24th June Demonstration - Invest in Health Not War

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Call for Global Demonstrations on 24 June 2004 to Demand that the Bush Administration:

- Reduce Military Spending and War Actions: Spend More Money on AIDS, Tuberculosis, Malaria, Malnutrition and Poverty;
- Help Ensure that the World Health Organization's Plan to Treat Three Million People with AIDS by 2005 Receives the Resources it Needs to Succeed;
- Stop Undermining Public Confidence in Safe, Effective Anti-AIDS Medicines;
- Stop Using AIDS Money to Marginalise Minorities and Undermine Access to Condoms and Reproductive Choices;
- Stop Pursuing a Pseudo-Scientific Response to the HIV Epidemic;
- Stop Using Bilateral Pressure to Undermine the Doha Declaration on TRIPS and Public Health;
- Give the Promised $15 Billion for AIDS to the Global Fund to Fight AIDS, TB and Malaria (GFATM) - Not the US President's AIDS fund (known as PEPFAR).

We, the undersigned, are organisations from around the world that campaign for human rights, the alleviation of the HIV epidemic and women's rights to reproductive choices. We are deeply disturbed by the actions and policies of the Bush Administration that undermine the prevention and treatment of AIDS. The effect of the US government's unlawful war in Iraq has been to divert international attention away from global health and poverty. Hundreds of billions of dollars are being spent on the military instead of investing resources in the biggest threats to human security today: AIDS, TB, malaria, malnutrition and poverty.

In 2003, the United Nations estimated that 2.5-3.5 million people died of AIDS, one million of malaria and two million of TB, yet these diseases can be treated. An estimated 800 million people endured malnutrition, which continues to play a major role in half of the more than ten million annual child deaths in the developing world. In many countries women undergo back-street abortions and risk death because they are denied the right to make reproductive choices. Inappropriate moral judgments stigmatise condom use and distribution, thereby putting millions of people at risk of

HIV and other sexually-transmitted infections. The spread of HIV is fuelled by the oppression of sexual minorities and draconian legislation aimed at sex workers and intravenous drug users. Successfully reducing HIV infections and giving more people with AIDS access to life-saving medicines requires the promotion of human rights and investment in developing world health systems. The World Health Organization (WHO) has called for three million people with AIDS to be treated with life-saving antiretroviral medicines by 2005, but the Bush Administration has shown little political will for promoting this objective or human rights.

In January 2003, the Bush Administration promised $15 billion over the next five years to alleviate the HIV epidemic. This was cautiously welcomed by human rights and AIDS organisations. Yet the expenditure approved by the US Congress as part of this commitment for 2004 is only $2.4 billion. The total amount of US aid money for 2004 is $17.55 billion. Yet the military budget approved for 2004 is already $368.2 billion, an amount that does not reflect the $87 billion war supplemental requested by the Bush Administration. Much of this military budget is being used to fight the so-called War Against Terror and to sustain the occupation of Iraq. We acknowledge the threat of terrorism. However, the most important and widespread threats to global security are the ones exacerbated by poverty and lack of development: the HIV, malaria and tuberculosis epidemics, as well as malnutrition. Alleviating these problems together with promoting human rights and negotiating solutions to world problems through international institutions is the best way to ensure long-term global security. This was partially recognised by the Clinton Administration when it declared AIDS a national and global security threat in late April 2000.

Unfortunately, the Bush Administration has shown insufficient regard for these problems, as well as for the expertise of international institutions such as the United Nations, the WHO and the GFATM. The Bush Administration's stance on key prevention and treatment issues contradicts the extensively researched positions of these international institutions. For example, a third of PEPFAR's prevention funds are earmarked for abstinence-until-marriage programmes. While promoting delayed sexual activity is an important part of life-skills education, this should not be framed in moral judgments concerning marriage or at the expense of condom promotion and distribution, especially to youth. The Bush Administration refuses to acknowledge the vital importance of access to and information about condoms in the general population and it has been party to unscientific actions and statements questioning the efficacy of condoms, for example removing information on condoms from the website of the US Centers for Disease Control. President Bush has also taken the extraordinary step of reinstating and extending the Reagan-era Global Gag Rule on family planning organisations, cutting US funding as well as donations of contraceptives when these organisations provide information on abortion to their patients. We are concerned that current US policy is informed by a religious fundamentalist agenda. Furthermore, obstacles continue to be placed in the way of accessing more affordable medicines, by blocking competition between generic medicines and patented brand-name drugs. In particular, the Bush Administration is blocking access to generic fixed-dose combination medicines that will allow more people with AIDS in the developing world to go onto life-saving antiretroviral treatment and reduce the number of pills they need to take on a daily basis.

