

Protest - Page 8

### DAWN INFORMS Supplement

August 2001

This special supplement on Trade, AIDS, Public Health and Human Rights covers the intensifying struggle between pharmaceutical giants, Southern states and civil society organisations over the right to pursue national public health policies which meet people's needs; and related rights issues arising from the recent UN Conference on HIV/AIDS.

We celebrate with the Brazilian and South African people and national and international NGOs their victories over the US and the drug companies in the global campaign for medicines and people's health before patents and profits.

# TRADE, AIDS, PUBLIC HEALTH AND HUMAN RIGHTS

The United States withdrawal of its complaint to the World Trade Organisation against Brazil means the continuation of the most successful treatment program in the world. Brazil can continue to provide essential medication to its half-million HIV-positive people. It can continue efforts to provide affordable, generic medicines for life-threatening diseases for the 60 million Brazilians living in poverty. For the rest of the developing world, the decision is a major step forward in efforts to provide AIDS drugs to the millions of sufferers. Congratulations to the many NGOs, activist groups and humanitarians who have been involved in this important battle to make essential drugs and medicines more affordable and available to everybody rather than just to those who can pay.

### VICTORY IN DRUGS BATTLE

### US WITHDRAWL OF WTO CASE AGAINST BRAZIL

- a victory in the battle to provide affordable drugs to the poor

The US withdrawl of its complaint with the World Trade Organization (WTO) that sought sanctions against Brazil for allowing the use of life-saving generic HIV/AIDS drugs was described by Oxfam America as "a victory in the battle to provide affordable drugs to the poor". As DAWN members were informed "there is no doubt that it is a major step forward. In fact it is being interpreted as a moratorium on TRIPS in areas related to public health." (See page 20)

The announcement which came on the eve of the **UN General Assembly** Special Session on HIV/ AIDS was the result of active lobbying by a diverse group of people who have been supporting efforts to make medicines more affordable /available to poor people throughout the world. See Dawn letter page 3.

The US withdrawal came in the wake of a similar victory in April when 39 drug companies dropped their

### UN General Assembly Special Session on HIV/AIDS (UNGASS)

The Heads of State and Government and Representatives of States and Governments, met for the twenty-sixth special session of the General Assembly of the United Nations, in New York 25 to 27 June 2001. They met "as a matter of urgency, to review and address the problem of HIV/AIDS in all its aspects as well as to secure a global commitment to enhancing coordination and intensification of national, regional and international efforts to combat it in a comprehensive manner". Preparations for the UNGASS began with many preparatory meetings - Angela Freitas represented DAWN at these meetings see her report page 3. The UNGASS resulted in a Declaration of Commitment on HIV/AIDS. (See pages 9-11)

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lawsuit against the South African government. The suit sought to block implementation of a 1997 South African law that would make it easier to acquire lifesaving medicines for more than 4 million South Africans living with HIV/AIDS. Like the proponents of apartheid before them, these companies acted to maintain the rules of a system that denies the value of black lives in favor of minority privilege. The result in Africa has been murder by patent". (See page 5 Global Apartheid)

There is no doubt that increasing pressure on the US and the multinational companies over the last 12 months led to these victories. International and regional meetings have declared their support for Brazil and called for changes to be made in the WTO regulations so that drugs can be more affordable for developing countries.

A major reason for the "Brazil victory" is the success of their AIDS programme. During the 1990s, local manufacture of cheap generics reduced treatment costs by 70% and allowed the government to prescribe free anti-retrovirals to HIV/AIDS patients. Since 1996 Brazil has halved the mortality rate, decreased the hospitalization rate by 80% and dramatically reduced the rate of mother-to-child transmission. (See Oxfam briefing paper P16)

The Brazilian AIDS programme has been hailed by the United Nations, the World Bank and medical professionals as one of, if not the most successful AIDS programmes in the world. (See Jane Galvao article page 6) Brazil's success provides inspiration to developing countries. It has shown that despite active opposition from the US and the powerful drug companies, a developing country can run a successful HIV/AIDS programme. Brazil's defence of its *Free Distribution of AIDS Drugs for All Programme* should be applauded for its honesty, integrity and concern for the welfare of its people. (See Minister's reply to charges by the United States page 8)

One of the reasons the US lodged its complaint against Brazil was "the threat of a good example," that is, the fear that the Brazil example would spread to other countries - see page 7. The retreat by the United States does not change the fact that the global trade system still favors profit over patients' lives. The questions remain unanswered - how many more people have to die unnecessarily? How many more orphans does it take? How much human suffering and misery is required before essential medicines and drugs are made available for everyone? Pressure continues mounting for the U.S. government and pharmaceutical

Viva Brazil! Brazil's AIDS programme is considered one of the most successful in the world. And it is because of strong unwavering political commitment. Brazil has shown that it is possible for developing countries to provide essential drugs and treatment for people living with HIV/AIDS. It continues to challenge the powerful US multinational drug lobby. In many countries being diagnosed HIVpositive is a death sentence. With no cure and treatment costing US\$10-12,000 a year which is beyond the means of most people, all you can expect if diagnosed HIV-positive, is discrimination, stigmatisation, ostracisation, unemployment and long lingering suffering while watching your family struggle to take care of you. For most people, it is better not to get tested.

But in Brazil, the availability of drugs and treatment for HIV-positive people encourages people to get tested. Brazil's policy clearly demonstrates that care and support for people with HIV/AIDS is necessary for prevention efforts to be successful. Brazil's policy has also led to the establishment of a successful pharmaceutical industry providing cheaper drugs.

Other factors which have contributed to Brazil's success include an open attitude towards matters sexual, less discriminatory attitude toward those with HIV/AIDS and close collaboration with civil society. Brazil's Free Distribution of Aids Drugs for All Programme provides hope for people with HIV/AIDS and valuable lessons for those involved in efforts to get cheaper medicines for all. It shows as Tina Rosenberg writes that the "Patent laws are malleable. Patients are educable. Drug companies are vincible. The world's AIDS crisis is solvable." (See page 14)

While Brazil's HIV/AIDS sufferers are enjoying access to free drugs, for those with HIV/AIDS in India and other parts of the world, the nightmare continues. India produces AIDS-related drugs. Its pharmaceutical firms have offered these drugs to other countries at a third of the price. But India is not providing these drugs for its own AIDS cases, why? (See page 18)

industry to use their patent rights and profits to promote rather than to abuse the human rights of people. The whole world will be watching the WTO when it meets in Qatar to discuss these life saving issues.

### LINKING THROUGH CLOSED DOORS

ngela Freitas represented DAWN at the Second Informal Consultation in Preparation for the UNGASS on HIV/AIDS 21st - 26th May and the Parallel Civil Society Sessions (facilitated by ICASO) 21-24th May. Angela was one of two representatives from feminist organisations from the South (the other being the AIDS Law organisation) who participated in the Parallel Civil Society Sessions (facilitated by ICASO) held 21-24th May to review and propose amendments to the "Draft Declaration of Commitment", to raise key issues from the civil society perspective to be included in the

document; to articulate the advocacy strategies aimed at influencing the negotiation and to support the work of friendly delegations. About 150 people, representing various HIV/Aids related NGOs, networks, groups, grassroots people living with HIV/ Aids, researchers and UNAIDS staff attended the parallel sessions. Countries represented: United States, Canada, Venezuela, Argentina, Brazil, India, China, Zimbabwe, Uganda, Morocco, Namibia, Ireland, Spain, Ukraine, United Kingdom and Norway. Countries of the South were subrepresented.

democratic. The major issues raised by NGOs as being problematic in the text were access to medical care and treatment, intellectual property rights and HIV/AIDS drugs, the definition/listing of vulnerable groups, full participation of people living with HIV/AIDS, the human rights approach, the role of civil society (NGO's and CBO's), goals and targets, financial resourcesgender and culture

The dialogues were not exactly valued by delegations or even by the secretariat. Timing, lack of secretariat support, few delegations attending and the

"resistant countries" did not show up. Although the sessions became a dialogue with existing partners, they were very fruitful in clarifying important aspects being Official debated. delegations lacked basic knowledge on HIV/ AIDS and benefited from the debate with the NGOs.

In February DAWN faxed letters to the Geneva offices of the WTO, Brazilian Delegation, and US Mission for European Offices of UN and Other

**PUT LIVES BEFORE PROFITS** 

"Development Alternatives with Women for a New Era (DAWN) wishes to add its protest against the request by the United States of America for the establishment of a Panel on "Brazil - Measures Affecting Patent Protection", lend its support for the two attached Declarations issued by community activists at the Community Forum and at Forum 2000, and draw your attention to the recent article by Tina Rosenberg which was published in the New York Times titled "Look at Brazil: Patent laws are malleable. Patients are educable. Drug Companies are vincible. The world's AIDS crisis is solvable." Member States and the World Trade Organisation are urged to put lives first not profits."

Organisations:

#### PARALLEL CIVIL SOCIETY SESSIONS

The sessions identified the weaknesses in the language of the Draft Declaration, with respect to major areas of concern including "prevention and treatment"; Meager targets and goals; "treatment and support" and "measurement" and non inclusion of resolutions and recommendations recently adopted by the UN Commission on Human Rights and WHO. While the sessions were very productive, there was "an immediate and clear protest regarding the treatment given by the UN/UNGASS Secretariat to NGOs attending the informals" This led to the statement which appears on pages 13-14.

