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ACCESS TO ARV TREATMENT:
AID, TRADE AND GOVERNANCE IN UGANDA

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Contents

Abstracts

Access to antiretroviral medicines (ARVs) for AIDS treatment creates a field binding local and global governance. Local modalities of AIDS treatment are governed by the context of global trade through the implementation of patents on medicines in the World Trade Organisation (WTO), and within the context of global aid through development assistance. While industrialized countries, on the one hand, set aside donations to fight AIDS in developing countries, on the other hand, the same countries use the WTO to prevent developing countries from accessing cheap medicines. Uganda's success in reducing HIV prevalence is unique among African states, and it is considered the most promising candidate for effectively "scaling up" ARV treatment on the basis of its history of dealing with the pandemic. Yet, despite the many interventions addressing HIV/AIDS and dramatic price reductions of ARVs, only a minority of the infected population is currently receiving treatment, and promises of universal coverage for all who need it seem unrealistic. Our paper examines how the disconnect between international and national priorities on the one hand, and between aid and trade on the other, are currently affecting access to ARVs in Uganda. In spite of the political discourse of equality in treatment, the realities of funding suggest the difficult choices will be made from the level of policy to that of individual. Thus, global governance of trade and of aid will both shape and rely on individuals in charge of "implementation" which must be examined outside the sanitizing context of development discourse. We introduce our use of governance in this paper, and then discuss the global governance of aid to AIDS and global governance of trade and AIDS. The second half of the paper examines the Ugandan case study beginning with a political background and examination of aids policy, followed by the history of ARV provision and advocacy for ARVs, a discussion of the national health system and then aid initiatives and trade of ARVs in Uganda. Finally, we draw preliminary conclusions from our case on the conflicts between global and local governance of trade and aid to AIDS.

Adgang til Anti-retroviral (ARV) medicin til behandling af AIDS i udviklingslandene skaber nye koblinger mellem lokal og global regulering. Lokale tilgange til behandling af AIDS er reguleret dels inden for de retningslinier for patenter på medicin, der gælder i den globale regulering af handel i verdenshandelsorganisationen (WTO), og dels de reguleringsformer der eksisterer inden for international udviklingsbistand. Mens industrialiserede lande på den ene side donerer penge til bekæmpelse af AIDS i udviklingslande, sætter de samme lande begrænsninger for adgang til billig medicin gennem WTOs handelsregime. Ugandas succes i forhold til bekæmpelse af AIDS er unik blandt afrikanske stater. På basis af landets historiske tilgang til epidemien, bliver Uganda set som et godt land for opgradering af programmer til AIDS

behandling. På trods af dette, de mange tiltag på AIDS området og reduktioner i prisen på AIDS medicin, er det kun en minoritet af den smittede del af befolkningen, der har adgang til AIDS medicin i dag. I dette working paper undersøger vi, hvilke konflikter der er mellem internationale og nationale prioriteter på den ene side, og mellem udviklingsbistand og international handelsregulering på den anden side, samt hvordan disse konflikter påvirker adgangen til ARV medicin i Uganda. I modsætning til den politiske diskurs om lige adgang til behandling, er international bistand forbundet med svære prioriteringer på nationalt og individuelt niveau. Derfor bliver global regulering af både handel og bistand påvirket og skabt af de individer der implementerer reguleringen nationalt. Først introducerer vi vores brug af begrebet 'governance' (regulering), som bliver brugt i forbindelse med global regulering af udviklingsbistand og handel i relation til AIDS. I den anden halvdel af working paperet ser vi på Uganda som case: den politiske baggrund og udviklingen i Ugandas AIDS-politik, Ugandas programmer og tiltag for adgang til ARV medicin, en diskussion af det nationale sundhedssystem og endelig ARVs set i sammenhæng med handel. I konklusionen præsenterer vi ud fra casen, hvilke konflikter der kan ses i mellem globale og lokale reguleringsformer for adgang til AIDS medicin og hhv. handel og bistand til AIDS

Introduction

Access to antiretroviral medicines (ARVs) for AIDS treatment creates a field binding local and global governance. AIDS is now a pandemic threatening the stability and socio-economic viability of most developing countries, especially countries in the sub-Saharan Africa, and it is creating new and conflicting governance assignments (De Waal 2003, Boone & Batsell 2001). Important conclusions from recent studies on national governance and AIDS show that a strong and engaged government is of major importance in combating AIDS at the national level, but these governments are lacking finance and infrastructure to run the programs needed for treatment (Putzel 2003, Lurie 2004). The examples of Thailand and Brazil demonstrate the importance of pairing prevention with treatment to combat HIV&AIDS. However, engagement in treatment requires renegotiating local, national and global governance.

"Governance" of AIDS can be analyzed at the global level though looking at the twin regimes of governance of trade and governance of aid. At the local level, governance implies the processes of coordinating a multi-sectoral prevention effort with a functioning system of national health care service provision. Developing country governments have a central role in local governance of AIDS as "governments must be at the centre of AIDS prevention and treatment efforts" (Boone & Batsell 2001:13). Yet the legacy of the neo-liberal politics of 1980s and structurally-adjusted economies has not left developing countries well-equipped to meet the challenge of HIV/AIDS. While there is an obvious need for rebuilding the economic infrastructure, social service delivery systems and state institutions (Lurie 2004, Boone & Batsell 2001) in light of the pandemic, global and local processes of governance must also be understood and altered if these systemic changes are to take hold.

Local modalities of AIDS treatment are governed by the context of *global trade* through the implementation of patents on medicines in the World Trade Organisation (WTO), and within the context of *global aid* through development assistance by multi-lateral AIDS initiatives and bilateral agencies. While industrialized countries, on the one hand, set aside donations to fight AIDS in developing countries, on the other hand, the same countries use the WTO to prevent developing countries from accessing cheap medicines. The Trade-Related Intellectual Property Rights (TRIPs) agreement should govern global trade to allow developing countries to disregard the most strident property-rights protections for medicines, but this did not lead to increased ARV access in poor countries. Very few countries have made use of provisions to grant compulsory licenses and import the cheaper generic medicines. Why have developing countries not taken advantage of the opportunity to access cheaper drugs through trade?

While the context is different from country to country, trade governance must be understood in the context of international development aid. Some donor countries use bi-lateral trade negotiations to assure that the intellectual property rights of their citizens are upheld. Hence, a developing country that disregards pharmaceutical patenting may be characterized as acting against the interests of its own donors and disrupting the cooperative relationship between states who give and those who receive aid. This dilemma has been raised in recent debates such as at the International HIV/AIDS Conference in Bangkok in July 2004. The political rift between Europe and the US was enlarged by President Chirac of France who stated: "Forcing certain developing countries to drop… [WTO] measures in the framework of bilateral trade negotiations would be tantamount to blackmail" – clearly criticizing American pharmaceutical interests' power in influencing US bilateral relations.

Uganda is one of very few countries known to have successfully addressed the HIV/AIDS epidemic since its origin in the 1980s. The country's success in reducing HIV prevalence is unique among African states, and Uganda is considered the most promising candidate for effectively "scaling up" ARV treatment on the basis of its history of dealing with the pandemic. Still, AIDS is a part of the every day lives for Ugandans. Despite the many interventions addressing HIV/AIDS and dramatic price reductions of ARVs, only a minority of the infected population is currently receiving treatment, and promises of universal coverage for all who need it seem unrealistic. Our paper examines how the *disconnect between international and national priorities on the one hand, and between aid and trade on the other, are currently affecting access to ARVs in Uganda.* We introduce our use of governance in this paper, and then discuss the global governance of aid to AIDS and global governance of trade and AIDS. The second half of the paper examines the Ugandan case study beginning with a political background and examination of aids policy, followed by the history of ARV provision and advocacy for ARVs, a discussion of the national health system and then aid initiatives and trade of ARVs in Uganda. Finally, we draw preliminary conclusions from our case on the conflicts between global and local governance of trade and aid to AIDS.

Governing HIV/AIDS – a Multilevel Approach

A BRIEF BACKGROUND ON ARVS

Initially, ARVs were local technologies, confined to serve patients in medically-elite circles in the West. However, they quickly became global technologies, with both structured and unregulated transference from elites in rich countries to those in poor ones. The first ARV, Zidovudine (AZT) was approved in 1987 as a sequential monotherapy (Wohlert 2003: annex 3). AIDS treatment with ARVs changed dramatically in the mid-1990s when protease inhibitors and viral load testing were introduced. Now there are four classes of ARV treatment available and these are combined along clinical guidelines and according to the patient, resistance patterns and side-effects. Twenty of these products are now listed on the WHO Essential Drugs List covering eight different types of ARVs (WHO 2004c). Never before have drugs that are so costly been needed by so many people. The consequences of withholding them have been compared to genocide.

Thus, from their inception, the bio-medical and technical activities constituting ARVs have been enmeshed in complex social, economic and political divisions. Indeed the daunting politics of drugs is likely to be the main reason why many African governments have, thus far, concentrated their efforts toward small-scale prevention programs based on information and education (Putzel 2003). Joep Lange, President of the International AIDS Society points to national governance problems and lack of incentives for effective treatment: "In Africa we are dealing with dysfunctional states. We are pouring huge amounts of money into states that don't have the capacity to deliver. . . There is nowhere in Africa that you can't get a cold beer or a Coca-Cola. . . [yet] everybody thinks people involved in healthcare are going to deliver at no cost" (Boseley 2004).