The Bush Administration has placed religious fundamentalist convictions above science, undermining access to and use of condoms, reproductive choices and access to generic medicines. This has lead to a critical editorial in the prestigious medical journal The Lancet describing US policy on HIV/AIDS as "perhaps one of the best examples of ideology impeding sound public health policy."* While the South African government has been correctly criticised extensively for its unscientific approach to the HIV epidemic (which now seems to be changing slowly), it is the Bush Administration that now champions irrational responses to the epidemic.

We therefore call for an International Day of Action on 24 June 2004 to say to the Bush Administration: **Invest in Health, Not War!**

** Lancet Reference: 2002 Jul 13; 360 (9327): 97.*

Questions and Answers

How much money did the Bush Administration pledge to alleviating AIDS in Africa and the Caribbean and how much has actually been given?

In his annual State of the Union address in January 2003, President Bush announced the provision of an additional $10 billion to AIDS programmes in Africa and the Caribbean. This should have brought to $15 billion the US government's total commitment following a $5 billion allocation under the Clinton Administration that had yet to be disbursed. The US Congress eventually appropriated $2.4 billion in 2004, and the total amount released so far is just $350 million.

To whom is the money being given?
Most of the money is intended for distribution through the bilateral President's Emergency Plan for AIDS Relief (PEPFAR), which currently targets 14 countries: Botswana, Cote d'Ivoire, Ethiopia, Guyana, Haiti, Kenya, Mozambique, Namibia, Nigeria, Rwanda, South Africa, Tanzania, Uganda and Zambia. A relatively small portion of the Bush Administration's pledge, just $1 billion over five years, is intended for the GFATM.

What is the GFATM?
The Global Fund to Fight AIDS, TB and Malaria (GFATM) is an independent, multilateral institution established in 2002 with the purpose of funding programmes in developing countries aimed at treating and preventing the three highest-mortality infectious diseases in the world. Its success is necessary for the WHO to meet its goal of treating three million people with AIDS by 2005. The GFATM aims to constitute a major source of the $27 billion in economic assistance to developing countries that the WHO Commission on Macroeconomics and Health has suggested is needed by 2007 (growing to $38 billion by 2015), yet the GFATM remains underfunded, receiving only $658 million so far in 2004. Partly this is due to the US government failing to commit sufficient funds to it, but the European Union, Canada, Australia and Japan all need to contribute more money to the Fund.

The trend of attempting to foil efforts to access cheaper generic medicines has continued over the past few months. Members of the Bush Administration have undermined public confidence in the safety and efficacy of fixed-dose combination (FDC) generic antiretroviral medicines approved by the WHO. These medicines are an essential, affordable tool for the treatment of HIV on a massive scale. The Bush Administration clearly would prefer to use PEPFAR money to purchase brand-name antiretrovirals, in order to satisfy the drug manufacturers among its campaign donors. The Administration's allegations against generic FDCs, particularly those announced by Mr. Randall Tobias, the former CEO of Eli Lilly appointed by President Bush to be the US Global AIDS Coordinator, are based on pseudo-science. Despite the unity of expert opinion at the US-initiated FDC conference in Botswana this past March that the current standards in place for approving fixed-dose combinations are acceptable, the Bush Administration has persisted with this agenda.

In late April, Mr. Tobias stated, "Maybe [FDC] drugs are safe and effective. Maybe these drugs are, in fact, exact duplicates of the research-based drugs [sold in the United States]. Maybe they aren't. Nobody really knows." (Zavis, Associated Press, 28 April) This is incorrect. The WHO has put in place a stringent process, known as prequalification, for recommending antiretroviral medicines that are safe and effective. The term prequalified is used because it is still the prerogative of each country's own regulating authorities to approve the drugs for domestic use. To date, ten fixed-dose combination medicines have been prequalified. In South Africa, at least one FDC containing an entire antiretroviral regimen is awaiting approval by the Medicines Control Council (MCC), and it is already widely used through special exemptions granted by the MCC. Tobias' statement, made in South Africa, was aimed at fuelling the already confused debate in the country about the safety and efficacy of antiretroviral medicines.