Specific working groups were formed to debate the various themes and contents, produce statements and amendments and strategize for advocacy. A list was organized of 'resource persons' for each thematic area and the working groups operated rather efficiently.

#### Official Delegations - Civil Society Dialogues

Two dialogues took place on May 21st and 23rd. The preparation for these sessions was very efficient and

#### The Press Conference

The main objective was to publicly express the NGO dissatisfaction with the proces. Testimonials were given by a variety of NGO representatives. (Few people were selected to give their testimonies: an Indian lawyer, a North

American referred to the success of the Brazilian policy; one person [male] living with HIV/Aids from Ukraine who was a member of the official delegation but had not been able to enter the negotiation room - he emphasised . the importance of having civil society representatives in the managing body of the fund if ever it would be created and a Venezuelan insisting that HIV/Aids was political and human rights issues and not exclusively a health problem. He also underlined the urgent need to change governmental mentalities as a strategy to fight against the discrimination currently affecting gay men, drug users, and sex workers. At the conference it was also announced that the Gay and Lesbians Proud Day street march would take place in late June, one day before UNGASS.)

#### **Daily Briefings**

Daily briefings by NGO representatives in official delegations provided information on what was happening inside the closed rooms. They provided an opportunity for NGOs and other representatives to inform about their linkages with delegations and suggest questions to be raised in the dialogue sessions. For the Brazilian NGOs,

the briefings were critical to efforts to become members of delegations and to jointly design strategies for the

document negotiations.

The head of the Brazilian Delegation, Rose Muñoz, requested, through DAWN and Pella Vidda, for space in the last briefing (May 24th) because in the dialogue of the previous day she was not given the floor by the chair and she wanted to express her position to NGOs. She and the NGOs interpreted this episode as manipulation to silence the Brazilian voice. In the briefing she informed that the Brazilian Delegation had requested an appointment with the chairs to ask for explanations. She reaffirmed the Brazilian commitment to defend the full participation of civil society in the UNGASS process and agreed to channel the letter proposed by NGOs to the Chair of the General Assembly of UN - and to press the Group of Rio to struggle for some contents in the document and try "to go as far as possible. Rose also informed that, in case the work was not finalized until May 26th; the Group of Rio would do its best to reach agreement with respect to the most important aspects contained in the Declaration.

#### The Countries' Ballet

"I was able to integrate the Brazilian delegation for the last two days of negotiations. Being inside the room was, in many ways, to revive the experience of the Beijing +5 trenches. The big difference was very few women in the gallery or in the corridors, and the majority of those left on Friday. I must say this was not exactly a nice experience to be practically alone (with Cynthia Rothschild) in the middle of the quite well known ballet of official delegations whenever sexuality and gender is at debate."

Some of Angela's findings before she went into

the room included:

11 countries had representatives of civil society in their

delegations;

The slow pace of the work was a deliberate strategy of 'delay'. The US had even proposed that the document should be kept in its original form without

any change or amendment;

The overall picture was quite similar to what has been witnessed in the Plus Five processes. Whenever the text mentioned gender, human rights, sexual and reproductive rights, family (ies), civil society participation, economic issues, and most particularly foreign debt there was no agreement. Additionally there were harsh disagreements with respect to intellectual property rights of HIV drugs, free distribution of the drugs and the financing and creation of a Global Fund to support prevention and treatment in the poorest countries;

The countries spoke in blocks. The Islamic countries

were very organized.

The US delegation hyper tuned with Bush's politics gave a lot of trouble. It was contrary to distributing syringes for drug users as a risk reduction strategy, to debt swaps proposals to transform debt in credit for STD/AIDS prevention. The US also openly defended private intellectual property rights in spite of the cost implications.

If the US government and the pharmaceutical companies get their way, Brazil, and any other developing country, will be prevented by WTO rules from insisting that patented products be produced locally, a measure which can ensure the development of a domestic pharmaceutical industry, bring down drug prices, and reduce the foreign-exchange costs, thus ensuring more secure and affordable access to medicines. If Brazil is also prevented from allowing parallel imports in cases where there is no local production, the prices of medicines will be higher than need be, with corresponding hardship for patients and their families. With the loss of both these policy options, the Brazilian health ministry would be in a much weaker position to negotiate affordable prices with the big drug companies. If PhRMA succeeds in obtaining the additional policy reforms that it seeks, the control of new medicines will be largely in the hands of a few international drug companies. This would cripple the government's ability to manage its medicines policy for the public good

Australia, the US and India were not in support of

the 'rights based approach'.

Group of Rio (the new version of SLAC) was fully in support of gender language, access to treatment, human rights, adolescents, the various definitions of vulnerable groups, and NGO leadership in HIV-aids. The cohesion of the group was evident and it had great leadership / and legitimacy in the plenary.

China, Cuba, Egypt and Algeria worked together in the human rights session and bravely resisted the incorporation of the vulnerable groups terminology under "rights based approach" or even "access to

treatment".

- At a certain point India, United States and South Africa got together without Brazil to reach agreement with respect to drugs and drugs costs. India, in particular, was harshly resistant to the text proposed by the Group of Rio for ' Care Support and Treatment'
- In regard to this stalemate, the Brazilian head of delegation explained to NGOs that while Brazil produces the drug in public labs, other countries do not. In the case of India, for instance, the production is done by a private company. These countries, therefore, do not have the capacity to buy the drugs and will have much difficulty in accepting any proposal concerning "differentiated prices". Brazil position is that the creation of the Global Fund is the way out of this deadlock. But it must be combined with bi-lateral negotiations between producers and consumers.
- The discussion on "families" was, once again, long and exhausting (the term appears in the final paragraph on communities and people living with Aids);

Excerpt from Global Apartheid by Salih Booker, William Minter

"In mid-April, worldwide protests forced an international cartel of pharmaceutical giants to withdraw a lawsuit against the South African government. The suit—an effort by "Big Pharma" to protect its enormous profits—sought to block implementation of a 1997 South African law that would make it easier to acquire lifesaving medicines for more than 4 million South Africans living with HIV/AIDS. Like the proponents of apartheid before them, these companies acted to maintain the rules of a system that denies the value of black lives in favor of minority privilege. The result in Africa has been murder by patent.

The global pattern of AIDS deaths—2.4 million in sub-Saharan Africa last year, out of 3 million worldwide; only 20,000 in North America but most in minority communities—also evokes the racial order of the old South Africa. To date, access to lifesaving medicines and care for people living with HIV and AIDS have been largely determined by race, class, gender and geography. AIDS thus points to more fundamental global inequalities than those involving a single disease, illuminating centuries-old patterns of injustice. Indeed, today's international political economy—in which undemocratic

institutions systematically generate economic inequality—should be described as "global apartheid."

Global apartheid is an international system of minority rule whose attributes include: differential access to basic human rights; wealth and power structured by race and place; structural racism, embedded in global economic processes, political institutions and cultural assumptions; and the international practice of double standards that assume inferior rights to be appropriate for certain "others," defined by location, origin, race or gender.

Global apartheid thus defined, we believe, is more than a metaphor. The concept captures fundamental characteristics of the current world order missed by such labels as "neoliberalism," "globalization" or even "corporate globalization." Most important, it clearly defines what is fundamentally unacceptable about the current system, strips it of the aura of inevitability and puts global justice and democracy on the agenda as the requirements for its transformation.

When delegates and demonstrators gather in New York for the UN General Assembly Special Session on HIV/AIDS on June 25, the future of global apartheid will be the subtext underlying the millions of words exchanged. Shooting ahead of the world's response for twenty years, the AIDS pandemic is now exposing old fault lines as well as new fissures. That is why the debate on AIDS is increasingly becoming a debate on what kind of world we want to have: a world that nurtures our common humanity or a system that protects and promotes global minority rule.

Article from the Nation circulated by Maria Riley from the Gender and Trade Network.

Other interesting trends became evident when I was finally able to get into the closed room:

 China spoke against the human rights of people living with HIV / Aids and of the vulnerable groups at large in the Follow Up session of the text.

The Indian delegate stayed physically isolated from

other countries and groups.

 The Holy See was entirely silent. The delegate spent all the time in the three sessions I attended typing emails on his laptop.

 To respond to the many doubts and queries on the Global Fund, the chairs called Peter Piot, Executive Director of UNAIDS, to speak about Available Resources for the HIV-aids Epidemics (there is a full WHO document on the subject that may be found in their web page).

#### The Group of Rio

The Brazilian delegates constantly surveyed and defended key issues, especially in regard to the production and access to HIV-aids and other drugs as well by insisting that a functional public health system is a critical factor in dealing with epidemics. Brazil also played a major role in facilitating agreements between the Group of Rio, the US, the EU and Japan in respect to these issues.

#### In the final stretch

Delay tactics including inaccuracies and omissions from the daft text led to the draft declaration not being ready before the end of the scheduled session. By the time Angela Freitas left the meeting at 10.00 pm Saturday 26th May delegations were working on the 34th para of the Preamble, of which 20 paras had been fully adopted.

