are some PWAs involved in counseling and adherence support in some NGO programmes but in others, no. There is some mistrust from the positive community towards the NGO community because there is an impression that NGOs have used positive people but have not involved them in equal leadership in the programmes. As a result we don't have the ideal participation of positive communities within the NGO programmes or the government programmes. As a result the positive networks do their own thing, the NGOs do their own thing and the government does their own thing. There's no cohesive structure bringing all three together, which is critical for care.

ROLAKE NWAGWU, NIGERIA

I got on a drug trial, a Roche trial, where I was given Viracept, zidovudine and Hivid for six months. They said you pay for two months and Roche will pay for four months. They took advantage of our ignorance and desperation where we had to pay about 1000 dollars for the two months. So we did the trial and even as I speak now, I have no idea what the results were or what my viral load was or anything. So I asked the doctor, after the six months, then what? Because from what I read I knew there must be some continuity. He said, no, don't worry, but that was the end of it. Six months and that was it. At that time HIV was relatively new, so it was anything goes, and before you can sell drugs in the country you must do a trial. So trials were going on all over the country and people were being used as guinea pigs. The patients were hand picked because they had to be able to afford to be on the trials. And these people were middle class or professionals who were very secretive about their status; who would rather die than tell; who feel they had everything to lose, so they were vulnerable.

ANASTASIA KAMLYK, BELARUS

Our government says we have problems with alcoholism, why should we be concerned with drug users who make this big problem for themselves?

We had a central HIV centre but it was discontinued. Now you have to go to your local doctor for your medical treatment. But who is this doctor? They have no training. Maybe in Russia the training is better, but in my home in Vladivostok, people don't have access to treatment and they don't know about it. In Moscow there is more money, but in my city no one can afford treatment.

have a durable response. We are doing surveillance in high- and low-nevirapine use settings to see if nevirapine use is driving resistance in the wild. Those are BI-sponsored studies.

There are also cooperative trials all over the world. There are also investigator initiated studies where, for example, we supply drug for NIH or CDC trials.

The data is published. We give patients their resistance results. I presume the large network trials communicate the results to participants.

KARYN: How do you ensure community participation in the trials?

BOEHRINGER: My concern is to assure the trial is ethical and doesn't hurt anyone. The standard is: would you do that to a patient you were treating? It's a reasonable standard.

KARYN: You should actively promote adherence to ethical principles and not just leave it up to local investigators.

BEN: Do you have a mechanism to collect long term safety data in developing world?

BOEHRINGER: We don't have any long-term trials in the developing world other than HPTN. We have long-term data from 2NN (a head-to-head comparison of nevirapine with efavirenz), where we will look at lipids and look at genomics. 2NN was a global trial, so there is some diversity in the long-term data. Nevirapine was developed in an era when you did a one-year study and you were done. Tipranavir is being done differently. We will go 3 to 5 years in diverse populations, with 30% in women. I doubt there will be another large 2NN trial.

GREGG: Glaxo agreed to meet with local community and will ask their partners to seek community input into trial design.

BOEHRINGER: We meet with ECAB and ATAC, what more should we do?

JOHN: It's really about involving HIV positive people at all levels to enrich the quality of what you're doing. We would like to see this model implemented in a standard way around the globe.

GlaxoSmithKline

GLAXO: For Glaxo-sponsored trials, the company guarantees a supply of Glaxo drugs for a maximum of two years after study completion if the patient has a clinical benefit. After two years, we expect the drugs will then be supplied by the private or public health care sector.

For Glaxo-supported trials, there is a written commitment obtained from a third-party or the Ministry of Health prior to study initiation. Glaxo will work with the third party to ensure that the medications are in place. If we don't get these commitments in writing we cancel the collaboration.

LUBNA: Do you provide drugs at reduced price in these countries?

GLAXO: Yes, if it is part of our commitment. If we go into a country to develop our CCR5 inhibitor as a drug to deal with resistant virus, then we will go to a population that has already been exposed to therapy. In low income countries, where patients are treatment naïve, we would not go.