Generic medicines have to be shown to be pharmacologically equivalent to brand-name medicines before they are approved. The usual (and best) way of demonstrating this is through what is called a bioequivalence test. The bioequivalence standard requires similar quantities and availability of the active ingredient in brand-name and generic formulations, and is defined by absorption parameters generally falling between 80% and 125% of those obtained with the brand-name drug under the same testing conditions. The FDCs prequalified by the WHO have successfully passed bioequivalence tests. Mr. Tobias certainly was not questioning the use of bioequivalence for approving generics. Most generic medicines approved by the US Food and Drug Administration (FDA) are approved based on bioequivalence testing. Therefore, Tobias could only have been calling into question the fact that generic FDC antiretrovirals combine

the two or three drugs against which they are tested for bioequivalence into one pill. What he and other apologists for the Bush Administration seem to be suggesting is that generic FDC antiretrovirals can only be approved once they go through clinical trials. But this is unacceptable because there is no reason to believe that combining the medicines into one pill materially affects the validity of bioequivalence. Many combination medicines, both brand-name and generic, are approved by regulatory authorities around the world (including the FDA) and there is nothing inherent about drugs being in combination that affects their safety or efficacy. Indeed, one of the most important medicines in South Africa's public health system is a four-in-one tuberculosis FDC. It has been used for a number of years and benefited thousands of patients and it was approved on the basis of bioequivalence, not full clinical trials. It is particularly ironic that the Bush Administration has a sudden concern for the safety and efficacy of extensively-tested essential medicines when it certainly does not show the same concerns with regard to genetically modified foods, which might in the long run prove safe but certainly are not essential.

Following criticism of Mr. Tobias' unsustainable arguments at a recent high-profile WHO meeting, the Bush Administration has retreated and released a statement saying that FDC manufacturers can apply for fast-tracked approval through the FDA to become eligible for purchase through PEPFAR funds. This was to head off further embarrassment at a World Health Assembly meeting. However, while this compromise suggests a position that is more reasonable than the one articulated by Mr. Tobias, it is still insufficient. The FDA is responsible for regulating medicines in the United States, although some other countries take their cue from FDA registrations. WHO prequalification should be sufficient for donors and the decision to distribute FDCs should lie with countries' own regulatory authorities. Applying for FDA approval is usually a time-consuming and expensive process, costing hundreds of thousands of dollars, and it is questionable whether there is sufficient incentive for generic companies to pursue an FDA application. While the statement admitted the possibility of waiving FDA fees and reducing application times to six weeks, this has been stated in vague terms. At least one US official has already stated that six weeks is the best-case scenario and is only realistic for combinations of separate drugs packaged in the same blister packs, which are not the same thing as FDCs.

This latest compromise by the Bush Administration is part of a long history of blocking access to generics and then relenting when faced with pressure. The trend has been that as the possibility of distributing generic medicines has come closer, the US government has done everything it can to create obstacles to their availability.

If the Bush Administration proceeds with its new policy that FDCs must be registered with the FDA before PEPFAR funds can purchase them, then it must at a minimum commit unambiguously to the waiving of FDA fees and registration within no more than six weeks of application. Bureaucratic delays in distributing medicines to developing countries have a very tangible cost: lost lives.

If the Bush Administration donated most of its AIDS relief funds to the GFATM, which can and does fund the purchase of generic antiretrovirals, the issue of PEPFAR being restricted to FDA-approved drugs would largely disappear.