However, addressing treatment of the epidemic would require considerable spending on health systems, testing facilities, treatment, treatment of opportunistic diseases, care, and expansion of the prevention programs already in place. The cheapest annual costs of ARV drugs for one person in the developing world ranges from $244 for generic triple-drug therapy[1] to $500-$600 for branded drugs (MSF 2004). "Standard" monitoring of ARV therapy includes regular determinations of plasma HVI-1 RNA load and peripheral blood CD4+

[1] As we will describe later in the paper, the Clinton Foundation has brokered generic prices as low as $140 per year, but these prices are not yet available and will only affect some developing countries (MSF 2004).

lymphocyte counts, and the cost exceeds that of the ARV drugs in most developing country settings (Lange 2002:4).[2] Multiplying this amount with the number of HIV-infected people who need drugs results in annual spending needs that are many times the existing annual health budgets. Therefore, the scope for developing country governments to autonomously set the agenda in treatment is extremely limited. Thus, understanding the governance regimes of ARVs requires a meaningful analysis of the interface between national and international actors. It would be naïve to surmise that equitable systems for providing life-saving drugs could exist outside their historical context of overlapping indices of inequality. Global political economy, race/ethnicity, gender, regionalism, religion, nationalism and politics will all impact the way that the ubiquitous "roll out" of ARVs will take place in developing countries, however, dealing with all these aspects altogether lies beyond the purpose of this paper.

GOVERNANCE AND AIDS

This article takes it point of departure from the concept of *governance* that emerged in development theories of the 1990s in reaction to the impasse between the state-centered and market-oriented discourses of the 1980s. Our use of *governance* deviates from the existing literature on AIDS and governance in which a state-centric use of the term marks "governance" as a government performance evaluator. In some functionalist forms of common usage, governance "is defined as performance arising from the government's ability to control and manage activities and resources to produce desired outcomes, including satisfying people's needs" (Hirst and Thompson 1996, used in Osei-Wedie 2001:56). Still determinist, but dysfunctional interpretations of AIDS and governance, such as De Waal (2003) and Pharaoh & Schönteich (2003), lay the foundation for analyzing the links between AIDS and governance, but touch very little on the realities of AIDS treatment. De Wall hypothesizes that the epidemic will cause governance crises and pose major threat to peace and security in Africa, and that "…the curtailment of life expectancy that we are witnessing in southern Africa may cause a reversal of historic processes of development" (2003:1-2), as we have not yet seen the real political and economic consequences of the disease.

With a decrease in life expectancy at birth to only 45 years, it is clear that social and political pressures on governments to deal effectively with the epidemic will grow. In Zimbabwe, average life expectancy in 2000 declined by almost 50% from 70 years to 38 years due to

[2] Less-costly mechanisms of monitoring are being tested, including field-trials in Uganda, but these are beyond the scope of this paper and are not yet considered viable for ARV monitoring.

AIDS (Pharaoh & Schönteich 2003). "Today, a generation of young Africans is growing up watching their peers fall sick and die, while the governing institutions do little or nothing" (De Waal 2004:20). AIDS has two major impacts on national governance, namely in terms of institutional capacity and political participation, as there will be a loss of human resources including experiences and networks. However, this apocalyptic interpretation of the governance impact of HIV/AIDS in Africa is lacking a substantive evidential base, and some argue that such an approach will lead to negligence and shirking of responsibility by states in the developed countries (Pharaoh & Schönteich 2003). Osei-Hwedie argues for the case of Botswana that the gravity of the HIV/AIDS situation challenges good governance primarily on the capability of the health sector to meet the needs of HIV/AIDS patients (Osei-Hwedie 2001). Our analysis also elucidates the importance of the health sector; however, we argue for Uganda that governance challenges stem from both the epidemic and its response, and we link the health sector to international politics.

Drawing on the work of Abrahamsen (2000) and others, we use a more encompassing notion of governance as developed by McCarney et al. (1995). They suggest that "governance offers a new way of thinking about development" (McCarney et al.:93), as the concept refers to the processes and actors involved in governing rather than merely the government itself as earlier development theories did. Thus, governance opens up to a broad range of actors that are not necessarily embedded in the nation state, but might exist at the global or the local community levels. Although the concept has the potential limitation of being over-encompassing, and lacking the elegance of statist models, it offers a better understanding of the often contradicting governance structures of developing countries. Our use of governance is not denying the necessity of state actors both internationally and nationally, but instead we concentrate on the dynamic processes of power negotiation that shape the parameters of action available to developing country state actors. This notion of governance processes does not imply that supportive donors, effective policies, and a functioning health care system *alone* form a sufficient constellation to save the lives of the millions who are already infected with HIV or those who are still likely to become infected in the future. Certainly, prevention campaigns, individual behavioral choices – both sexual and health-seeking – and social/cultural values also play a role in the efficacy of any treatment of the epidemic: however, our focus is on global and local governance processes of treatment that shape the context of developing country access to ARVs.

In analyzing the case of ARVs in Uganda, governance can be seen as the overlapping (or individual) actions of local, national and international/global actors as they all exercise political, economic and administrative authority in governing AIDS in Uganda (see also UNDP 1997).

In most developing countries the government is not capable or ready to drive the scale-up in AIDS treatment due to lack of infrastructure and limited financial resources. Therefore the national governments here are not directly engaged in agenda-setting– rather if seen from an overall perspective, treatment of AIDS stems from models of global governance. In fact, aid to AIDS may actually have deleterious governance implications. Brautigam and Knack (2004) show that in African countries including Uganda, high levels of aid have been associated with declines in the quality of governance. They propose that this relationship results from institutional weakening and the provision of perverse incentives that accompany large amounts of aid. If their hypotheses are correct, then aid to AIDS – a sizeable amount of largely uncoordinated aid efforts – may lead to poorer governance at the same time as it requires better governance for its success.

Aid to AIDS – A Global Perspective

In international development circles, there is a common perception that AIDS is getting the lion's share of development assistance funding and is subsuming other important development interventions due to the severity of the pandemic and the successful lobbying of AIDS organizations. However, AIDS advocates argue that in light of the number of people affected by the disease and its social, political and economic implications, development assistance for prevention and treatment of the disease is paltry. Historically, most aid money has gone toward prevention efforts, and some to palliative care and orphan support. However, international drug-access activism by groups like TAC (Treatment Action Campaign in South Africa) and MSF (Medicins Sans Frontiers), combined with decreasing drug prices, have shifted donor interest toward AIDS treatment with ARVs.

Spending on HIV/AIDS issues has increased dramatically. UNAIDS estimates that institutional spending on the disease for 2003 was $4.7 billion, representing a 20 per cent increase from the previous year's spending level and a 500 per cent increase over spending on AIDS in 1996. Of this spending, non-domestic sources make up approximately 57% of HIV/AIDS spending in all low and middle-income countries (UNAIDS 2004a). For the poorest countries, like Uganda, most of the AIDS budget comes from international donors. International development assistance for AIDS in all developing countries was approximately $1.6 billion in bilateral aid and $600 million in multilateral aid for the year 2003. The largest share of this aid went to sub-Saharan Africa (56%), followed by Asia and the Pacific (18%), Western Asia and North Africa (9%), Latin American and the Caribbean (9%) and Eastern Europe (1%) (*ibid.*, estimates are from 2000 data the most recent available by region).

Of the donors, the biggest spenders in 2003 were The Netherlands ($41,725,670), USA ($17,890,000) and Norway ($13,877,802). The largest donor over the period between 1995 and 2003 was the United States, as shown in table 1.

Table 1: Donor Contributions to the UNAIDS Core Budget 1995-2003

Rank	Donor	Total Contribution in US$
1	USA	129,390,000
2	Netherlands	114,860,653
3	Norway	62,208,704
4	Sweden	43,091,026
5	UK	39,123,796
6	Denmark	32,901,247
7	Japan	28,216,490
8	Canada	22,435,432
9	Belgium	19,503,677
10	Switzerland	15,922,214

(UNAIDS 2004a)

However, when making aid comparisons, one should note the sizable difference of GDP between the US (at $10857.2 billion GDP) with any single European country, for example, the Netherlands (at $509.3 billion GDP). Furthermore, the US spends more than $15 billion annually to combat AIDS domestically where 900,000 people are living with the disease, but less than 1/5 of this amount to fight AIDS globally, where approximately 42 million people live with AIDS (Booker 2004:5). UNAIDS estimates that US$ 12 billion will need to be spent annually on AIDS in low- and middle-income countries by 2005—a figure that is expected to rise to US$ 20 billion annually by 2007 (Hankins et al. 2004).

Yet, in spite of the increasing interest in ARV access, coverage in developing countries remains minimal. As shown in Table 2, a mere 2% of persons living in Africa who were estimated to need treatment were actually receiving it in 2003. This stands in sharp contrast to 84% of those living in the developing countries of the Americas, namely Brazil where there is a radically different commitment to state-sponsored ARV treatment for all.

Table 2: Coverage of Adults in Developing Countries with ARV Therapy

Region	Number of People on Treatment	Estimated Need	Coverage
Africa	100 000	4 400 000	2%
Americas	210 000	250 000	84%
Europe (Eastern Eur. Central Asia)	15 000	80 000	19%
Eastern Mediterranean	5 000	100 000	5%
South-East Asia	60 000	900 000	7%
Western Pacific	10 000	170 000	6%
ALL WHO Regions	400 000	5 900 000	7%

(WHO 2003:5)

There are three major funding initiatives for transferring aid to AIDS in resource-poor settings: the Global Fund to fight AIDS, Tuberculosis and Malaria (the Global Fund), the US President's Emergency Plan for AIDS Relief (PEPFAR) and the WHO and UNAIDS Global Initiative to Provide Antiretroviral Therapy to 3 Million People with HIV/AIDS in Developing Countries by the End of 2005 (WHO's 3X5 Plan). Each of these has its own project level governance requirements, and while all claim to work within existing national health systems, in practice, they are often setting the agendas of these institutions and competing for their skilled personnel.