"The work was as painfully slow as in Beijing+5".

#### Conclusion

Freitas concluded that there is scope for women's oganisations and HIV/AIDS NGOs to collaborate more in the future. While the networks and NGOs attending the HIV-UNGASS informals are experienced in international HIV/AIDS conferences, efficient in collective planning and advocacy strategizing, many were not experienced with the UN system. As frequent travelers on the road to "international UN declarations" (Beijing, Cairo and the plus fives etc), women's organisations can assist HIV/AIDS NGOs with their knowledge of UN language, procedures, and the political dynamics involved in negotaitions. Feminists can benefit from learning more about HIV/AIDS specifics.

It is critical that the women's organizations can be more directly involved in the process from now on. This involvement, besides strengthening the NGO advocacy work is the only way to guarantee (at least) the retention of language and definitions consecrated in Vienna, Cairo, Beijing and the Plus Fives. The participation of women's NGOs should be as representative of the various regions from the South as possible. Various NGO mechanisms are already established for consultation and advocacy which women's organisations can support and help to improve. There is an urgent need to establish national and regional linkages and dialogue among women (and men) involved, to create a consensus on gender, human rights and sexual and reproductive rights – which is the feminist agenda – and aspects relating to the HIV epidemic, that constitute the HIV/AIDS and PLWA platform.

### **BRAZIL - People First, Profits Later**

espite opposition from corporate interests, the United States "and international adversaries of the calibre of the World Bank and the World Health Organisation" Brazil's policy of providing "free and universal distribution of anti-retroviral medication for AIDS treatment in the public health system" has been so successful that it is difficult to accept arguments against such a policy without appearing evil, unprincipled and inhuman.

Jane Glavão who holds a doctorate in public health, works in the Health Ministry National STD and AIDS Coordinating Committee International Cooperation and is a member of the Citizenship and Reproduction Commission Governing Council, Brazil outlines why Brazil has been successful in an article on Brazilian policy of anti-retroviral medication distribution - an exception or a right?

"Although the decision to distribute medication may be viewed as a technical and political choice, mobilisation of civil society has been a key for its maintenance." One of the lessons to be drawn from the Brazilian response to the HIV/AIDS epidemic is the importance of mobilizing civil society, particularly people living with HIV/AIDS to participate in the decision making process at the earliest opportunity. This process has helped to maintain and expand the rights of HIV/AIDS victims in Brazil.

Key elements in the success of the distribution system were the existence of united Health System (SUS), a network of professionals trained in HIV/AIDS diagnosis, and the strengthening of public laboratories. Criteria to administer anti-retrovial drugs were dawn up by advisory committees for adults, adolescents and children. And "patient support has proven to be a key element in patient adherence to the treatment." The cost is totally funded by the National Treasury through the Health Ministry.

Distribution of medication for opportunistic infections was initiated in 1998. Anti-retroviral therapy was first offered in 1991 but the triple therapy, known as the "cocktail" took off after the XI International AIDS Conference held in Vancouver (Canada) in 1996.

In the 1980-June 2000 period, a total of 190,949 AIDS cases were registered – 143,000 men and 47,949 women. It's estimated that in 2001 around 90,000 patients will receive anti-retroviral medication in the country (95% adults and adolescents, and 5% children) – see http://www.aids.gov.br.

An estimated 536,000 people are infected with HIV in Brazil, in the 15-49 age group. Of these, 181,609 are women and 12,898 are pregnant (or 0.4% of all the country's pregnant women). For this reason, Brazil is adopting HIV monitoring for pregnant women, aimed at preventing vertical HIV transmission. The recommendations are as follows:

- Universal offer of anti-HIV tests during prenatal care
- Chemoprophylaxis for pregnant women, starting in the 14<sup>th</sup> week of pregnancy, during labor, and for the newly born baby.
- Replacing breast-feeding with artificial milk or pasteurized human milk, available from milk banks<sup>9</sup>

The federal government is charged with acquisition of anti-retroviral drugs, while state and municipal

governments are responsible for purchasing the drugs needed to treat AIDS-related infections". The evolution of Brazil's expenditures are as follows:

	Percentage of Health		
	budget		
1996 – US\$ 34 million	0.24 %		
1997 – US\$ 224 million	1.19%		
1998 – US\$ 305 million	1.82%		
1999 – US\$ 335 million	3.18%		
2000 – US\$ 332 million	3 %		

"The main arguments of opponents to so-called developing countries allocating funds to purchase these medications focus on their cost, adherence to treatment, and possible failure to take or receive the medication. One of the consequences is the highly debated appearance of more resistant virus strains. They recommend that those countries should invest in prevention, not in treatment. Despite difficulties, the Brazilian policy has proven that prevention cannot be dissociated from assistance and treatment".

The Brazilian government has demonstrated how the involvement of civil society to implement state funded activities that promote the rights of everybody to treatment and information, can be a winning combination.

Access to anti-retroviral drugs is related to costs, production of medicines, the pharmaceutical industry, and legislation on patents and its intersection with national priorities. How Brazil has handled opposition from the US and pharmaceutical companies provides some important lessons for other countries. Brazil's universal distribution policy has been possible "due to the innovative approach of disregarding certain patents". A decree by the President - which is allowed for under the WTO rules and regulations - where compulsory licensing is allowed in cases of national emergency and public interest. Brazil defines public interest as "facts related, among others, to public health, nutrition, defense of the environment, as well as those of paramount importance for the country's technological and socioeconomic development."

Brazil's policy of providing free medical treatment for people with AIDS has also led to an increase in domestic production, transfer of technological know-how in production, centralized purchasing, storage, and distribution of

### The WTO TRIPS Agreement

The 1994 WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), introduced after sustained lobbying by TNCs, was the most significant extension of patenting rights in the twentieth century. It obliges member states to grant at least 20-year patent protection in all fields of technology, including medicines. This enables already powerful pharmaceutical TNCs to consolidate their market domination on a global scale. Longer patent periods delay the appearance of the low-cost generic equivalents which traditionally supply developing-country needs. Only the expensive, patented version of new medicines will be available. At a time when millions of people are already unable to afford essential medicines, and when public health is threatened by a combination of new diseases and drug-resistant variants of old killers, WTO rules will further reduce access to modern medicines.



From P6

medicaments. "In 1999, 47% of the anti-retroviral drugs, equivalent to 19% of the expenditures, were purchased from national companies (92% from state-run laboratories and 7% from the private sector), while 53% of the drugs, corresponding to 81% of expenditures, were acquired from multinational pharmaceutical industries. Currently, six state-run laboratories manufacture seven out of twelve anti-retroviral drugs used.

Although selling in the international market isn't a priority yet—"the possibility of fulfilling occasional needs of anti-retroviral drugs on the part of partner countries could be considered".

In the 1995-99 period, deaths were reduced by 54% in São Paulo, and 48% in Rio de Janeiro. It's estimated that around US\$ 472 million were saved through decreasing costs of hospitalization and treatment of opportunistic infections

For further information, (http://www.aids.gov.br)

From: Oxfam Briefing paper

TRIPS was just one of the agreements signed at the conclusion of the Uruguay Round of multilateral trade talks. Countries could not opt out of any of the agreements, nor register a reservation on specific clauses – it was an indivisible package. Many developing countries did not fully understand the implications of the TRIPS agreement. Others knew it was not to their advantage, but expected gains from other agreements, such as greater access to rich-country markets for their exports. Regrettably, those expectations have not been met.



#### The threat of a good example

Corporate fears that their commercial interests in Brazil's large pharmaceutical market are under threat are compounded by anxiety about Brazil's example spreading to other countries. Indeed, Brazil has offered to supply other poor countries with advice, technology and ARVs for dealing with HIV/AIDS, and is an international leader on the broader issue of access to medicines. For example, at the 1999 World Health Assembly, despite vehement opposition from the US delegation, Brazil pressed for an active role for the World Health Organisation in monitoring the price of medicines world-wide and in evaluating the impact of WTO patent rules. In June 2001, it proposed to the UN General Assembly special session on HIV/AIDS that developing countries should be able to make or import generic drugs for treating AIDS and opportunistic infections. As President Cardoso said recently in the New York Times, 'Brazil has raised this banner because it is a cause that has to do with the very survival of some countries, especially the poor ones of Africa... This is a political and moral issue, a truly dramatic situation...'. These actions by Brazil form part of a larger international movement seeking to ensure that vital drugs are affordable to poor people and poor countries. It is this broader context which helps explain why Brazil is now in the firing line for its medicines and patents policies. Oxfam

One of the lessons learnt from the Brazil experience is the need to stand up to the US and the powerful drug lobby. The response from Brazil's Minister of Health to threats and criticisms from the White House Trade Office (USTR) is "a good example of how a government, in the interests of the health and well-being of its people, responds to a defender of corporations" The United States is not accustomed to Latin American countries defending their own interests.