How has the Bush Adminstration undermined access to condoms in developing countries?
As early as mid-2001, the Bush Administration removed all references to condom effectiveness from the US Centers for Disease Control website. Subsequent funding allocations and policy documents render it clear that the Administratrion views condom promotion as appropriate primarily for so-called high risk groups. In reality, individuals who engage in any kind of sexual activity at any stage of their lives must have the information to protect themselves and their partners and the ability to act on that information through unrestricted access to contraceptives and reproductive choice. While PEPFAR does not openly ban funding for comprehensive sex education or condom promotion, a full 1/3 of the Plan's prevention funds are reserved for promoting abstinence-until-marriage (this restriction is advisory for 2004-5 but becomes mandatory in 2006). This funding structure is unrealistic and refuses to take into account the complex social and economic problems that put young people at risk for early sexual activity and exposure to HIV.

How has the Bush Adminstration undermined access to reproductive choices in developing countries?
The so-called Mexico City Policy, also known as the Global Gag Rule, was first established by US President Ronald

Reagan in 1984, prohibiting any organisation receiving family planning funds from the US Agency for International Development (USAID) from providing information about abortion. The Global Gag Rule was later suspended by President Bill Clinton, but reinstated in January 2001 as one of the Bush Administration's first official acts. In August 2003, President Bush extended the Gag Rule to cover US Department of State funds as well. Many of the affected family planning organisations that choose to reject the Gag Rule's restrictions then find themselves unable to obtain donated USAID contraceptives and are forced to cut services and raise fees.

Why is the Bush Administration against reproductive choice and condom access?
President Bush and many members of his Administration use religion to excuse intolerant fundamentalist political policies. They believe that abortion and condom use are wrong. They fail to understand that access to condoms is an essential component of any large-scale workable HIV prevention strategy and that reproductive choices, including the right to an abortion, are critical for the empowerment of women in the developing world.

What are fixed-dose combination (FDC) antiretroviral medicines?
Fixed-dose combination antiretroviral medicines are an important breakthrough for treating people with AIDS, because they combine some or all the antiretroviral medicines a patient has to take into one pill. In general, three different antiretroviral medicines have to be taken twice daily by people on treatment. This used to require patients to take many pills a day -- as many as 18 not being uncommon. Research in a South African hospital has shown that the number of pills patients take a day is a critical factor affecting patient adherence to their treatment. (AIDS. 2003 Jun 13;17(9):1369-75.) Patient adherence is critical to the success of treatment and reducing drug resistance. With the gradual improvement of antiretroviral technology, pill counts have come down for most patients. Some fixed-dose combination medicines reduce the pill count to two pills a day.

Furthermore, because the only three-in-one FDCs are manufactured by generic companies, they are frequently cheaper than the equivalent, but separate, medicines produced by brand-name companies.

How has the Bush Administration undermined access to generic fixed-dose combination antiretroviral medicines used for treating AIDS?
The US government's undermining of access to cheaper medicines precedes the Bush Administration. The pharmaceutical lobby is a powerful force in US politics and contributes generously to presidential elections, usually to both Democrat and Republican candidates. Its primary interest is to protect itself against competition from cheaper generic medicines, by lobbying for more stringent patent protection both in the US and internationally. Under the Clinton Administration, South Africa was placed on a trade watch-list when it enacted legislation to make medicines more accessible. Following activist pressure, the Administration relented. (Since his Presidency, Mr. Clinton's foundation has worked to reduce the prices of AIDS medicines, particularly generics, as well as monitoring tools.)

The Bush Administration has a worse record on blocking access to affordable medicines than the Clinton Administration. It attempted to stop a World Trade Organization agreement at Doha, Qatar, which improves access to generic medicines for poor countries. Again, following activist pressure and a firm, unified stance by developing world negotiators, the US government backed down. Paragraph 6 of the the Doha Agreement left certain matters unresolved, so the Bush Administration advocated for a resolution of the paragraph that would have restricted access to generic medicines. Again activist pressure coupled with a firm stance by developing world negotiators resulted in the US backing down. Nevertheless, the Bush Administration continues to undermine the Doha Declaration by pursuing bilateral trade agreements with developing countries, reducing the options for making generic medicines more accessible that these countries would otherwise have under the Doha Declaration.

Suggested Actions for 24 June:
Pickets at or marches to US consulates and embassies, letter-writing and fax campaigns to the White House, US

embassies and consulates, press conferences, awareness events.