THE GLOBAL FUND

The Global Fund is an independent, private foundation in partnership with governments, and is governed by an international board. It is strictly a funding and not an implementing agency. The Global Fund differs from bilateral initiatives in its more balanced decision-making process of including donors and recipients. Since its inception in January 2002, the Global Fund has dispersed $2 billion to 121 countries and is now in its fourth round of funding proposals (The Global Fund 2004a).

"AIDS", "drugs" and "Africa" have been dominant themes in procuring money from the Global Fund. Over three rounds, 60% of all funds have gone for HIV/AIDS,[3] 60% of all funds have gone to Africa,[4] and 46% of all funds have gone to drugs and commodities[5] (The Global Fund 2004a). Scaling-up ARV treatment has been an important part of the fund's agenda. The first outcome noted in its progress report is "More than 700,000 people on antiretrovirals, tripling current coverage in developing countries" (The Global Fund 2004a). The Fund's activities are ambitious and expensive. The Global Fund estimates that it needs $1.56 billion for 2004 and $3.58 billion for 2005 to meet the budgets of accepted proposals, however this is unlikely to happen as the funding gap for 2004 was $70 million by mid-year commitments during what has been a bumper year for aid money to AIDS (*Ibid.*). Funding comes to the Global Fund primarily from nation-states, but also from foundations and individuals on a completely voluntary basis, and commitments are thus, not legally binding.

[3] The other 23% went to malaria and 17% to tuberculosis.

[4] Compare to: 20% to Asia, Middle East and North Africa, 20% to Latin America, the Caribbean and Eastern Europe.

[5] Other expenses were 25% for human resources, 15% for physical infrastructure and the rest for monitoring and other activities.

In April 2004, recipients of Global Fund support, together with those funded by the World Bank's MAP and UNICEF, were the beneficiaries of a pricing agreement negotiated by the Clinton Foundation (The Global Fund 2004c). The Clinton Foundation negotiated with five manufacturers of ARVs[6] and five manufacturers of HIV/AIDS diagnostic tests.[7] The price for the most commonly used first line treatment regime was as low as $140 per person per year, and the prices for machines, training, reagents and maintenance is up to 80% cheaper than diagnostics previously available (*Ibid.*). In June 2004, The Global Fund committed $968 million to fund its fourth round of proposals: 70 percent of which will go to Africa and almost half of which will go to HIV/AIDS.

One of the largest contributors to the Global Fund, the US government, is not permitted by law to contribute more than 33 per cent of the total paid-in funding to the Global Fund. Officially, there are attempts to "harmonize efforts" to fight HIV/AIDS with the US PEPFAR, and to "prevent overlapping efforts and conflicting priorities" (The Global Fund 2004b). However, unofficially, the more recent PEPFAR is perceived as duplicating many of the Global Fund's activities. US President Bush requested urged the Congress to provide no more than $200 million to the Global Fund, in spite of promises to European countries that the US would contribute $1 million. Congress allocated $547 million in 2004 but Bush again requested only $200 million for the Global Fund in 2005. It seems that the US commitment to fiscal year 2005 will be reduced because sufficient funding for the remaining 67% of the budget has not been raised by other donors (McNeil 2004). While the US likes to remind other donors that it is the single largest donor to the Global Fund, this fact does not take into account the size of the US economy compared with other donors. The combined economy of EU countries is comparable to the US, but their contributions are nearly twice as much. The US secretary of health and human services, Tommy G. Thompson, became the chairman of the Global Fund in early 2003, making some other donors fear an American takeover, but the corresponding lack of financial support has suggested that PEPFAR will continue to receive US priority.

[6] Aspen Pharmacare Holdings in South Africa, and Cipla, Hetero Drugs Limited, Ranbaxy Laboratories, and Matrix Laboratories in India.

[7] Beckman Coulter, Inc. and BD (Becton, Dickinson and company), manufacturers of CD4 tests and Bayer Diagnostics, bioMerieux and Roche diagnostics, makers of viral load tests.

US PEPFAR

In US President Bush's "State of the Union" Address in January 2003, he promised a $15 billion, five year mission to combat AIDS in Africa and the Caribbean. The President's Emergency Plan for AIDS Relief (PEPFAR) would be in Bush's words, "a work of mercy beyond all current international efforts to help the people of Africa" (The White House 2003). In a May 2003 State Department ceremony with African ambassadors, Bush authorized $3 billion in spending for the first year of PEPFAR, but the 2004 budget was limited to $2 billion. Of the $15 billion, $9 billion is actually new funding going to the 15 focus countries.[8] PEPFAR spending is allocated by programs: 55% for treatment, 20% for prevention (one third of which goes to controversial abstinence-only programs), 15 % for palliative care, 10 % for orphans and vulnerable children, $1 billion over 5 years to the Global Fund and $5 billion to bilateral HIV/AIDS programs. PEPFAR's funding modalities that require a minimum $1 million for grant requests and circumvent existing national bodies and NGO consortia exclude many community-based organizations and NGOs from applying for PEPFAR funding.

PEPFAR's strategy paper includes an emphasis on providing "Technical assistance in policy development" including "treatment-related policy issues" and "TRIPs and other trade agreements." As we discuss later for the case of Uganda, this most likely means pressuring local officials into enacting national patent policies that uphold the most restrictive interpretations of intellectual property rights and make breaking patent monopolies more difficult. Together with all US HIV/AIDS initiatives, PEPFAR is led by a controversial figure appointed by President Bush, Randal Tobias, a wealthy Republican supporter and former CEO of a major pharmaceutical company, Eli Lilly.[9] One of Tobias's first actions was to make clear that PEPFAR funds could not be used to purchase generic ARV combinations under the justification of quality concerns. PEPFAR money for ARVs was restricted to buy products approved by the Food and Drug Administration (FDA) as the US argued that the generic versions were not proved to be effective (Times of India 2004). He told a group of African journalists, "Maybe these drugs are safe and effective. Maybe they aren't. Nobody really knows" (Casriel 2004).

[8] Botswana, Ivory Coast, Ethiopia, Kenya, Mozambique, Namibia, Nigeria, Rwanda, South Africa, Tanzania, Uganda and Zambia in Africa, and Guyana and Haiti in the Caribbean. Vietnam was recently declared the 15th PEPFAR country after pressure in the US to support a non-African country.

[9] Prof. Jeffrey Sachs, of Columbia University's Earth Institute and special advisor to UN Secretary General Annan on the AIDS crisis, called this appointment "surreal" noting that "this is an emergency that requires someone who's worked in the field and knows it thoroughly. We don't need someone who raises all sorts of questions about commitment and agenda" (Lobe 2003:1).

Yet the most popular generic two-pill-per-day combination was already approved by the WHO's formal prequalification process and by the regulatory authorities in many of the countries where the drugs have been used as successfully as brand-name varieties.[10] The WHO-approved generics have been purchased by the Global Fund, the World Bank, and UNICEF, but Tobias insisted that they must be reviewed for "safety and effectiveness" by the US Food and Drug Administration (FDA) before they could be approved for PEPFAR. The benefits of a two pill per day regime costing approximately on fifth of the brands' six pill per day regime fueled protests both internationally and within the US. In response to activists and US lawmakers, the US announced a FDA "fast-track" approval scheme for ARVs that could approve "high-quality" drugs in as little as two to six weeks (Lobe 2004:1).

Tobias claims that the FDA approval will provide the "gold standard" for quality ARVs. Yet, Paul Zeitz, director of the Global AIDS Alliance, points out the problems of institutional sovereignty presented by the US move. "Setting up the FDA as a global, supranational health authority is a very dangerous precedent. WHO was asked by its member states to establish an international standard called the pre-qualification process so that it could play the role of honest broker for both the global North and the global South. Now the US is undermining the credibility of that international program" (Lobe 2004:2). Furthermore, activists question the intentions of the US initiative that appears to be timed to coincide with the development of a combination pill by three big US pharmaceutical manufacturers – Bristol-Myers Squibb, Gilead Sciences and Merck. Two other western companies, GlaxoSmithKline of Britain and Boehringer Ingelheim Corp. have also expressed interest in producing single pill combinations that would compete with the popular generics.

It is clear that negotiating further bureaucratic and logistical hoops for approval of ARVs is more taxing on smaller, Southern-based producers of generics than on western pharmaceutical companies. NGOs are skeptical towards the process of accelerated review as the FDA only considers fast track applications from companies who have had their products through many different clinical trials. This takes a longer time and costs money for research and development to do trials on products that have already been tried by the original producer. In the FDA guidelines for review of HIV Drugs, it is estimated that it takes a company 3-4 years to develop appropriate information for an approval unless the company already has the test data

[10] This led to much criticism from a range of international NGOs and African governments. MSF (2004) made a thorough test of one of the generic fixed dose combination (Triomune) in Cameroon and showed it to be as good as other treatments but easier to take (MSF 2004).

approved by FDA (i.e. if a the combination drug is made of already approved drugs it will be approved) (USDDHS 2004). After the complete application, approval will take 6 weeks. In practice, this means that only the patent holders have access to the fast track approvals. In the above mentioned speech from Randall Tobias he further states: "If we don't apply appropriate scientific scrutiny to this vastly expanded flow of AIDS medicines, we will run the risk of causing the HIV virus to mutate and overcome specific drugs or even whole classes of drugs … it could leave Africa even worse off than it is today" (cit. Randall Tobias, Ip-Health 2004).