### Brazil's Minister of Health response to the USTR

In response to US criticism of its Free Distribution of Aids Drugs for All Programme, Brazil's Minister of Health, José Serra charged the US with being protectionist because it "resorts to all manner of non-tariff barriers in order to obstruct Latin American exports from entering its market". Citing specific examples (steel and orange juice) which has resulted in Brazil "shouldering huge trade deficits with the United States since the middle of the last decade", the Minister highlighted the hypocrisy of the United States using free trade arguments when in fact the White House Trade Office (USTR) is defending the selfinterest of the phamaceutical industry " which has a disproportionate influence on the Bush administration. ... It is of course well known that the USTR specialises in the defence of the interests of the American economy and not in global free trade".

Accused of violating WTO regulations, the Minister pointed out that "in Brazil, we are effectively doing nothing that the United States is not doing itself".

Brazil's Patents Law "adheres scrupulously to the guidelines of the World Trade Organisation of which the United States is a signatory. This law sets forth two options for compulsory licensing. The first applies when

the production of a particular drug is not carried out in Brazil after a period of three years has elapsed. The other is when the prices of certain patented drugs are considered abusive".

The first measure has not been employed to date. "The United States has a similar measure in its own legislation but, as usual, the United States does not wish other countries to adopt legal measures that the United States has already adopted in defence of its own interests".

"The second measure has not been used either, but the ... fact that we might be prepared to do so has led to a number of foreign laboratories to lower their prices - Merk -Sharp reduced the price of two AIDS drugs for Brazil by two and a half times. This has resulted in a saving for Brazil of \$US 40 million per annum ".

While the Government of the United States is critical of the Brazilian AIDS programme, many others - the United Nations, the World Bank and the American press, consider it to be "one of ... - if not the very best - in the whole world." The statement concludes: "There is no way that the Brazilian Government will retreat on this issue".



#### MAKING A PROTEST

Angela
Freitas, left,
and Sonia
Corrêa in an
anti-United
States protest
in support of
Brazil's right
to produce
and distribute
HIV/AIDS
drugs and to
put people
before profit.

### **Declaration of Commitment on HIV/AIDS**

### "Global Crisis - Global Action"

The draft declaration which was prepared by UNAIDS experts acknowledges many of the "best practices" which have been learnt after over two decades of HIV/AIDS prevention efforts. One of these "best practices" is the importance of the "full involvement and participation of people living with HIV/AIDS, young people and civil society actors in the design, planning, implementation and evaluation of programmes" (Section 33). First discussed with NGOs, members of civil society and others active in HIV/AIDS-related work in February 2001, the consultation process continued in May.

While the process to reach agreement on the proposed Declaration was fraught with problems, there is no doubt that the efforts of NGOs including DAWN ensured improved wording of many sections of the Declaration. Much remains to be done. DAWN representative Angela Freitas pointed out in her report "official delegations lacked basic knowledge on HIV/AIDS." Another "best practice" is respect for and implementation of the provisions of three UN instruments - the Convention on the Elimination of Discrimination Against Women, the Convention on the Rights of the Child and the Universal Declaration on Human Rights. The Declaration identifies issues which organisations working with marginalised groups such as women, youth, children and People living with HIV/AIDS should jointly pursue at the national, regional and international levels. It acknowledges care and support for people with HIV/AIDS including the availability of affordable drugs, as an essential component of prevention efforts. And it sets specific targets and suggestions for monitoring and evaluation.

#### Some examples:

#### Acknowledgement of special vulnerability of women

Section 4 notes "with grave concern that all people ... are affected by the HIV/AIDS epidemic, further noting that people in developing countries are the most affected and that women, young adults and children, in particular girls, are the most vulnerable;

**Section 14** stresses "that gender equality and the empowerment of women are fundamental elements in the reduction of the vulnerability of women and girls to HIV/AIDS";

Section 75 acknowledges that Conflicts and disasters contribute to the spread of HIV/AIDS and that ... internally displaced persons and in particular, women and children, are at increased risk of exposure to HIV infection;

### With regards to Access to medicines, the declaration recognizes that:

"access to medication in the context of pandemics such as HIV/AIDS is one of the fundamental elements to achieve progressively the full realization of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health" (Section 15)

"effective prevention, care and treatment strategies will require ... increased availability of and non-discriminatory access to, inter alia, vaccines, condoms, microbicides, lubricants, sterile injecting equipment, drugs including anti-retroviral therapy, diagnostics and related technologies as well as increased research and development (section 23);

"the cost availability and affordability of drugs and related technology are significant factors to be reviewed and addressed in all aspects ... there is a need to reduce the cost of these drugs and technologies in close collaboration with the private sector and pharmaceutical companies" (section 24); and acknowledges that

"the lack of affordable pharmaceuticals and of feasible supply structures and health systems continue to hinder an effective response to HIV/AIDS in many countries, especially for the poorest people and recalling efforts to make drugs available at low prices for those in need (section 25) welcomed the efforts of countries to promote innovation and the development of domestic industries consistent with international law in order to increase access to medicines to protect the health of their populations; and noting that the impact of international trade agreements on access to or local manufacturing of, essential drugs and on the development of new drugs needs to be further evaluated (section 26).

#### Target:-

By 2005: reduce the proportion of infants infected with HIV by 20 per cent, and by 50 per cent by 2010, by: ensuring that 80 per cent of pregnant women accessing antenatal care have information, counselling and other HIV prevention services available to them, increasing the availability of and by providing access for HIV-infected women and babies to effective treatment to reduce mother-to-child transmission of HIV, as well as through effective interventions for HIV-infected women, including voluntary and confidential counselling and testing, access to treatment, especially anti-retroviral therapy and, where appropriate, breast milk substitutes and the provision of a continuum of care; (section 54)

#### At the Global level

Explore, with a view to improving equity in access to essential drugs, the feasibility of developing and implementing, in collaboration with non-governmental organizations and other concerned partners, systems for voluntary monitoring and reporting of global drug prices; (section 103)

The Declaration emphasizes that Care, support and treatment are fundamental elements of an effective response and sets the following targets

By 2003: ensure that national strategies, supported by regional and international strategies, are developed in close collaboration with all sectors ... to strengthen health care systems and address factors affecting the provision of HIV-related drugs, including antiretroviral drugs, inter alia affordability and pricing, including differential pricing, and technical and health care systems capacity. ...in an urgent manner make every effort to: provide ... the highest attainable standard of treatment for HIV/AIDS, including the prevention and treatment of opportunistic infections, and effective use of quality-controlled anti-retroviral therapy ...; to cooperate constructively in strengthening pharmaceutical policies and practices, including those applicable to generic drugs and intellectual property regimes, in order to further promote innovation and the development of domestic industries consistent with international law; (section 55)

ensure that national strategies are developed in order to provide psycho-social care for individul and young people by: ensuring access of both girls and boys to primary and secondary education, including on HIV/AIDS in curricula for adolescents; ensuring safe and secure environments, especially for young girls; expanding good quality youth-friendly information and sexual health education and counselling service; strengthening reproductive and sexual health programmes; and involving families and young people in planning, implementing and evaluating HIV/AIDS prevention and care programmes, to the extent possible;

develop and/or strengthen national strategies, policies and programmes, supported by regional and international initiatives ... through a participatory approach, to promote and protect the health of those identifiable groups which currently have high or increasing rates of HIV infection or which public health information indicates are at greatest risk of and most vulnerable to new infection as indicated by such factors as the local history of the epidemic, poverty, sexual practices, drug using behaviour, livelihood, institutional location, disrupted social structures and population movements forced or otherwise;

#### Specific Targets set

9. Welcoming the commitments of African Heads of State or Government, at the Abuja Special Summit in April 2001, particularly their pledge to set a target of allocating at least 15 per cent of their annual national budgets for the improvement of the health sector to help address the HIV/AIDS epidemic; and recognizing that action to reach this target, by those countries whose resources are limited, will need to be complemented by increased international assistance;

#### Need for an integrated approach

11. Recognizing that poverty, underdevelopment and illiteracy are among the principal contributing factors to the spread of HIV/AIDS and noting with grave concern that HIV/AIDS is compounding poverty and is now reversing or impeding development in many countries and should therefore be addressed in an integrated manner;

#### Research and development

section 70 - 74 highlights that "with no cure for HIV/AIDS yet found, further research and development is crucial"

#### Resources

The HIV/AIDS challenge cannot be met without new, additional and sustained resources.

Section 80-90 deals with resources required to implement the Declaration. It aims at a target of annual expenditure of US\$ 7 billion and US\$ 10 billion by 2005, calls on the international community to provide assistance for HIV/AIDS prevention, care and treatment in developing countries on a grant basis; urges developed countries ... to strive to meet the targets of 0.7 per cent of their gross national product for overall official development assistance and the targets of earmarking 0.15 per cent to 0.20 per cent of gross national product as official development assistance for least developed countries ... and ... without further delay implement the enhanced Heavily Indebted Poor Country (HIPC) Initiative and agree to cancel all bilateral official debts of HIPC countries as soon as possible, especially those most affected by HIV/AIDS, in return for their making demonstrable commitments to poverty eradication and urge the use of debt service savings to finance poverty eradication programmes, particularly for HIV/AIDS prevention, treatment, care and support and other infections (section 87).