MAURO: How about making the drugs available to the rest of the population at a reasonable price?

GLAXO: These countries have access to preferential prices. For example, lamivudine in South Africa was available in the private sector, but not available otherwise. In that case, we continued to provide lamivudine to subjects for six years. But it was not available from the Ministry of Health. So we assure continuous supply whether sponsored or supported.

BEN: If the Glaxo study includes a non-Glaxo drug will you supply it?

"Medical research is only justified if there is a reasonable likelihood that the populations in which the research is carried out stand to benefit from the results of the research."

Paragraph 19; Ethical Principles for Medical Research;
World Medical Association Declaration of Helsinki (2000).

GLAXO: If it is not available, then yes.

LEI: I think you have shifting ethical standards. Providing only two-year access to study drugs after the trial ends would not be feasible in the US. You need to reevaluate your policy.

GLAXO: The two years is supposed to be enough to get registration and get the drug available on the market. It's also possible that the patient will have to switch after two years. For the development of Lexiva in South Africa, we agreed to continue to provide drug. It's the way we work.

MAURO: Why don't you simply say "until the drug is available" instead two years.

GLAXO: The policy was put in two or three years ago. If you ask your collaboration partner to provide drug for 10 years, it can be difficult to reach an agreement. If we are too strict we will never do a trial.

GREGG: Let's talk about super-regional research needs. We need interaction studies with methadone and other drugs in Eastern Europe.

GLAXO: We've been discussing how to get more involved in Eastern Europe. There are few large research organisations to work with. It's not that easy to start these studies in these countries. We would like to see proposals from these countries.

JOHN: How about interaction studies with meth-amphetamine or ecstasy?

GLAXO: We have no specific studies, even in the developed world.

KARYN: Why is only 100mg lamivudine dose available in China?

GLAXO: Negotiations are in progress to let them produce lamivudine. There is a trial in discussion.

Augustin Chella, Zambia

There is a lack of information on antiretroviral treatment and there is a lot of misinformation about antiretrovirals in the Zambian population. The community in general has a lot of misinformation and the medical professionals also have a lot of misinformation about ARVs. There are rumors that antiretrovirals are a cure for HIV or that if you take them you can't transmit HIV anymore. The professionals have no experience with the treatments, they have no access to Internet and they don't get linked to sources of information, so all they have is the little knowledge they've acquired from hearsay.

Subha Ragavan, India

We don't have a rigorous evaluation of the successful use of these drugs. There are a handful of providers, you can count them on your fingers, mostly in private practice, that prescribe these drugs and have been prescribing for a long period of time. They have considerable knowledge and have educated themselves by going to the conferences. But with regard to the knowledge of the government doctors, who will be serving the poor, which are the majority of the infected, we need to evaluate them. Because all of them have received maybe one or two day courses on HIV, and most of the knowledge they may gain is through their own initiative through reading.

Partnership for HIV-positive People in Clinical Research

The involvement of HIV-positive people in clinical trial design and implementation must be extended beyond the current partnership parameters in developing countries. The ad hoc approach currently used to involve the community is inadequate. Involving HIV-positive people in decisions that affect them optimises the benefits, adds value, and enriches the knowledge to be gained from clinical research. Mechanisms should be established to allow HIV-positive persons to participate in these decisions in a regular and structured way anywhere research is conducted. Community perspectives and considerations should always be sought and valued, beginning with the protocol design stage, especially on the scope of inclusion and exclusion criteria, during the development of the informed consent process and throughout the study.

John Daye, National Association of People with AIDS (NAPWA), Australia

JAMES KAMAU, KENYA

Ignorance is one of the biggest hindrances. In fact one of the things that we are planning to do in a big way is treatment literacy education. That is very necessary. Lack of knowledge of HIV issues is one of the biggest problems we have in Kenya today. We need to incorporate a school curriculum; we need to train the teachers. We need a plan for teaching professionals. We have two dangers here. We haven't even trained most of the doctors and soon we are going to catch up with resistance. They not even aware of the first-line treatments, how are they going to deal with resistance?