A recently released report from the US Government Accountability Office (GAO) suggests some of the implications such an influx of money is having on the local governance of ARVs in recipient countries. This PEPFAR evaluation of July 13, 2004 noted both that the program is "running very well" and that "there are problems at all kinds of levels" (Nakashima/Brown 2004). Central to the problems noted in PEPFAR is the controversy over generic ARVs. According to the GAO report "most of the staff interviewed said that they have not received specific guidelines on whether they can use PEPFAR money to purchase generic antiretroviral drugs" (*Ibid.*). According to the medical director of Partners in Health, an NGO receiving at least $1 million from PEPFAR for 2005, "You're trying to figure out who can buy what with what money" a process described as "very confusing" (*Ibid.*). There was similar confusion in Uganda as PEPFAR was getting started in the country, and representatives from a number of treatment organizations expressed confusion over whether they or others could buy generic drugs. Of course, local implementers are finding ways to circumvent the policy such as using PEPFAR money to train health workers, pay salaries and buy other equipment, while funding drugs from other sources.

Critics claim that the PEPFAR plan is redundant at best and deceptive at worst (Lobe 2004). Some see Bush's support of big pharmaceutical companies behind the tendency to support brand name drugs over generics, the US Christian Right behind the emphasis on abstinence, and the Congressional hard-line unilateralists behind PEPFAR's bypassing of the Global Fund (see Sontag 2004). "Rather than join the world's AIDS battle plan – with the Global Fund as financier and monitor, the World Health Organization as technical advisor and the Joint United Nations Programme on HIV/AIDS (UNAIDS) as coordinator – Bush has created his own controversial strategy with a separate set of rules for his 15 recipient countries" (Casriel 2004). According to the Director of the Global Aids Alliance, an AIDS advocacy group, "At this point, the Bush plan is hurting more than it's helping" (*Ibid.*). Sean Healy, an economist with the Campaign for Essential Medicines (MSF), has noted that the weight of so much money, coupled with a demand for fast roll-out has had unintended consequences in the local contexts as embassy officials note that the sheer speed with which money is being pushed into

the field is overwhelming their staff (Healy 2004). He also gives the example of Botswana, arguably a "best case scenario" with good governance, less corruption and a relatively wealthy economy. Even Botswana has been unable to absorb the treatment funds available to it. Thus, we can expect even greater ARV-governance problems in countries that are less institutionally fortunate. Like others, Healy suggests a shift from the current emphasis on drugs to one on building adequate delivery systems, an altogether more long-term and expensive task.

WHO'S 3 X 5 PLAN?

The third and most ambitious global initiative is known as the 3X5 Plan. On 22 September 2003, the Director-General of WHO, together with the directors of the Global Fund and UNAIDS, declared the lack of access to ARVs to be a "global health emergency" and responded with the launch of the "Treat 3 Million by 2005" (3 X 5) Initiative (WHO 2003). The elaborate goal of the 3 X 5 is "for WHO and its partners to make the greatest possible contribution to prolonging the survival and restoring the quality of life of individuals with HIV/AIDS, advancing toward the ultimate goal of universal access to antiretroviral therapy for those in need of care, as a human right and within the context of a comprehensive response to HIV/AIDS" (*Ibid*.:9). The WHO carefully situated this new initiative within the existing resource and budgeting frameworks of Poverty Reduction Strategy Papers (PRSPs), sector-wide approaches (SWAPs) and striving to reach the Millennium Development Goals (MDGs) for HIV/AIDS, health and development more broadly. WHO's strategic framework outlines five pillars of the 3 X 5 campaign:

1. global leadership, strong partnership and advocacy
2. urgent, sustained country support
3. simplified, standardized tools for delivering antiretroviral therapy
4. effective, reliable supply of medicines and diagnostics
5. rapidly identifying and reapplying new knowledge and success (*Ibid*.:11).

The fourth pillar is to be implemented through the creation of a "AIDS Medicines and Diagnostics Service (AMDS)" which will not actually purchase drugs, but will coordinate efforts to improve access. WHO, through this AMDS provides an internet-based information hub for demand forecasts, prices, sources, patents, customs and regulatory matters. This should enable national authorities and programme implementers to make the best use of available medicines and diagnostics. Also, AMDS will link to the WHO Procurement, Quality and Sourcing Project (pre-qualification) for assessing products and manufacturers on quality issues. WHO states that "in the later phase of the 3 X 5, the AMDS may facilitate the procurement of

essential medicines and diagnostics by aggregating demand on behalf of buyers and supporting joint competitive and open negotiations or tenders" (Ibid.:21).

One of the critical aspects of WHO input into ARVs access is the WHO Prequalification Project, established in 2001. This service was designed to give UN procurement agencies a choice of a range of quality medicines for treating HIV/AIDS, malaria and TB, but now other major initiatives such as the Global Fund are also relying on WHO's prequalification process to standardize drug purchases. So far, 42 brand name medicines and 61 generics have met the WHO prequalification process, including 62 ARVs and 33 other medicines for AIDS-related illnesses (WHO 2004b). Recently, WHO has approved 3 fixed-dose combination drugs (one brand and two generics) which has sparked controversy and confusion over whether these drugs can be used in American-funded initiatives. The WHO prequalification procedure is able to claim non-involvement in the disputes over patents and access, on grounds of national relativism:

> In soliciting applications from companies, WHO does not question whether the products presented are patented or generic, since patent laws vary according to different national legal systems. It suffices that a company is duly authorized for pharmaceutical manufacture in its own country and that the final product meets stringent standards of quality, efficacy and safety (WHO 2004b).

The estimated total cost of the 3 X 5 plan is at least $5.5 billion. WHO plans to deploy "emergency missions" in a total of 15 countries where accelerating access is most urgent.

AID TO AIDS: TOO MUCH OR TOO LITTLE?

"AIDS treatment" has arguably become the most-popular agenda item for international donors working in highly-affected countries, particularly in Africa. Not since the promise of the "Green Revolution" has such an apparently technological "fix" been promised to halt the suffering and death of so many people. Yet, the provision of ARVs as the answer for AIDS is deceptively simple and donors are being confronted with the realities of providing these much-demanded commodities in diverse and challenging national contexts. Ironically, the more interest there is in funding and "scaling up" ARVs in developing countries, the more complicated and conflicting the governance implications may be.

Examining the national governance of AIDS treatment in developing countries, more donors, more money and more conditionalities can lead to institutional weakening and perverse in-

centives for poor governance as described by Brautigam and Knack (2004). This is not difficult to imagine when one considers that in addition to the three major global AIDS treatment initiatives, there are hundreds of smaller ones in Uganda alone, and the number of organizations of various sizes getting involved in ARVs continues to mushroom. For example, Uganda's largest donor, the World Bank through its Multi-Country HIV/AIDS Programs (MAP) committed $1.6 billion to African countries, and remains one of the largest potential buyers of ARVs. UNICEF, the international children's organization working in 158 countries with the goal of ensuring that all children survive and thrive through adolescence has been rapidly expanding its work in ARV procurement and spent $111 million during 2003 in its HIV/AIDs programs. The governance implications of so many organizations, large and small, embracing a goal of ARV access will be explored in our examination of the case of Uganda.

At the level of global governance, the proliferation of aid to AIDS treatment may alter the playing field of international trade, where the poorest countries have been considered such small players in this market, as to merit special treatment under international provisions. If the ARVs scale up with donor money is actually realized in many developing countries, then competition for buyers will take on entirely different forms, with donors as the major purchasers of ARVs. Thus far, international pharmaceutical companies have successfully convinced the major donors to continue purchasing brand-name drugs under justifications of quality assurance, but these debates are being continually re-opened. AIDS drugs are not simply "given" by donor countries to recipients, but are sold by companies which hold significant political clout in donor countries. These companies have a vested interest in the governing of international trade and AIDS. Thus, the governance of trade and AIDS is a critical, but often neglected factor of the realities of developing country access.

Trade and AIDS

THE DEVELOPMENT OF AN INTERNATIONAL TRADE REGIME

Since the Second World War, international trade has increasingly been governed in a multilateral trade system. This system was built on the ideas that liberal trade and a free world market would benefit all parties and prevent an economic recession similar to the one in the 1930s (Nicolaides 1994). The intention was to build an International Trade Organization, but this could not be formalized because of differences in trade interests among the negotiating parties. However, the initiative and the following negotiations resulted in the establishment of the General Agreements on Tariffs and Trade (GATT), an ongoing negotiation of how to decrease trade barriers – mainly tariffs – across international borders. GATT was not an international organization but a multilateral treaty covering trade. GATT was formed around principles of reciprocity and non-discrimination meaning that if one country gave up or lowered a tariff barrier, countries benefiting from this should give similar concessions. These principles kept the negotiations going throughout GATT rounds and resulted in lower tariff barriers during the period from the 1950s until the early 1970s.

Few developing countries engaged in GATT negotiations as their trade interests (mainly agricultural products) were not included. As the negotiations and concessions were all voluntary, developing countries could benefit from industrialized countries lowering their trade barriers, without being forced to give similar concessions themselves. In the 1970s, the oil crisis combined with the entrance of new competitive producers from the newly industrialized countries led to an increase of non-tariff barriers in most industrialized countries, and emphasized the weakness of GATT. Although the number of negotiation parties in GATT had increased from 23[11] in 1947 to 123 in the late 1980s, GATT's voluntary system was inadequate in dealing with periods of economic recession. Thus, the Uruguay Round of consultations resulted in the formation of a new trade-governing body, the World Trade Organization (WTO) in 1995.