The Declaration calls "for speedy and concerted action to address effectively the debt problems of least developed countries, ... particularly those affected by HIV/AIDS ... debt reduction, such as debt swaps for projects aimed at the prevention, care and treatment of HIV/AIDS; (section 88)

The Declaration expresses "Support the establishment, on an urgent basis, of a global HIV/AIDS and health fund to finance an urgent and expanded response to the epidemic based on an integrated approach to prevention, care, support and treatment and to assist Governments inter alia in their efforts to combat HIV/AIDS with due priority to the most affected countries, notably in sub-

Saharan Africa and the Caribbean and to those countries at high risk, mobilize contributions to the fund from public and private sources with a special appeal to donor countries, foundations, the business community including pharmaceutical companies, the private sector, philanthropists and wealthy individuals; (section 90).

#### Global AIDS and Health fund

UNGASS "achieved a high degree of consensus that the new fund would focus on HIV/AIDS, tuberculosis and malaria, would promote an integrated approach to the three diseases, and would be geared to strengthening and expanding existing development processes rather than designing new projects. It is planned that the fund will be up and running by the end of 2001. It will be open for contributions from governments, foundations, the private sector and individuals."

#### **UNGASS Fact Sheet**

As of 7 August, contributions pledged to the Global AIDS and Health Fund amounted to just under US\$ 1,400 million. (Source: <a href="http://www.un.org/News/ossg/aids.htm">http://www.un.org/News/ossg/aids.htm</a>)



### Regional HIV/AIDS statistics and features, end of 2000

Region Epidemic star with HIV Adult prevalen (#) for adults living with HIV/Al	ce rate (*)		en living with HI tive adults who			children newly infected de(s) of transmission
Sub-Sahara Africa	late ' 70s early	' 80s	25.3 million	3.8 million	8.8%	55% Hetero
North Africa & Middle East	late '80s	400 000	80 000	0.2%	40%	Hetero, IDU
South & South-East Asia	late '80s	5.8 million	780 000	0.56%	35%	Hetero, IDU
East Asia & Pacific	late '80s	640 000	130 000	0.07%	13%	IDU, Hetero, MSM
Latin America late '70s early	' 60s	1.4 million	150 000	0.5%	25%	MSM, IDU, Hetero
Caribbean late '70s early	' 60s	390 000	60 000	2.3%	35%	Hetero, MSM
Eastern Europe & Central Asi	a Early ' 90s	700 000	250 000	0.35%	25%	IDU
Western Europe	late ' 70s early	' 80s	540 000	30 000	0.24%	25% MSM, IDU
North America late '70s early	′ ' 80s	920 000	45 000	0.6%	20%	MSM, IDU, Hetero
Australia & New Zealand	late ' 70s early	' 80s	15 000	500	0.13%	10% MSM
TOTAL	36.1 million	5.3 million	1.1%	47%		

<sup>\*</sup> The proportion of adults (15 to 49 years of age) living with HIV/AIDS in 2000, using 2000 population numbers # Hetero (heterosexual transmission), IDU (transmission through injecting dug use), MSM (transmission among men who have sex with men)

Source: UNAIDS

#### **FORUM 2000 DECLARATION**

The persons and organisations which work in human rights, participating at the Conference on Horizontal Technical Cooperation in Latin America and the Caribbean on HIV – AIDS, Forum 2000 in Rio de Janiero, 7 - 11th November, 2000:

- Exhort UNAIDS to adopt a proactive behaviour leading to concrete results related to the universal access to all the medicines in all the countries where there is no access.
- Ask UN to declare HIV-AIDS a problem of humanity and therefore all the scientific research
  related with the subject are a universal good, taking effective measures to liberate patents, review
  TRIPS agreements to minimize the negative consequences on public health in the so called
  developing countries, as well as effectively support the use of the exceptions which exist in the
  current TRIPS agreements.
- Ask governments to assume the political responsibility for universal access to HIV-AIDS medicines.
- Ask international agencies which support countries where there is no access to drugs to recommend governments to take effective decisions.
- Exhort countries to allow the production and importing of generic medicines, and to act in solidarity through collaboration in technological transference with the countries with few resources.
- Demand an immediate and drastic price reduction on medicines for countries with few resources, as already done with vaccines.
- Regret the absence or the small number of PWHIV/AIDS from countries with few resources, in the Region, in this Forum such as Haiti, El Salvador, Honduras, Paraguay, Belice, among others.
- Exhort persons and organizations to present complaints to the Interamerican Commission on Human Rights and The UN Human Rights Committee Humanos since their decisions are compulsory for member States.
- We adhere to the Rio de Janeiro Declaration presented at the Community Forum which preceded Forum 2000.

The 54th World Health Assembly held in Geneva in May 2001 agreed on a Resolution on Scaling up the Response to HIV/AIDS The preamble to the recommendations made by the 54th World Health Assembly recognised that:-

AIDS is a crisis of unprecedented proportions that threatens development, social-cohesion, political stability, life expectancy and places a devastating burden on many countries and regions;

effective drugs to prevent and treat opportunistic infections exist and are urgently needed and can be made rapidly available; where it has been available, antiretroviral therapy has reduced mortality and prolonged healthy lives, that recent reductions in prices create a new opportunity to extend this benefit to those that would otherwise not be able to afford them;

various regional initiatives, including the Declaration of the Heads of African States to tackle HIV/AIDS, tuberculosis and other infectious diseases as an integral part of the agenda for promoting poverty reduction and sustainable development and the Declaration of Quebec City of the heads of State and Governments which emphasises that good health and equal access to medical attention, health services and affordable medical drugs are vital for human development and for achievement of

political, economic and social objectives;

the Assembly also recalled 'efforts to make drugs available at lower prices for those most in need' and that the Constitution of the World Health Organisation provides that the enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition, and considering that progressive realisation of that right should involve access, on a non-discriminatory basis, to health facilities, prevention, care, treatment and support in the context of HIV/AIDS;

acknowledged that: the lack of affordable pharmaceuticals continue to be an obstacle as is the lack of feasible supply structures and health systems to an effective response to HIV/AIDS in many countries and especially for the poorest people ... all countries must continue to emphasise widespread and effective prevention, including ... access to inter alia vaccines, condoms, microbiocides and drugs.

#### **RIO DE JANEIRO DECLARATION**

The persons and organizations at the Latin American and Caribbean Community Forum on HIV-AIDS, held in Rio de Janeiro, from November, 5th to 6th, 2000:

- Demand the US government to withdraw the complain against patent laws in Argentina and Brazil at the WTO.
- At the same time we complain against the interference of the US government in the elaboration of the Dominican Republic patent laws.
- Demand Latin American and Caribbean governments an adequate and strict control of the quality of drugs approves and distributed by the private or public networks, produced locally or abroad, not taking into account neither who produces nor commercializes them, nor if they have or lack approval in other countries or institutions, be they patented or off-patent.
- The States should provide permanently the national regulatory institutions with the appropriate human and economic resources humanos y economicos to verify the quality of all drugs.
- We demand WTO, WHO, PAHO, UNAIDS and the governments of the so called
- developed countries to ensure that patent legislation serve the right to life, health and human dignity and do not constitute an obstacle for the access to treatment of the persons which require them.
- We also ask the so called developed countries to oppose pressures and measures against legislation which facilitates the delivery or trading or production of drugs.
- We call on WTO, WHO, UNAIDS, and governments to support that the right to life, health and human dignity be superior to the economic rights.
- We demand the pharmaceutical companies to withdraw or liberate patents of HIV-AIDS drugs and other severe conditions in the so called developing countries.
- We demand the pharmaceutical companies not try to use persons or organizations which work or live with HIV-AIDS to favour their own interests.

### PLEA FROM NGOs - Listen to us

Many representatives from NGOs and groups traveled to New York in response to an invitation from the President of the General Assembly, eager to participate in the consultations before the UN General Assembly's Special Session on HIV/AIDS. The General Assembly had passed a resolution calling for involvement of civil society in the development of a Declaration of Commitment to be signed by all 189 UN member states in June. The NGOs quickly discovered the reality of the UN's declared commitment to work more closely with NGOs and civil society groups. While a handful of countries supported civil society's contributions, two brief "dialogue" sessions - scheduled during 'dead hours' - went unattended by the majority of countries. The United States made a formal complaint resulting in all NGO representatives being asked to leave the room, including those with ECOSOC accreditation who are normally entitled to observe country delegation negotiations. The inexperience of NGOs with the UN system, the lack of support from the Secretariat and the attitude of delegations caused a lot of frustrations. This led to the NGOs issuing a demand for more meaningful inclusion in the process.

### Countries snub HIV/AIDS and human rights experts:

NGOs call upon UNAIDS, UN Secretary-General Kofi Annan, and President of the General Assembly Harry Holkeri to:

- encourage member states to include civil society and particularly people living with HIV/AIDS on their national delegations to the June meeting,
- encourage member states to attend the sessions

- they themselves have billed as a "dialogue" with civil society, ·
- ensure that civil society representatives can
  participate meaningfully in the discussions by
  having access to preparatory processes between
  now and the June meeting, and in June being
  present in the observers gallery and having access
  to official delegates.