DELME CUPIDO, NAMIBIA

The Chief Pharmacologist has told me that they have much the same problems that people with TB have: people come and don't come again, they skip their appointments, they share their drugs, which I think is a huge problem. The doctors, sadly, I think, are very uneducated about treatment. I've heard horror stories about doctors telling patients that they are not aware of treatment and turn patients away. Someone went to their doctor after being diagnosed and the doctor said, "Forget about this treatment thing. What you should do is use immune boosters."

PAISAN SUWANNAWONG, THAILAND

I just went to a new doctor in the biggest hospital because my doctor was at a conference and he just looked at my file without asking me anything. Then I said I have been sick for a week and have a problem with my mouth. The doctor never touched me or asked me a question. This is a doctor at the best hospital in the country.

CHRIS: Who is going to collect adverse events in new populations in Papua?

GLAXO: Surveillance does not happen in Indonesia. That is difficult enough to do in Europe, but we can't replace the health authorities.

LEI: Your company has benefited from PMTCT studies, but how many mothers got treatment afterwards? How many are still alive?

GLAXO: In regions where PMTCT trials are done, no-profit drugs are available.

JAMES: In Kenya, most of the mothers who receive PMTCT treatment can not afford continued therapy afterward. This leaves many orphans.

GLAXO: You are right, it is important that mothers are able to continue to care for their offspring. But some women who give birth do not yet need treatment and others do. So we are looking at ways to prevent transmission during breast feeding.

JAMES: Even those with CD4 that is currently too high to need immediate treatment, they still deteriorate very fast.

OLIVE: Have PLWHAs been involved in the design of PMTCT studies and on review committees?

GLAXO: We can look at proposals to persuade IATEC to work with community members.

SUBHA: Do you have consultation with the community in the design of Glaxo studies?

GLAXO: We have no problem going to the ECAB.

MAURO: I think we mean consult with the local community.

GLAXO: It depends on the resources needed. We do not have a formal mechanism to discuss clinical design with local communities. It's a matter of the number of people who are working locally. People in the field are involved with monitoring clinical trials and such.

GREGG: We have a long history of engagement but it's not acceptable to consult in the US and EU and not in the other areas where you do trials.

GLAXO: We can control our own trials, but not the Glaxo-supported trials. In CDC studies, patients are represented on the steering committees. Some groups use web sites to communicate the progress of the trial.

SVILEN: Maybe your local reps can try to reach out to community. Currently there is no contact and talking to ECAB alone is inadequate.

DELME: We can assist you by directing you to local groups.

SIMON: The investigator guidelines could include the requirement to include local representation and consult. It would help break barriers with local doctors to say you value local community consultation.

JOHN: It is about Glaxo seeking out HIV-positive people and adopting a framework which recognises their needs all around the world.

GLAXO: We will review our contracts. We think this is a good idea.

"At the conclusion of the study, every patient entered into the study should be assured of access to the best proven prophylactic, diagnostic and therapeutic methods identified by the study."

Paragraph 30; Ethical Principles for Medical Research;
World Medical Association Declaration of Helsinki (2000)

Discussion Summary

During the three-day World CAB meeting, participants questioned company representatives about pricing and research policies and asked the pharmaceutical companies to:

Review pricing policies within low and middle income countries

- The economic development criteria used to set prices are often unrealistic
- Rigid pricing structures produce inequitable outcomes
- Disparities between regions are often not justified
- The continued relevance of Accelerating Access Initiative (AAI) pricing agreements is questionable
- The gap between no-profit prices and prices in middle income countries is too wide

Promote product availability and utility

- Drugs need to be registered and marketed in middle income countries with small markets
- Explore simplifying regimens, including co-formulating and co-packaging with drugs from other manufacturers, including generic makers
- Guarantee the development and distribution of paediatric formulations
- Extend shelf-life of products for tropical regions

Halt promotion of suboptimal therapies (e.g. Trizivir in Moldova)