WTO is a formalized international organization based on the agreements and ideas from the heritage of GATT. The ongoing tariff negotiations follow the principles of reciprocity and non-discrimination set out in the GATT system, but the concessions given are binding. If one

[11] The original contracting parties in 1947 were: Australia, Belgium, Brazil, Burma, Canada, Ceylon, Chile, Cuba, France, India, China, Lebanon, Luxembourg, The Netherlands, New Zealand, Norway, Pakistan, Great Britain, South Africa, South Rhodesia, Syria, Czechoslovakia and USA

trading partner discriminates against another, the aggrieved can bring a law suit in the WTO Dispute Settlement System in order to force the other part to comply. Besides from tariffs, the negotiations forming WTO included new trade topics like the General Agreements on Services (GATS), agriculture, Trade Related Investments Measures (TRIMS), and Trade Related Intellectual Property Rights (TRIPs). Developing countries were pushing for agricultural products and textiles to be part of the negotiations, while industrialized countries wanted intellectual property rights, investments and services to be part of WTO. The result was a 'package deal' in which all countries would benefit in some areas and give concessions in others. However, agriculture was still not included at that time. Developing countries got *special and differential treatment* onto the agenda, meaning that poorer countries can make other demands for tariff reductions, longer implementation periods, and promises of technical assistance from the industrialized countries. A "package deal" means that in signing on to WTO membership, countries must comply with all the different agreements made in the Uruguay Round document, even those which do not benefit their national industry. The key distinction between WTO agreements and all previous trade governance systems is that all WTO agreements are legally binding. Today, WTO consists of 146 member states, most of which are developing countries (Martin & Winters 1996; WTO 1994; Shrinivasan 1999). In 2001, a new round, the Doha Development Agenda, was launched to develop the WTO trading system, especially within agriculture. Developing countries had pushed for further rounds of negotiation as they had not benefited substantially from the Uruguay Round, and they are most in need of market access for their agricultural exports.

WTO is the main actor governing world trade as it covers almost all countries that, to a large extent, follow its rules. However, there are also other agreements governing trade, and in the last 20 years many bilateral and regional trade agreements have been established in order to ease trade within countries. Initially, many developing countries made regional trade agreements in order to develop their regional markets and national industries. However, these have decreased in scope with the increase of bilateral agreements made with industrialized countries. These bilateral agreements tend to give the developing countries better access to the advanced markets of industrialized countries. However, in doing so, they require the developing countries to grant concessions that go beyond the WTO agreements. Some examples of such bilateral trade agreements are the EU Everything But Arms Agreement (EBA), the EU Economic Partnership Agreements and the US engagement in NAFTA and the Free Trade Agreement of the Americas (FTAA). The FTAA negotiations have recently been stalled because the US wished for strong protection of intellectual property rights while most of the partners from South American countries would not commit themselves to measures reaching further than the TRIPs Agreement. The US also made the non-reciprocal

preferential trade agreement with a number of sub-Saharan countries called Africa Growth and Opportunity Act (AGOA), giving duty- and quota free access to a number of products from African countries. However, these countries are supposed to follow specific governance policies (political, economic and security) set out by the US (Gibbon & Ponte (forthcoming)).

Developing countries had two incentives for participation in the WTO: to be able to negotiate trade in a common forum and to increase access to markets in developed countries. As a numerical majority in an international organization, the developing countries have opportunities and concessions they would not have as individual negotiators in bilateral agreements. However, most developing countries are still engaged in voluntary trade agreements with the large trading parties, and these require greater concessions than the WTO. This relates further to governance of aid as much of the technical assistance to developing countries in terms of trade is bound to political and economic interests in industrialized countries. One example is the USAID's involvement in implementing the TRIPs Agreement in several African countries by providing technical assistance and donor support. As we will explain later, the result has been law reforms that extend beyond the agreements from WTO.

A GLOBALIZED PATENT SYSTEM IN THE TRIPS AGREEMENT

The international trade regime set out in WTO impacts AIDS policies today as medicines are goods to be traded rather than essential products to national health systems. WTO has an important impact on access to medicines – including ARVs – in member countries, especially those countries without a large pharmaceutical industry to supply the home market. TRIPs is the most important agreement governing access to medicines by covering patents, copy rights, trademarks etc. Underlying TRIPs is an inherent conflict between the discourse of private property rights of inventors of new medicines on the one hand, and the discourses of human rights and the rights of sovereign states to protect peoples' health on the other (Joseph 2003). TRIPs discussions between developing and industrialized countries have reached into economic, ethical, social, security and political realms. Diverse standpoints and activism have come from civil society groups, international agencies, industrial actors, academics, and governments. Developing countries' access to ARVs has served as the test case of justice in the formation of a global political economy. While the patent obstacle to ARV access has been formally resolved in the WTO, this has not yet led to increased access to ARVs in developing countries.

The TRIPs Agreement was passed as a part of the text in the Uruguay Round establishing the WTO in 1995 (Correa 2000, Richards 2004). This agreement covers a range of intellectual

property rights, and stipulates that all member countries must provide minimum protection of intellectual property rights in their domestic legislation. Among other things, the TRIPs Agreement establishes twenty years as the minimum duration of patents on new products or processes. Although patents are not granted globally – the inventor needs to file a patent in every country or region – they are globalized as the inventor has the rights to file the same patent in any country for the same period. This approach is based on one of the principles of WTO, "national treatment", where foreign companies or citizens must adhere to the same rules as national ones. TRIPs was institutionalized by the US, Europe and Japan to protect their citizens from profit losses due to infringements of their intellectual property rights (copying) in countries not offering sufficient protection. By accepting intellectual property rights, the states grant a time-limited market monopoly to the innovator of a new product in order for the innovator to be able to cover the expenses supposedly-used on research activities. The World Bank (2001b) has estimated that the industry of these innovative countries will get rent transfers of more than $20 billion in royalties and market shares when the TRIPs Agreement is fully implemented. Obviously this surplus will come from the technology importing countries, including developing countries (Bellmann et al. 2003). The countries that opposed the TRIPs Agreement were those without protection of intellectual property. One of these was India, whose patent system only gave monopoly rights for 7 years on most products, and only for processes if pharmaceuticals. This had led to the development of a large generic pharmaceutical industry based on reverse engineering of patented products without spending money on research and development of new products (Keayla 1998, Zaveri 1998).

The intention with the TRIPs Agreement was not to prevent developing countries access to essential medicines. However, as AIDS is a relatively new disease and ARVs are new products still working under patents without alternatives (as there are for malaria and tuberculosis)[12], ARV access restrictions resulted from TRIPs implementation. During the negotiations of the TRIPs Agreement, India warned against a scenario of decreased access for the poor (Zaveri 1998, Keayla 1998). Granting a monopoly right in the WTO could eventually lead to companies having global monopolies on essential products which would limit access to medicines. India had experienced a decrease in prices with the development of a national pharmaceutical

[12] Even though there are products off patent to treat malaria, the new and more efficient ones are all working under patent. In the case of tuberculosis there has been no new molecules developed for the last 30 years. One of the explanations could be the fact that the countries in which the prevalence of tuberculosis is high all have small markets and till now poor patent laws. Therefore there has been no incentive for innovation in tuberculosis.

industry as there was no monopolistic market on medicines. The lower prices increased access to medicines and benefited public health in general. In order to ensure that the TRIPs Agreement would not infringe upon nation states' rights to protect public health, this point was mentioned in the overall principles of the agreement. The principles of the TRIPs Agreement (Article 8) (WTO 1994:323) clearly state that all member countries have the rights to protect public health as long as this is done within the provisions of the Agreement[13].

The main provision for countries to use in case of high prices and national emergencies is to issue a compulsory license. By granting a compulsory license to a producer of medicine, the government waives the rights of the patent holder in order to enhance access. In this way the country authorizes other parties to produce the product for a limited time without the consent of the patent holder. Compulsory licenses can be granted in "…situations of national emergency or other circumstances of extreme urgency" (Article 31, b) and must be limited to the purpose it was authorized for (Article 31, c). Furthermore, the text states that "any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use" (Article 31, f). These formulations were intended to give governments authority to override the patent rights in situations like the HIV/AIDS pandemic[14]. As the TRIPs Agreement was formulated, there were no obstacles to providing cheap medicines for the population in an emergency situation as long as the purpose was limited and the medicine did not enter other markets.

Although the TRIPs Agreement contains provisions that developing countries could use in theory, in practice, there were many obstacles to implementation. One of the obstacles was that the HIV/AIDS epidemic was difficult to define as a "national emergency". The spread of the HIV virus has been known since the 1980s, and therefore the pharmaceutical industry argued that this was not an emergency, but a failure of governments to prevent a predictable outcome; thus, they should not "pay" for a governance failure. Another obstacle was the limitation of a compulsory license to provide only for the domestic market. For countries without a sufficiently-developed national pharmaceutical industry to produce the products under compulsory license, or countries with a small domestic market where production may

[13] These provisions are in this case found later in Section 5 on patents (WTO 1994:331 ff.) where Article 30 and 31 on *Exceptions to Rights Conferred* and *Other Use Without Authorization of the Right Holder* are found.

[14] A similar emergency (although with only few people directly involved in the epidemic) was present in the US during the anthrax attacks following September 11. At that time there was uncertainty if there would be enough Ciprofloxin and if the government should by-pass the patent legislation in order to purchase generics.

not be profitable, it was difficult to make use of a compulsory license. The result was that only countries with a strong pharmaceutical industry and large populations, such as Thailand, Brazil and India, were able to make use of the provisions.