If civil society experts are to have so little

### **Brazil - Shredding Myths and Lighting the Way**

Until a year ago, the estimated 32.5 million people in the developing world living with HIV had little hope of survival. The triple therapy (announced in 1996) that has made AIDS manageable in wealthy nations was not within the reach of the poor because of three things - cost, attitude and timing. The only AIDS-prevention means available to poor countries was through educational programs and condom promotion; or to cut mother-to-child transmission and treating some opportunistic infections.

Brazil has "shredded" these three myths and inspired developing countries to realise that access to cheaper medicines and treatments is within their reach, Tina Rosenberg writes in her article, "Patent laws are malleable. Patients are educable. Drug companies are vincible. The world's AIDS crisis is solvable". (See www.dawn.org.fj) Ms Rosenberg movingly interweaves personal stories with efforts by countries to make lower cost drugs available to people living with HIV/AIDS; the obstacles they faced including the "dubious" arguments of the powerful drug companies and the role of the United States Government.

"Brazil is showing that no one who dies of AIDS dies of natural causes. Those who die have been failed—by feckless leaders who see weapons as more alluring purchases than medicines, by wealthy countries

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#### From P13

opportunity to address the Assembly, it becomes all the more important that they be present to observe the proceedings.

The marginalization of civil society bodes ill for the achievement of serious political commitment to global and domestic leadership on AIDS. "This policy of marginalization, along with the failure to provide adequate interpreters for the NGO sector, significantly affects people living with HIV/AIDS from countries of Eastern Europe, which are the groups most effective in influencing the passiveness of the official delegations from their countries," said a representative of the All-Ukraine Network of People Living with HIV/AIDS.

Leadership must be shown by both developed and developing nations. Wealthy nations must:

- commit to canceling the debt of developing countries;
- contribute substantial resources towards a minimum \$16 billion global fund for HIV/AIDS;
- take immediate steps towards meeting their agreed upon commitments to allocate 0.7 percent of GDP towards overseas development assistance;
- immediately cease pressuring those countries that act to protect and promote the health of their people.

NGOs around the world call upon all developed and developing countries to demonstrate their political will by:

- increasing domestic funds for responding to HIV/ AIDS.
- taking immediate legislative and other initiatives to secure access to low-cost, safe and effective treatment, including antiretroviral medication

immediately compiling an international Drugs
 Pricing Data Bank containing information about
 drug procurement and manufacturers, to provide
 data for the management of national policies in
 respect of access to anti-retrovirals and drugs for
 the treatment of opportunistic infections.

Governments cannot betray the public trust by rolling back the international commitments they have already made to respond to this global crisis. Some governments are pushing for weaker commitment to the promotion, protection and fulfillment of basic human rights than already exist in international instruments. "If countries are unwilling to even name those groups most affected and at risk - such as men who have sex with men, injecting drug users, transgendered individuals and sex workers - then the declared commitment rings hollow," said Richard Elliott of the Canadian HIV/AIDS Legal Network. Global Treatment Access Campaign: Action Ciudadana Contra el SIDA, Venezuela ACT UP New York, USA All-Ukraine Network of People Living with HIV/ AIDS, Ukraine

Canadian AIDS Society, Canada
Canadian Treatment Advocates Council
Canadian HIV/AIDS Legal Network, Canada
Development Alternatives with Women for a New
Era (DAWN), Brazil
Health GAP Coalition, USA

International Gay & Lesbian Human Rights Comm. International HIV/AIDS Alliance, UK Lawyers' Collective, India

Norwegian NGO working group for UNGASS on HIV/AIDS

(notably the United States) that have threatened the livelihood of poor nations who seek to manufacture cheap medicine and by the multinational drug companies who have kept the price of antiretroviral drugs needlessly out of reach of the vast majority of the world's population ". Can the Brazil experience be replicated in other countries? Rosenberg concludes a resounding yes for virtually all the countries of Latin America and Eastern Europe, most of Asia and the former Soviet Union and at least 10 countries in sub-Saharan Africa. Pilot programs in Ivory Coast and Uganda show that at well-run clinics, patients have the same rate of adherence as in Europe and the United States. Countries would need international help - to establish effective health services and distribution systems; to create more awareness about the effects of the drug companies' policies on the lives of poor people and to promote political commitment. In other words, the debate about whether poor countries can treat AIDS is over, Rosenberg writes, the question is how.

#### Some excerpts from Ms Rosenberg's article.

#### **Shredding Myths**

Health system too fragile? On the shaky foundation of its public health service, Brazil built a well-run network of AIDS clinics. Uneducated people can't stick to the complicated regime of pills? Patients must stick to a rigorous and complicated schedule of pills, some taken with food, some without. Failure to do this can create a more resistant strain of virus. Brazilian AIDS patients have proved just as able to take their medicine on time as patients in the United States. The benefits of Brazil's program have been enormous. In 1994, the World Bank estimated that by 2000 Brazil would have 1.2 million H.I.V.-positive people. In fact it had half that many. The epidemic has stabilized, with some 20,000 new cases each year for the last three years. The treatment program has cut the AIDS death rate nationally by about 50 percent so far, and each AIDS patient is only a quarter as likely to be hospitalized as before. It has also improved the overall state of public health. Involvement of community groups and civil society, especially people with HIV/AIDS in the planning, implementation and support for the programme is a major reason for Brazil's success. But it is how Brazil has reduced the cost of drugs which has caused problems for those who are more concerned with profits than human lives.

#### How Brazil cut the cost of drugs

Brazil does not pay market prices for antiretroviral drugs. In 1998, the government began making copies of brand-name drugs. The price of those medicines has fallen by an average of 79 percent. Brazil now produces some triple therapy for \$3,000 a year, with the potential of dropping to \$700 a year or even less.

By defying the pharmaceutical companies and threatening to break patents, among other actions (all within the WTO rules), Brazil has made drugs available to everyone who needs them rather than continuing to accept the wisdom of allowing pharmaceutical companies to enjoy a 20-year monopoly to sell their drugs at whatever prices they choose. While the pharmaceuticals and the rich have thrived under this system and new drugs

have been invented, for billions of people the medicines have remained out of reach.

Since Brazil started making generics of AIDS drugs, their cost has plummeted. The price of AIDS drugs with no Brazilian generic equivalent dropped 9 percent from 1996 to 2000. The price of those that compete with generics from Brazilian labs dropped 79 percent. But just the credible threat of generic competition is enough to get manufacturers to lower their prices.

Poor countries must use the provision of the existing rules of international trade to be exempt from this contract. And developed countries and international assistance agencies must help rather than obstruct efforts to save people from AIDS. Brazil has been able to treat AIDS because it had what everyone agrees is the single most important requirement for doing so: political commitment.

#### Why not use compulsory licensing?

There is no legal reason that other countries cannot do the same as Brazil. Those who may be bound by international trade rules can use the WTO loophole that allows countries to make copies of patented items in certain situations, including that of a national emergency. Compulsory licensing is the term used where countries can manufacture or import a generic copy of a drug, paying the patent holder a reasonable royalty. Of all the tools available to poor countries, compulsory licensing is what the drug companies fear the most, since it represents the most direct assault on control of their patents The United States has issued compulsory licenses in situations far less dire than those of AIDS-ravaged poor nations. Recent ones have been for tow trucks, stainless-steel wheels and corn seeds. According to a WTO official, governments could also choose to import generic drugs instead of making them.

Reasons cited for why countries have not used compulsory licensing to get cheap medicines include lack of political commitment, corruption or opposition from the powerful drug companies and the threat of trade sanctions by the United States Government. they were willing to lower their prices. The economies

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### **Excerpts from Oxfam Briefing paper**

An excellent summary of the issues appears in Oxfam Briefing paper *Drug Companies vs. Brazil: The Threat to Public Health* May 2001. This briefing was prepared by the Policy Department of Oxfam (Great Britain) for Oxfam International as part of the 'Cut the Cost of Medicines' campaign. DAWN has been supporting this campaign All campaign reports are available on the Oxfam GB website (www.oxfam.org.uk). These include more detailed analyses of the issues concerning access to medicines, particularly in relation to patent rules and corporate social responsibility, as well as Oxfam's coverage of the legal action brought by pharmaceutical companies against South Africa. http://www.oxfamamerica.org/news/cutcost.html

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#### Corporate pressure on Brazil

The dispute between the drug companies and Brazil is currently focused on the price of two of the twelve anti-retrovirals (ARVs) needed by Brazil for effective treatment of the virus. The two medicines, efavirenz and nelfinavir, are expensive, consuming a third of the ARV budget. The price is high because they are under patent in Brazil, and therefore cannot be copied by local manufacturers or imported from generic suppliers. At the end of March 2001, after lengthy negotiation, Brazil finally

#### Rosenberg from P15

of scale and guaranteed markets could drop the price of a year's triple therapy to below the \$700 that Cipla could muster today.