- Halt corporate activism to win trade advantages in excess of those provided by World Trade Organization agreements
- Do not undermine Doha language
- Do not lobby for bi-lateral trade agreements between U.S. and developing nations
- Extension of patent terms to 30 years
- Research data as intellectual property

Conduct relevant, responsible and ethical research in developing regions

- Publish details of clinical trials being conducted in the developing world
- Assure usefulness and rationale of these trials to their particular settings
- Assure informed consent in local languages
- Assure continued availability of tested drugs at affordable prices after research is concluded
- Perform long-term side effects research among diverse ethnic groups
- Perform interaction studies with opiates and amphetamines

Incorporate PLWHA involvement at all levels

- In the design and conduct of clinical trials in developing world settings
- In discussions with government, NGOs and drug companies
- In the design of treatment literacy programmes for patients and professionals

Further information

Organisation websites of the participants are:

AIDS Treatment Activist Coalition (ATAC), USA
http://www.atac-usa.org
Agua Buena Human Rights Association
http://www.aguabuena.org
AIDS Foundation East-West (AFEW), Russia
http://www.afew.org
All-Ukrainian Network of PLWH, Ukraine
http://www.network.org.ua
European AIDS Treatment Group (EATG)
http://www.eatg.org
Forum for Collaborative HIV Research, USA
http://www.hivforum.org
Georgian Plus Group, Georgia
http://www.georgia-plus-group.port5.com
Gay Men's Health Crisis (GMHC), USA
http://www.gmhc.org
HIV i-Base, UK
http://www.i-base.info
Jouranlists Against AIDS, Nigeria
http://www.nigeria-aids.org
Legal Assistance Centre, AIDS Law Unit, Namibia
http://www.lac.org
Network of African People Living with HIV/
AIDS (NAP+), Zambia
http://www.naprap.org
National Association of People with AIDS (NAPWA),
Australia
http://www.napwa.org.au
Plus and Minus' Foundation, Bulgaria
http://www.aidsbg.info
Solidarity and Action Against the HIV Infection in India
(SAATHII), India
http://www.saathii.org
Treatment Action Group (TAG), USA
http://www.aidsinfonyc.org/tag
Treatment Action Campaign (TAC), South Africa
http://www.tac.org.za

Further reading:

The Médicins Sans Frontières publication *Untangling the web of price reductions: a pricing guide for the purchase of ARVs for developing countries* begins by stating: "The lack of clear information on pharmaceutical prices on the international market is a significant barrier to improving access to essential medicines in developing countries. The situation is particularly complex in the case of antiretrovirals." This excellent document provides clear and verified information for potential buyers and the 6th edition can be accessed on the MSF website.

The report from the *International Treatment Preparedness Summit* in Cape Town 13-16 March 2003 which includes extensive recommendations from the community for successful antiretroviral treatment programmes can be accessed on the SAATHII website.

Other websites:

Global Fund to fight AIDS, Tuberculosis and Malaria
http://www.theglobalfund.org
MSF—Médicins Sans Frontières
http://www.msf.org
UNAIDS
http://www.unaids.org
WHO
http://www.who.int
World Bank
http://www.worldbank.org
WTO
http://www.wto.org

Companies at the meeting:

Boehringer Ingelheim
http://www.boehringer-ingelheim.com
GlaxoSmithKline
http://www.gsk.com
Roche
http://www.roche.com

"If there's one thing we've learned about testing and treatment, it's that the involvement of the community is decisive. If 3 by 5 is to make the intended impact, it must call on the community for help, and jettison the lip-service to which so many are addicted. And the key elements of the community are the People Living with HIV/AIDS, who are the real experts, and must be acknowledged as such. They should be consulted on every aspect of the treatment process, and they should be seen as helping to mobilise the community to work, in an equal partnership, with the medical facility dispensing the treatment. Wherever this formula has been genuinely applied, testing increases exponentially, stigma and discrimination drop significantly, and adherence rates are generally higher — I repeat, higher —than they are in this city of San Francisco."

Stephen Lewis, Plenary Speech, 11th Annual Retrovirus Conference, San Francisco, 2004.

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