Slowly realizing these obstacles for countries to protect public health, it became clear that there was a need for an expanded interpretation of the TRIPs provisions to ensure access to medicine in developing countries. This became clear when 39 transnational pharmaceutical companies filed a case against South Africa for overruling patents on ARVs (Joseph 2003). This case did not directly concern the TRIPs Agreement, as South Africa had until 2005 to implement a new patent legislation. Rather, it was a case against the South African government's breaking of its own patent law. However, this case became a symbol of how intellectual property rights of private companies are in a position to affect national governments' room for maneuver. The strong reaction from the global civil society indicated what would happen with the implementation of the TRIPs Agreement in the near future. The pharmaceutical companies withdrew from the case because it threatened their public profile. The South African court case influenced the political demands by African countries that took joint action to demand public health protection during the next round of WTO negotiations. At the same time, Indian companies were able to produce copies of ARVs at much lower prices than the branded products. This coincidence of issues of intellectual property rights combined with increasingly successful programs of providing ARVs to resource poor settings set the ground for what became the Doha Declaration in 2001.[15]

THE DOHA DECLARATION

The Doha Declaration on the TRIPs Agreement and Public Health (hereafter the Doha Declaration) was agreed to at the Doha Ministerial Meeting in November 2001. The Doha Declaration (WTO 2001) states directly that the TRIPs Agreement should be interpreted and implemented in a manner that promotes access to medicines for all. Furthermore, it states that member states have the right to grant compulsory licenses, the freedom to determine the grounds for this, and the right to determine what constitutes a national emergency or other

[15] One of the topics that are still not dealt with is how research and development can be focused at the more serious diseases facing the population in developing countries. The vast majority of research and development is aimed at diseases found in the industrialized countries (dietary products, baldness, virility, and other lifestyle medication) although tropical diseases are responsible for 80% of the world loss of disability adjusted life years (DALYs). This might be explained by Africa's low share of the pharmaceutical world market. In 2003 this share was 1 – 1.2% (Africa Research Bulletin 2003) and had decreased from 1.3% in 2000 (IMS Health 2000).

circumstances of extreme urgency. This official interpretation of the agreement answers the problems facing countries of declaring HIV/AIDS a national emergency.

However, the second problem of granting a compulsory licence only for supplying the national market was not addressed thoroughly in the Doha Declaration. The Declaration recognized the problem and the ministers asked in the declaration for the TRIPs Council (the authority administering the TRIPs Agreement outside the official ministerial meetings) to find a solution before the end of 2002. However, the TRIPs Council did not succeed to find this solution until August 30th 2003 (known as the "August 30th Solution" (WTO 2003)). It was easy to find ways of letting some countries without manufacturing capacity import drugs, but difficult to make provisions for other countries to export to these countries. To do so would support the generic industries in countries like India, Brazil and Thailand at the expense of the patent owners in countries like the US and UK. Furthermore, there is uncertainty of how to avoid the generic products escape their domestic markets and enter . Still, in the Doha Declaration, least developed countries that are not already protecting pharmaceuticals had their implementation period extended by another 10 years. Now they have until 2016 before they have to grant patents on pharmaceuticals.

After the August 30th Solution, only one industrialized country so far, Canada, has passed a Patent Amendment Law allowing Canadian pharmaceutical companies to produce generic versions of patented medicines to supply developing countries making use of compulsory licenses. So far, this law has not been used, but the possibilities are there for developing countries to access copied generic medicines from Canada. The sources of generic medicines used today are primarily manufacturers in India and Brazil as their price levels are low and there are no patents on pharmaceuticals in their home markets. Both countries will have to comply with the TRIPs Agreement by January 2005, but so far it looks like they will make similar amendments to the one in Canada in order to keep their generic exports to e.g. Africa (Chaudhuri 2002). Accessing the generic ARVs requires that African countries make use of the provisions in the TRIPs Agreement and implement the Doha Declaration in their patent laws. So far only Zambia, Zimbabwe, and Mozambique have granted compulsory licenses for national companies to produce ARVs, and this has happened very recently and the products are still not available. The overall reluctance by developing countries to grant compulsory

licenses links to the politics of development assistance as some donors restrict the suppliers of ARVs for their programs to patent-holding companies.[16]

TRADE IN WHOSE INTERESTS?

While the rationale behind the TRIPs Agreement came primarily from the US industry, there were incentives for the developing countries to engage in the TRIPs Agreement. First of all it was of major interest to the technology exporting countries (mainly in Europe, US and Japan) to have intellectual property covered in an international trade organization. In order to get concessions on other areas like agriculture and textiles, it seemed important for developing countries to engage in negotiations on intellectual property. Although agriculture and textiles were not delivered in the Uruguay Round, both are now being addressed in the Doha Development Agenda. Second, within the development discourse of the major donor agencies, trade and economic growth have taken an important position as development indicators and a membership of WTO was seen to be important for this (UNCTAD 2004). Thirdly, there were promises from foreign investors that intellectual property rights would increase and facilitate foreign direct investment and technology transfers in developing countries (Maskus 1999). This argument was mainly used by industrial organizations from developed countries and came as an answer to developing countries pledge for technology transfers for many years. However, it is now clear that many other factors are determining foreign direct investment and technology transfers as the investments have not yet flown into the African countries.

Not surprisingly, pharmaceutical companies investing in research and development of new medicines welcomed the TRIPs Agreement. These companies received increased for investing in research and the ability to export world wide without the fear that other companies would copy their products. Consumers are paying higher prices because of the monopoly status of patented products. This is the trade-off in intellectual property rights, giving incentives for research and paying by granting monopoly for a specific time (Mansfield 1986). This argument holds when the customers have money to buy the product, but in the case of ARVs in Sub-Saharan Africa, it is clear that most patients cannot be expected to afford to pay for their drugs. Therefore, NGOs argue, the companies do not lose customers by letting them access copied products, as there is hardly any purchasing power in that market. However, with the

[16] As discussed earlier, the US PEPFAR initiative has a clause that all ARVs must be approved by the US FDA. This is in contrast to most other access initiatives that allow countries to buy from producers approved by the WHO, along with the branded products are several generic products, some of which are developed to ease distribution in resource poor settings and lower cost (The Guardian 9-7-2004).

major funding coming in now via the Global Fund, WHO and PEPFAR, the purchasing power for these markets is increasing.

The pharmaceutical companies holding the patents for ARVs do not act as a single group. Although they sometimes cooperate in making united statements through their business associations, they have different policies towards developing countries. One company has expressed that "infringement of intellectual copyright laws to allow poor countries cheap access to AIDS drugs would be the thin end of a dangerous wedge. Pirating would run riot across the world – and global business will suffer" (Washington Post 27-12-2000:7). This is a serious and interesting statement as it has happened several times that products sold at discounted prices to developing countries, for instance in the Accelerated Access Initiative, have shown up in the European market and therefore not benefited the intended group (New Vision 2003, Whyte et al. 2004). Another company has recently taken a different stand stating that they will not file patents on any of their patented products in all countries in Sub-Saharan Africa (Roche 2004). At the same time they have lowered their prices in these countries by one third.

In theory, there should be no obstacles to having the cheapest treatments available for those who cannot afford them, as the industry has dramatically lowered prices and the TRIPs Agreement now gives room for compulsory licenses and parallel imports. In practice, however, this is not the case. One example is the US PEPFAR donations for ARV treatment in Africa, as described in the earlier section on the PEPFAR initiative. A second way to limit the loss of the pharmaceutical companies in the developed countries is by including intellectual property rights in bi-lateral trade arrangements with developing countries. Although it is only recently that intellectual property has been recognized as a trade related topic, this has been a main feature of trade agreements initiated by the US with several developing countries as well as Australia. As described earlier, the WTO TRIPs Agreement guarantees only minimal intellectual property rights, but countries are free to engage in stricter bilateral agreements. This has been put forward by US in the Free Trade Agreements of the Americas (FTAA) and in free trade agreements with Australia. A third example is the granting of technical assistance to help developing countries in reforming their intellectual property laws by assisting them in the TRIPs implementation. This is done as part of the technical assistance industrialized countries are supposed to give developing countries to assist their WTO implementation. USAID was the main sponsor of the upcoming of a TRIPs compliant industrial property law in Uganda. Finally, the US has a special provision in their trade law from 1988 known as "Special 301" that allows for commercial retaliation against countries who are not upgrading their intellectual property laws. This law allows US to put countries they define as infringers of US intellectual

property rights on a special watch list and eventually boycott commodities from these countries.

In sum, after all the international trade negotiations from GATT to DOHA and TRIPs, compulsory licensing is still not used in most of the Sub-Saharan African countries. For some countries this can be explained by the fact that least developed countries have until 2016 to implement the TRIPs Agreement, but this only covers a few countries. Most African countries already have patent laws similar to those required by the WTO as part of their legal legacy of colonialism. However, in Mozambique, Zambia and Zimbabwe, compulsory licenses have been filed by the governments. These are the first examples of African countries making use of the provisions and are seen as an important step in implementing the Doha Declaration (WHO 2004e). Uganda is used widely as an example and test-country for HIV/AIDS programs and is often used as the good example of changing the vicious circle of HIV/AIDS. However, there are no signs that Uganda will take a lead position in terms of granting compulsory licenses for ARVs. This can be explained partly by the tradition of donor participation in the HIV/AIDS projects and partly on other types of national politics. Access and governance of ARVs in Uganda is the topic of the second half of the paper, and is based on two separate pieces of fieldwork by the authors in 2003 and 2004.