This is a price many countries could afford, especially when balanced against the savings in hospitalizations. But everyone agrees that AIDS treatment will require North America and Europe to purchase the medicines and to help set up the necessary health care network. In my calculus, applying the UNICEF system to AIDS would cost \$3 billion a year in antiretrovirals alone, assuming five million patients at \$600 a year. And the cost will increase as countries reach more patients. This is a large sum of money. It seems somewhat smaller, however, next to the wards of shaven-head babies or the collapse of a continent.

#### What the US can do

It is difficult to imagine the Bush administration endorsing such a global plan. There are, however, smaller, worthwhile steps the administration could take if it were so inclined. It should bury forever the bad old policy of intimidating countries that want to make or buy generics, especially through compulsory licensing. It can encourage agencies like the World Health Organization and UNAIDS to facilitate these purchases and the necessary training to make them work.

reached agreement on price with one of the patentholders, the US-based pharmaceutical giant, Merck & Co. Talks continue with the Swiss firm, Hoffman-La Roche, which has exclusive rights to market nelfinavir in Brazil under an agreement with Pfizer, the US patent holder. In both cases, the Brazilian government has warned the companies that, if they do not bring their prices down to affordable levels, it will override the 'market exclusivity' rights conferred by the patents, and authorise local production by Far-Manguinhos, the State-run Institute of Pharmaceutical Technology. It is important to note that this procedure, known as 'compulsory licensing', does not rescind the patent and, under WTO patent rules, requires payment of royalties to the patent holder. In order to be prepared for production, Far-Manguinhos has imported the necessary raw materials for testing and research from India. In March 2001, Merck wrote to say that it considered Far-Manguinhos was thereby infringing its patent rights. The Ministry of Health denied this allegation, and the matter remains unresolved to date.

The battle over these two drugs is the latest chapter in more than a decade of corporate pressure on Brazil to change its medicines policy and patent regime. Although PhRMA gives credit to Brazil for having introduced pharmaceutical patents in 1997, it maintains a steady barrage of complaints over important details of legislation and practice. In December 2000, it objected strongly to tougher price controls on medicines. The companies regularly use the threat of disinvestment to influence health policies, but through their close relationship with the Office of the US Trade Representative (USTR) they have a superior weapon: US trade sanctions, either applied unilaterally or approved by the WTO.

#### US government action against Brazil at WTO

The dispute at the WTO initiated by the USA places a considerable burden on Brazil and represents an intensification of US pressure on the country. The formal complaint focuses on aspects of Brazil's 1996 Industrial

Property Law. If the US government wins the case, Brazil must amend its law, or face penal tariffs on its exports to

the USA, authorised by the WTO. All other WTO member states will have to ensure that their legislation is consistent with the ruling. Oxfam is calling on the US government to withdraw the complaint. If the case proceeds, Oxfam believes the WTO should find in favour of Brazil on both legal and public interest grounds.

The technical arguments in the case are complex, but can be summarised as follows. Brazilian law permits the government to require a company in any industry to manufacture a patented product inside the country within three years of patent approval. If the patent holder does not meet this requirement, the government may override the patent and allow thirdparty manufacture, or liberalise the import of the patented product from the cheapest international source, without the patentholder's consent. This legislation could be used to encourage drug companies to produce essential medicines inside Brazil, thus reducing the high foreignexchange cost and ensuring the development of a domestic pharmaceutical

industry. It can also be used as a negotiating tool to pressure companies to reduce the high price of imported medicines. The USA claims that the law discriminates against imported products and therefore infringes WTO patent rules, known as the Agreement on Trade-Related Aspects of International Property Rights (TRIPS). The Brazilian government argues that US trade lawyers are disregarding the fact that Brazil's provision for local

manufacture of a patented product is a safeguard which can be invoked only in a case of 'abuse of rights or

> economic power' by a patent holder, and, as such, that it is TRIPS-compliant.

#### Conclusion

If the US government and the pharmaceutical companies get their way, Brazil's ability to provide needed medication to the half-million HIV-positive people in the country, or to provide other essential medicines at affordable prices, will be jeopardised. This will cause considerable human suffering in a country where sixty million people are impoverished.

Brazil, and any other developing country, will be prevented by WTO rules from insisting that patented products be produced locally, a measure which can ensure the development of a domestic pharmaceutical industry, bring down drug prices, and reduce the foreign-exchange costs, thus ensuring more secure and affordable access to medicines. If Brazil is also prevented from allowing parallel imports in cases where there is no local production, the prices of medicines will be higher than need be, with corresponding hardship for patients and their families. With the loss of both these policy options, the Brazilian health ministry would be in a much weaker position to negotiate affordable prices with the big drug companies. If PhRMA succeeds in obtaining the additional policy reforms that it seeks, the control of new medicines will be largely in the hands of a few international drug companies. This would cripple the government's ability to manage its medicines policy for the public good.

Brazil's successful resistance to pressure from the US government and the pharmaceutical companies, like that of South Africa, would have symbolic and political significance in the broader battle over rival priorities in global economic management - human development or corporate profit. More immediately, it would influence the fate of hundreds of thousands of people with HIV/AIDS, and a far larger number of impoverished people in desperate need of cheaper medicines.

### Threats to Brazil's medicines policy

Concerted action on HIV/AIDS by the Brazilian government and grassroots groups has averted a human calamity. In the early 1990s, it looked as though Brazil was heading for an AIDS crisis of devastating proportions. UN forecasts spoke of millions falling victim to the virus. Today, the number of HIV-positive people is estimated at half a million, a figure which is still far too high, but which can be seen as a positive result for policies in place since the mid-1990s. According to government figures, there has been an 80 per cent drop in hospitalisations for AIDSrelated diseases, and a 50 per cent drop in mortality rates since 1996, 146,000 hospitalisations have been avoided between 1997 and 1999, saving the health services US\$422 million. If one counts in the cost of drugs used to treat opportunistic infections, the savings are nearer to US\$500 million. UNAIDS, the UN Secretary General Kofi Annan, and many others have publicly praised these

achievements.

A factor in controlling the AIDS epidemic in Brazil has certainly been the intense effort in education and prevention, much of it carried out by voluntary groups, activists, and NGOs. A UNAIDS study, for example, showed that young people in Brazil were possibly the best-informed about HIV in the world. Another important

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## A Challenge to India: universal AIDS

India is another dismaying example of the HIV/AIDS epidemic. India does not recognize patents on medicine, and world trade rules do not require it do so until 2005. While Indian firms lead the world in the manufacture of generic AIDS drugs and offers the lowest prices for AIDS medicines. So why hasn't the Indian Government introduced free medicines for people with HIV/AIDS? Two arguments are provided - the difficulties of providing counselling, monitoring and compliance and cost. But as C. Rammanohar Reddy writes in an article in The Hindu, May 12, 2001 "Even for a developing country these are not arguments but only excuses to avoid providing care" Reddy convincingly argues that in the absence of universal therapy for its estimated 4 million Indians now infected with HIV, "the tragedy will become a catastrophe that is likely to surpass what is now unfolding in Africa." A summary follows:-

Indian pharmaceutical firms can offer AIDS medicines for an export price \$350 a year per patient, compared to US\$10,000 to \$12,000 in developed countries. But the Indian Government has shown no interest in providing free universal care to its HIV-infected population.

The Government have offered two reasons for why universal care is not possible in India: that counselling, monitoring and compliance are as important as affordability of drugs; and that even at \$350 a year the AIDS cocktail is not affordable in a country where the per capita annual income is only \$440.

But Brazil has shown that a successful programme can run on active health care combined with provision of generic versions of AIDS drugs is produced locally. And given the prices Indian industry has been able to offer plus the experience of Indian doctors there is no reason why India cannot administer

a similar programme to cope with its AIDS epidemic.

A careful listing of costs suggests that universal and free HIV therapy is feasible in India. A universal AIDS care programme in India would cost as little as 0.28 to 0.35 per cent of India's GDP. The Government has indeed considered a limited HAART programme. According to Mr. J. V. R. Prasada Rao, Director of the National Aids Control Organisation (NACO), it was unaffordable because this would be more than Central Government spending on all public health programmes (Rs. 810 crores in 2001-02). The NACO Director is hoping instead that India will receive some assistance from the proposed \$7-10 billion health fund which the U.N. is proposing for malaria, TB and AIDS.

The present compliance rates of 90 per cent and the success of the Brazil programme have clearly demonstrated it is possible for a poor country to devise an innovative compliance regime. There are no reasons

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factor in reducing transmission, morbidity, and death has been the free distribution of ARVs since 1996, including those needed to stop mother-to-child transmission. Currently, the health service provides free ARV treatment to 95,000 people. This is only possible because ten of the twelve drugs needed are not patented in Brazil and can therefore be produced as generics, without paying the royalties or monopoly prices that have to be paid in industrialised countries. Brazil was spending around US\$8,000 per patient per year in 1997. By increasing generic production, the annual cost halved by the year 2000, and is now just over US\$3,000. Thanks to hard bargaining with the companies, the price will fall further. These figures contrast sharply with the US\$10,000 cost per patient in the USA.

Aside from its HIV/AIDS programme, the Brazilian government has also been lauded for its National Drug Policy, launched in 1998. Dr Gro Harlem Brundtland, Director of the World Health Organisation, visiting Brazil last year, spoke warmly about the policy's stress on generic medicines, which she believes 'can make

drug markets more competitive and efficient and can contribute to the goals of improved equity, quality and efficiency in health... The current changes occurring in the Brazilian health sector represent an excellent opportunity to promote and benefit from these strategies.'