The following **organisations** have called for the International Day of Action on 24 June:

Action for Southern Africa (ACTSA), UK
ActUP/Cleveland, USA
ActUP/New York, USA
ActUP/Philadelphia, USA
Actwid Kongadzem NGO, Cameroon
Advocacy and Monitoring Network on Sustainable Development, Japan
Advocators of Processes of HIV/AIDS Programs, Kenya
Africa Action, USA
Africa Japan Forum, Japan
Alternative Information and Development Centre (AIDC), South Africa
AIDES, France
AIDS Acess Foundation, Thailand
AIDS Consortium, South Africa
AIDS Law Project, South Africa
AIDS Law Unit, Namibia
AIDS Legal Network, South Africa
AIDS Task Force of Greater Cleveland, USA
L'Alliance des Radios Communautaires (ARCOM), Mali
American Friends Service Committee (AFSC), USA
Artists for a New South Africa (ANSA), USA
Anti-Privitisation Forum, South Africa
Asia Japan Partnership Network for Poverty Reduction, Japan
Association de lutte contre le SIDA, Morocco
Association Espoir et VIE, France
Association Espoir pour Demain, France
Basic Income Grant Coalition (BIG), South Africa
Blue Diamond Society, Nepal
BUKO Pharma-Kampagne, Germany
The Centre AIDS NGO, Zimbabwe
Centre for Health Policy, Systems, Research and Analysis for Development, Mwanza
Children First, South Africa
Childolescent & Family Survival Organization, Nigeria
Common Ground, USA
Community HIV/AIDS Mobilization Project (CHAMP), USA
Ealing, Hammersmith and Fulham and Hounslow (EHH) London HIV Forum, UK
Egyptian Initiative for Personal Rights, Egypt
European AIDS Treatment Group (EATG), Europe
Feminist Women's Health Centre in Berlin, Germany
Friends of TAC (FoTAC), UK
Friends of TAC (FoTAC), USA
Gay Mens Health Crisis (GMHC), USA
Gays and Lesbians of Zimbabwe (GALZ), Zimbabwe
Georgian Plus Group, Georgia
Global Network of People Living with HIV/AIDS (GNP+)
Global AIDS Alliance, USA
Globalise Resistance, UK
Gruopo Portugues de Activistas sobre Tratamentos (GAT), Portugal
Grupo de Trabajo sobre Tratamientos del VIH/SIDA (gTt), Spain
Health & Development Networks (HDN), Thailand
Health GAP, USA
Healthpartners, Kenya
Hispanasida, Spain
HIV i-Base, UK
Housing Works, Inc., USA
International Community of Women Living with HIV/AIDS (ICW), UK
Intimate Friends Internationa, Cameroon
JOSRA Project, Kenya
Living Hope Organization, Nigeria
Make Art/Stop AIDS, India & USA
MASANGANE Treatment Project, South Africa
Minority AIDS Project, USA
MWENGO, Zimbabwe

New Mexico AIDS InfoNet, USA
Network Against AIDS (BSV Pacifist Peace Network), Germany
Network Earth Village, Japan
OneDiaspora Project, USA
Pan African Treatment Access Movement (PATAM), Africa
Paedagogics for Peace, Germany
Plus and Minus Foundation, Bulgaria
Positive Movement Belarus, Belarus
Positive Muslims, South Africa
Progressive Organization of Gays in the Philippines, Philippines
Rape Crisis Cape Town Trust, South Africa
Regional Network for Equality in Health (EQUINET), Zimbabwe
Reproductive Rights Alliance, South Africa
Rural Health Resources, USA
South Africa Development Fund, USA
South African Communist Party (SACP), South Africa
Southern African Contact, Denmark
Soweto Electricity Crisis Committee, South Africa
Student Christian Movement of Germany (ESG), Germany
Thai AIDS Treatment Action Group (TTAG), Thailand
Tanzania Gender Networking Programme (TGNP), Tanzania
Thai Drug Users' Network (TDN), Thailand
Thai Network of People Living with HIV/AIDS (TNP+), Thailand
Thai NGO Coalition on AIDS (TNCA), Thailand
Treatment Action Campaign (TAC), South Africa
Union Aid Abroad (APHEDO), Australia
Universities Allied for Access to Essential Medicines, USA, UK & Canada Youth Empowered to Succeed (YES), Kenya

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- US Government

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