Local Governance: The Case of Uganda

POLITICAL BACKGROUND ON GOVERNANCE IN UGANDA

Uganda is often portrayed as the good example showing how government interaction and good governance can counteract the vicious circle of HIV/AIDS (Putzel 2003, Boone & Batsell 2001). Yet, only recently has Uganda come to be known for "good governance". The apparently stable and internationally-lauded leadership rests on years of civil war, conflict and violence. Uganda was once known as the "pearl of Africa", but British colonial rule pitted the Southern-based Baganda against other ethnic groups, especially those in the north. Unequal regional development, ethnic favouritism, and the imposition of a bureaucratic authoritarian colonial system, unsurprisingly, did not give way to a democratic or accountable political system at independence in 1962. Politics revolved around constituencies based on religion, ethnicity, language, or region, and for more than two decades, conflict was the norm. The country experienced five official coups d'etat in the twenty years following independence.

The violence that drove out or killed off Uganda's politically disfavoured ethnic minorities under the regimes of Obote and Idi Amin was long regarded as the standard by which other African political crises were measured. Between 1971 and 1985, political violence was the cause of death of at least 800,000 Ugandans (Tripp 2004:4). After the military victory of the National Resistance Army (NRA), the very first official act of the government was to suspend party politics on the grounds that party competition exacerbated ethnic conflict in Uganda (Goetz 2003). Ironically, Uganda's violent political history and its conflict-weary society may have contributed to a broader political mandate for Museveni's social agenda around HIV/AIDS.

The "no-party" government of the National Resistance Movement (NRM) has brought political stability to most of the country (although the ongoing civil war in Uganda's north is a frequently overlooked exception). Yet over time, the NRM has concentrated power in the hands of its leadership to the exclusion of dissenting groups. The NRM leadership claims to have formed a grass-roots movement—generated from above. Still, Ugandans and international donors appear to accept the stability/democracy trade-off of Museveni's "broad-based" governance. The NRM has held several elections since 1986, but no real competition against Museveni has ever been allowed and the regime is characterized as semi-authoritarian, making only the concessions most necessary toward democratisation (Tripp 2004). Foreign donors have been ambivalent in their support of political pluralism, calling on Museveni to recognize the need for democratisation while supporting his style and policies of leadership.

Opposition leaders and the press have described Museveni as being more beholden to Britain and the US than to his own people *(ibid.*:20).

The NRM has prioritized economic growth based on neo-liberal reforms that led to a significant average economic growth rate of 7.1 percent per year in the late 1990s. The economic turnaround from state control to free market, with measurably high rates of success, has provided international credibility for Museveni's leadership. However, the capitalist success story has also come under domestic scrutiny (see Tripp 2004). Although the economy grew and poverty was reduced in the 1990s, inequality actually increased (Okidi and Mugambe 2002). An estimated 9 million Ugandans still live in poverty and the country's wealth is unevenly concentrated in the South (Tripp 2004:20). Uganda is highly dependent on donor assistance, estimated at $800 million for fiscal year 2003. The World Bank is the largest donor and the UK and the US are the largest bilateral donors. Museveni's charisma and pragmatism and Uganda's important role as an economic success story has led the international community to ignore red flags involving domestic human rights violations and Uganda's interference in the politics of its neighbors. Uganda's success in combating the AIDS epidemic has been an important component of ensuring that the country remains the darling of international donors.

UGANDAN HIV/AIDS POLICY

The Ugandan HIV/AIDS policy's success has become ubiquitous. In the early 1990s, Uganda reported the highest infection rates in the world, with an estimated 15 percent of the population living with HIV/AIDS. Yet by 2001, the country had managed to bring the prevalence down to 5 percent (Hogle 2002). The greatest declines in HIV incidence are thought to have taken place in the late 1980s and early 1990s. Figures from Uganda's National AIDS Control Programme suggest that the prevalence and incidence of HIV/AIDS are declining across all age groups and socioeconomic levels (Kirumira 2001). While Uganda's "success" has no doubt been shaped by and for an international agenda (see Parkhurst 2001), there is clear evidence that the early recognition of HIV/AIDS supported by donors and the decentralization program in Uganda has limited the spread of the disease (Fredland 1998, Putzel 2003). The country hosts one of the biggest AIDS care centers in Africa south of the Sahara, the Joint Clinical Research Center (JCRC) in Kampala, and was among the first recipients of the World Bank's Multi-Country HIV/AIDS Program I funding. Also, Uganda received funding in all

three rounds of the Global Fund and was the 11th largest recipient of 130 bodies requesting funding in the first two rounds.[17]

Uganda was one of the first countries to recognize AIDS as a major obstacle to development and to launch a multisectoral approach to combating the disease. A formal AIDS Control Programme was established in the Health Ministry in 1986, the year the NRM came to power.[18] After many of his top army officers were found to be HIV positive, Museveni put AIDS at the top of his agenda, and began a military approach to AIDS as a threat against which the Ugandan people must mobilize and fight (Allen 2002). In 1992 the Uganda AIDS Commission (UAC) was established under the office of the president to act as the coordinating body for all AIDS activities in the country. Funded by major donor agencies, the Ugandan government has promoted a multi-pronged strategy to combat AIDS, including public information campaigns, research, voluntary testing and counseling, safe blood transfusions, school health programs, home-based care for people living with AIDS, and a broad campaign to treat STDs. In March 2000, the government published a National Strategic Framework for HIV/AIDS to reinforce the objectives of the earlier policies and to expand their scope for coordination and capacity building, in-depth surveillance and a general baseline survey of the population, and better treatment of HIV-positive Ugandans (Parkhurst 2001, Government of Uganda et al. 2000).

National AIDS governance in Uganda has been characterized by strong, symbolic leadership from the top, and a "free market" of various AIDS-related interventions from below. The role of President Museveni in speaking about AIDS as a threat to all Ugandans, calling on all groups to get involved in the fight against the disease, and thus reducing the stigma and discrimination surrounding the disease has been critical to policy successes. However, the timing and context of Museveni's actions were critical. The Ugandan population had suffered more than fifteen years of repressive rule and violence, so the takeover by Museveni and the NRM was greeted with an intense desire for change and optimism. This historical period was ripe for radical policy reform, and the population may have been uniquely ready for new statements; therefore, "few leaders could expect to have the same impact on their populations as Museveni did in 1986" (Parkhurst 2001).

[17] Uganda was approved a total of $96,719,638 in the two rounds as documented by the Global Fund Observer, accessed online at www.aidspan.org/globalfund/grants

[18] Uganda's AIDS Control Programme was one of the first programs of this kind in Africa (Parkhurst 2001).

Museveni's leadership on AIDS was linked to democratization and the reconstruction of local government as a means of rebuilding social cohesion in the country (De Waal 2003). When the World Bank convened two "learning events" to discuss Uganda's progress based on the premise that "optimism now exists in the fight against AIDS in sub-Saharan Africa due to the dramatic declines in HIV prevalence observed in Uganda," they placed particular importance on the country's "social cohesion" (World Bank 2001a). Social cohesion is defined as "the norms and social relations embedded in the social structures of societies that enable people to coordinate action to achieve desired goals" (World Bank 2001a). In the aftermath of such high political instability, social cohesion has been an important goal of the NRM government. Museveni's leadership in communicating AIDS facts while rebuilding social cohesion was necessary for combating HIV/AIDS, while Museveni's success also enhanced social cohesion. However, the social cohesion formed around AIDS may be put to the test as ARV distribution takes hold. Will the protocols and priority groups devised by the government for allocating "free" ARVs be seen by the population as fair, or will they be interpreted as spoils in the ever-increasing political competition as the NRM struggles with calls for pluralism?

HISTORY OF ARVS PROVISION IN UGANDA

The Ugandan case is often set up as the successful example of blending government (both centralized and decentralized), private initiatives, and community responses and responsibilities to the HIV/AIDS epidemic (Collins and Rau 2000:42). The history of ARVs in Uganda is one of both formal public/private cooperation and informal supply systems known as the "public-private mix-up" (Whyte et al. 2004). The first ARV therapy in Uganda came in the form of study-trials for AZT conducted at JCRC in 1992. By 1996, triple drug therapy became available for a few paying patients, and in 1998 Uganda became one of the first four pilot countries in a study to examine the possibility of providing ARV therapy in low resource settings.

UNAIDS and the Ugandan Ministry of Health (MOH) conducted a pilot project called the HIV/AIDS Drug Access Initiative (DAI) (June 1998-March 2000). Part of this project involved creating a multidisciplinary National Advisory Board to make policy recommendations for provision of ARVs. The DAI operated in five treatment centers,[19] all located in Kampala. Patients were responsible for paying for their own ARVs, physician consulting fees

[19] Nsambya Hospital, Mildmay Palliative Care Center, Mulago Hospital, JCRC, and Mengo Hospital.

and lab tests, while the project paid for viral load and CD4 monitoring (Uganda MOH and UNAIDS 2004:4).

The DAI study was important for laying the groundwork in developing "centres of excellence" in Kampala which would then serve on the forefront of the national roll-out of ARVs. By March 2000, 905 Ugandan patients had accessed the DAI, and of those patients with access to anti-retrovirals, 58% were alive and remaining in care (Ochola, Weidle et al. 2000:13). DAI showed clearly the necessary links between economically-viable treatment and patient compliance with ARV regimes. Price fluctuations because of currency devaluation led to treatment interruptions for some patients in the DAI, and the recurrent costs of monitoring the virus were prohibitive for some (Uganda MOH & UNAIDS 2004:13). Also, under the DAI, partial suppressive ARV therapy (49% of patients) was considered justifiable because many patients could not afford triple drug therapy and partial viral suppression is better than none at all (Okera et al. 2003:3).