### Why Brazil can produce generic versions of new drugs, but not for long

Brazil did not adopt pharmaceutical patenting until 1996. It could therefore legally produce equivalents of expensive medicines patented before that date in the industrialised countries, or import them from India, which also did not have patenting on pharmaceutical products. Both countries are now obliged by the WTO TRIPS agreement to have national legislation in place by 2005 which provides patent terms of at least 20 years for all products and processes. The fact that Brazil met this requirement nearly ten years early is testimony to the intensity of US economic and political pressure, including the use of trade sanctions, although it also reflects a weak commitment on the part of the Brazilian government to a more independent economic development strategy.

Dawn Informs Supplement

### care is feasible

why improvements in other health areas in Brazil cannot happen in India. The growth of the Indian drug industry - already manufacturing up to 14 types of drugs - and its capabilities means that they can produce enough drugs for a universal programme. The low cost AIDS cocktails being produced in India were all patented before 1994 - prior to the TRIPS agreement of the WTO. It has been argued that patents on the next and more effective generation of drugs are likely to be protected by TRIPS, so local production will violate the WTO agreement. The Government can issue compulsory licences - provided for in TRIPS - to Indian firms so that they can produce and sell these drugs at affordable prices.

A 5 per cent surcharge on corporate and personal income taxes will yield enough to finance this universal programme. In the absence of such a programme, no more than 5 to 10 per cent of the HIV carriers, those who can afford the medicines, will be on HAART. The rest will have to make do with treatment

DAWN protested to US President Bush on 26 January and sent the following letter:

"We are outraged by recent statements in relation to the prevention and treatment of AIDS in Africa made by your new chief of the U.S. Agency for International Development, Andrew Natsios, in testimony before the House International Relations Committee, as reported in the Boston Globe last week.

Mr Natsios reportedly argued against giving antiretroviral drug treatment to Africans infected with HIV on the grounds that African AIDS sufferers "don't know what Western time is" and therefore cannot take anti-retroviral drugs on the proper schedule. He supplemented his argument by mis-advising that the drugs have to be 'kept frozen and all that'. He signaled that under his leadership USAID would therefore emphasise HIV preventive through "abstinence, faithfulness and the use of condoms", and through supporting the distribution of drugs that block transmission of the disease from mother to child and that fight secondary infections.

Mr Natsios' comments about Africans' inability to comprehend time are simply racist - anti-retroviral drugs are taken twice a day, which is hardly a schedule difficult to comprehend or implement. Mr Natsios' argument about inappropriate conditions in Africa for the drugs is also spurious - not a single anti-retroviral drug on the market today requires freezing.

Mr Natsios reveals ignorance of the consensus among AIDS experts on the necessity of focusing on both prevention and treatment to stem the AIDS pandemic. These experts include 140 Harvard faculty members. Mr Natsios' comments distort the true situation in Africa and are an attempt to mislead Congress. The remarks are untruthful, callous and offensive and unbecoming of the office to which he has been appointed. On behalf of the millions of African women affected by HIV and AIDS, we call on you to dismiss Mr Natsios from his new appointment as he is clearly unfit for the position."

of their "opportunistic" infections. This would only precede a gradual and wasting death from AIDS for hundreds of thousands of Indians. As HAART also contributes to a reduction in the virus transmission rate, its inaccessibility for most of the infected will only mean that the Indian population afflicted by HIV/AIDS already the second largest in the world - will keep growing.

The estimated 4 million Indians now infected with HIV cannot be abandoned to a wasting death when an affordable therapy is available. If the number of HIV infections is correct, the country is facing its biggest ever epidemic. The devastation will spare no region or socio-economic class. In the absence of universal therapy the tragedy will become a catastrophe that is likely to surpass what is now unfolding in Africa. The issue has long since ceased to be one of "violating" patents on drugs. It is one of respecting life. There is no alternative to a state-run universal and free programme that provides HIV therapy to any Indian who needs it.

#### INDIA FACING THE FIGURES

Like many other countries, the Indian establishment was in denial about the magnitude and implications for a long time. It wasn't until 1998 that NACO (National AIDS Control Organisation) began to conduct consistent HIV surveillance in each state. Thus no reliable numbers exist of the trends in overall prevalence before this period. Equally problematic, health groups and activists have had a great deal of ambivalence about HIV. Many, including some women health activists have argued that concern about HIV is being pushed in India as part of a 'western' agenda, and that India's major problems lie in traditional infectious diseases and public health issues. Nonetheless, a growing number of health groups working on the ground are doing innovative work in addressing the entire range of HIV issues - prevention, treatment, gender. sexuality, stigma, ethics. However NACO's own positions and ambivalence about the need to treat infected persons is a damper to effective programmes. The numbers are alarming in themselves. UNAIDS, June 2000, Report of the Global HIV/AIDS epidemic gives the following number for the end of 1999:

Estimated number of adults and children living with HIV/AIDS infection: 3.7 million

Adults (15-49) only: 3.2 million

Adult rate relative to the population in age-group: 0.7 %

Women (15-49): 1.3 million

Women as % of infected adults: 37 %

HIV prevalence rate (%) in young women (15-24): Low

estimate 0.4 %; High estimate 0.82 %

HIV prevalence rate (%) in young men (15-24): Low estimate 0.14%; High estimate 0.58%

Gita Sen

#### WTO DISCUSSION

### TRIPS AND PUBLIC HEALTH

On 20 June 2001 the WTO's TRIPS Council held a Special (one day) Discussion on TRIPS and Public Health. The meeting was called in response to public concerns worldwide on how patents were causing monopoly situations enabling exorbitant prices of medicines for treating AIDS and other diseases, making them unaffordable especially in developing countries. Developing countries led by the Africa Group requested the TRIPS Council to hold a special discussion. A Joint Paper was submitted by 47 developing countries, asking for action in the WTO to affirm that nothing in TRIPS prevents countries from taking measures to protect public health. Below is an excerpt from a Third World Network report of the Special Discussion of 20 June written by Cecilia Oh, TWN's Legal Advisor and Researcher.

#### **Summary and Background**

'The TRIPS Council's Special Discussion on TRIPS and Public Health was held on 20 June 2001 at the WTO headquarters in Geneva. The meeting saw an overwhelming number of WTO Members expressing the need for action before and at the Doha WTO Ministerial Conference on the issue of intellectual property rights and access to medicines.

Forty seven developing countries (including the African Group of countries, and countries from Asia, Latin America and the Caribbean) put forward a joint statement to the TRIPS Council, asking the Doha Ministerial Conference to take steps to ensure that "the TRIPS Agreement does not in any way undermine the legitimate right of WTO Members to formulate their own public health policies and implement them by adopting measures to protect public health".

The developing countries wanted affirmation of this common understanding as soon as possible, in order to clarify the differing (and restrictive) interpretations of the TRIPS provisions being advanced by some developed countries. They expressed concern that such restrictive interpretations would unduly limit their rights to undertake the full range of public health policy measures, for fear of legal challenge, either in domestic courts or before the WTO dispute settlement mechanism. Most countries which took the floor during the Special Discussion, including a number of developed countries, expressed support for the proposal for a clear statement by the WTO Ministerial Conference in November. The EC had welcomed the Special Discussion as a means of laying the ground for a "fruitful process" towards Doha. Norway's statement (which many regarded to be the most forthcoming and developing country-friendly among the statements of the developed countries) suggested that developed countries should exercise due restraint with respect to the dispute settlement actions, until legal certainty on the TRIPS provisions was achieved.

Towards the end of the morning session, many developing country delegates were hopeful that there

would be consensus on the way forward. The US statement, due after lunch, was keenly awaited. However, it turned out to be a disappointment.

The US statement seemed furthest away from the general line taken by the majority of the countries. In taking the position that strong patent regimes can produce benefits for countries, whether they be developed or developing, the US had refused to acknowledge the concerns of developing countries that TRIPS implementation would have negative implications for access to affordable medicines.

The TRIPS Council had agreed to hold the Special Discussion amidst growing public pressures — from developing countries and their governments, and public health and civil society groups in the South and the North — to address concerns that implementation of the TRIPS Agreement are having and will continue to have negative consequences on the access to, and availability of, affordable medicines.

#### The Follow Up Process

The TRIPS Council heard over 40 statements from Members, during the Special Discussion, which finally concluded around 8.00pm on the night of 20 June. By the end of the session, it was clear that the majority of the countries regarded the Special Discussion as only the start of a continuing process, with a tangible result expected at the end.

The next day, the Chairman of the TRIPS Council, Ambassador Boniface Chidyausiku of Zimbabwe, held informal consultations with Members for their views on the way forward. On the last day of the TRIPS Council meeting, Members agreed to an informal meeting scheduled for July 25, for further discussions. It is expected that a checklist of issues will be presented to Members to guide their discussions. It was also agreed that the TRIPS Council would hold another one-day Special Discussion on 19 September as part of its next formal meeting.

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