As of April 2000, the Ugandan Ministry of Health (MOH) took on the responsibility for managing ARV treatment access which had been previously dominated by UNAIDS (Okera et al. 2003, 2). In May 2000, five pharmaceutical companies announced the "Accelerating Access Initiative" a public-private partnership[20] together with international agencies and African states to provide access to HIV/AIDS-related treatments, including significant price reductions for anti-retrovirals. Drawing on experiences with the pilot initiatives, the MOH developed a "National Strategic Framework for Expansion of HIV/AIDS Care and Support in Uganda" to situate ARV access within the National Health Policy and the HIV/AIDS Health Sector Strategic Plan. The long-awaited "Antiretroviral Treatment Policy for Uganda" was issued in June 2003, and it had gone through all of the requisite channels to become a final policy document by late 2004.

HISTORY OF ADVOCACY FOR DRUGS ACCESS IN UGANDA

The first case of AIDS in Uganda was recognized in 1982 (Uganda MOH 2003a). 12% of the total annual deaths in Uganda are caused by AIDS, which is now the leading cause of death among people aged 15-49 years (Uganda MOH 2003a). Despite policy success, HIV/AIDS is still a major burden in Uganda. According to the Director General of the Ugandan Aids Com-

[20] For other examples of successful and unsuccessful public-private partnerships on public health issues, see Reich 2002.

mission 70,000 people died of AIDS in Uganda in 2002 (The Monitor, 1.12.2003). Although the number of new infected people each year has dropped significantly over the past years and Uganda is seen as a good example for other to follow, still about 100,000 people get infected with HIV/AIDS every year (Uganda MOH 2003b).

Museveni issued statements that paved the way for increasing access demands aimed at an international audience. For example, Museveni proclaimed: "It is very genocidal for one part of the world to have the cure for the AIDS disease while millions of people in another part are dying from the same" (*The New Vision*, 11-12-2002). Access has become a popular political issue in Uganda, and portraying the country as being on the forefront of ARV "roll-out" in Africa is important for national leadership. The Ugandan Ministry of Health announced in the press that "a total of 10,000 people, or one third of the 30,000 anti-retroviral users in Africa are in Uganda."[21]

As early as 13 August 2002, the government announced that they would provide free ARVs to 2000 people across the country.[22] There are also recurrent discussions about launching a manufacturing plant for generic ARVs in Kampala. Mike Mukula, from the ministry of Health told the press: "This is a matter of national priority and urgency to have the drugs locally manufactured." By December 2003, the Ministry of Health announced "Our ultimate goal is to provide universal access to anti-retroviral drugs, the national target is to reach 100,000 patients by 2007" (Bwalatum 2003). By June 2004, the Minister of Health launched a program in which, it was reported in *The New Vision*, "all AIDS patients in Uganda, will, in due course, be given free drugs, beginning with some 2,700 this year" (Wendo 2004). The Minister is reported as declaring "We have decided to make these drugs part of what we have been giving to everybody. The only difference is that there are specific centers where these drugs can be given, because of their delicate nature" (*Ibid.*).

However, the governance structures of ARVs in the country are complex and multiple, and the perceptions and outcome of unequal access have negative governance implications. Preferential access to anti-retrovirals, where some senior members of the government and army are provided with free or subsidized AIDS treatment, provides strong incentives for staying in office, leading to deleterious governance implications (De Waal 2003:15). Local media reports confirm the political significance of treatment access noting that "Ugandan

[21] IRIN News online at www.irinnews.org/AIDSreport.asp?ReportID=1750.
[22] *New Vision* (Kampala) Aug. 13, 2002, "Government to Offer Free HIV/AIDS Drugs Nationwide."

government gives ARV's to LRA [the revolutionary force in the Northern civil war] commanders to persuade them to denounce rebellion" (New Vision 20-11-2002). While the Ugandan government has been successful in taking credit for its laissez-faire approach toward reducing its HIV prevalence rates, it faces different challenges as the nature of the epidemic is altered according to the realities of treatment (see Richey 2005).

HEALTH SYSTEMS ISSUES IN UGANDA

The local governance of the influx of ARV-targeted funds into the health care delivery system in Uganda involves complex relationships between public and private provision. In the mid-1960s, Uganda boasted one of the best health care systems in Africa, consisting of "an excellent national referral and teaching hospital and a hierarchy of government health units and district hospitals, as well as many mission-run facilities" (Whyte and Birungi 2000). However, between 1976 and 1988, the number of patients attending government health units fell by half. Years of war, economic decline, and structural-adjustment-related cuts left Ugandan public health in ruins.[23] A recent Human Rights Watch report argued that the private sector, NGOs, and community-based organizations have begun restoration of health services together with the government, but that inadequate medical supplies, lack of trained staff, and limited access for Ugandans living in rural areas still prevail (Karanja 2003). Research conducted by the Delivery of Improved Services for Health (DISH) project noted that inadequate supplies and frequent stock-outs of STD drugs, condoms, and contraceptives, together with a lack of basic equipment and clinic expendables, discourages use by clients who see no reason to travel long distances to attend poorly equipped health units (DISH 2003). A similarly disheartening picture evolves from a retrospective study of maternal deaths in twenty hospitals from fifty-four randomly selected health centres in twelve randomly selected districts identified inadequate supplies of antibiotics, intravenous drug fluids, and blood for transfusion as among the top risk factors for maternal mortality in Uganda (Mbonye 2001). [24]

As treatment options expand, coordination between treatments and their providers, integration of various types of care for AIDS-related illnesses, and referrals (both vertically and horizontally) will not be possible without a stronger, more focused and effective government

[23] An issue of the Uganda Health Bulletin from the Ministry of Health was published on the theme "The Paradox of Uganda's Poor and Worsening Health Indicators in the Era of Economic Growth, Poverty Reduction and Health Sector Reforms" (Health Policy Analysis Unit 2001).

[24] Other risk factors were nonuse of family planning (arguably also an indication of health system failure), use of traditional medicine, and mothers' aged 15-19 or 30-50 (Mbonye 2001).

role. The expansion of ARV provision in Uganda is scheduled to happen in three phases. Provision at all Regional referral hospitals was completed in December 2003; provision at District and other hospitals (NGO) should be finished by December 2004; and provision at Health Center IV's is anticipated by December 2005. Of the constraints for the expansion of ARV provision identified by Dr. Namagala, MOH Programme Officer for the National ARV Therapy Programme, nearly all were inadequacies of the existing health system: insufficient personnel, inadequate infrastructure, logistics for supplies, management and distribution of the drugs, and data management all need to function better if the national programme is to work (Namagala 2004). Most health facilities cannot conduct their own laboratory analysis and must rely on JCRC. By early 2004, there were only 10 machines imported by the government for conducting CD+ analysis for use in the Provincial hospitals.

According to Dr. Cissy Kityo, Deputy Director of JCRC, most HIV-infected patients in Uganda report to health care facilities when they are in the advanced stages of AIDS (WHO stage 3 or 4), most present with serious opportunistic infections, and the vast majority of patients receive only palliative therapy and minimal laboratory testing (Kityo 2004). Unfortunately, the costs of treating opportunistic infections are often much higher than ARV treatment. For example, in Kampala, a two week regime for pneumonia costs approximately $115, toxoplasmosis costs $100, and meningitis costs almost $60 – compared to around $15 for two weeks of generic ARVs (*Ibid.*).

While the private sector is a major provider of ARVs, they have been slow to buy-in to the national procedures of accreditation and quality assurance, leading one study to conclude that the quality of private clinical service delivery is a problem in Uganda (Okera et al. 2003:5). An assessment of ARVs in Mbarara, Iganga, Tororo, Luwero and Mukono districts, conducted by Physicians for Human Rights, found that problems were similar across districts, and the differences in quality reflect the weight of the public sector versus private sector and NGO involvement (Carvey 2004). The latter were found to have greater funding, services available, working conditions and advocacy capabilities than their government counterparts. This led to differing levels of patient care as exemplified by the CDC project in Tororo District. According to the presenter, "The CDC doctors visit their patients, but the ones in the next bed are unhappy not to get visits from their own doctors."

De Waal argues that "the HIV/AIDS pandemic in Africa has unfolded at a time when the dominant approach to social action in Africa has been an NGO model" (2003, 18). In spite of a new recognition that the "capable state" is needed, the foundation for improving state capacity has been overwhelmingly eroded through the neo-liberal policies of the past 20 years.

The Ministry of Health was recently restructured at the behest of international donors to comply with decentralized development policy. Jeppsson et al. (2003) analyzed this restructuring and concluded that the foundation has been laid for the Ministry of Health to function in its new role as coach more than a player, but this process of moving toward a functioning relationship between the ministry level and the service delivery level is still incomplete.

The Ugandan government signaled a shift in its policy by agreeing to increase health sector spending with money it receives from the Global Fund (The Lancet 2004). Before the policy reversal, the government would have cut its own funding in response to funds from outside to maintain a predetermined expenditure ceiling; however the Global Fund monies are not meant to be used to maintain a balanced budget, but to improve health care provision in recipient countries. The new funds are to be used for the purchase of anti-retroviral drugs and for improving medical infrastructure. Yet the government's policy shift could be read in two very different ways: positively, that the state will now put funds into healthcare that might otherwise have gone for other expenditures (cynically, perhaps to support the large ongoing military commitments) or more negatively that the state will not be able to cap the levels of inflationary spending in the health sector to allow the fledgling institutions to "catch-up" to their funding levels.

Uganda has been noteworthy for its decentralized approach to scaling up levels of voluntary testing and counseling for HIV/AIDS (Contact Group on Accelerating Access to HIV/AIDS-Related Care 2001:9). However, the difficulties of wedding decentralized service provision with improving access for poor people are likely to increase with the integration of AIDS treatment as part of Ugandan's health care expectations. Kivumbi and Kintu (2002) examined the government's attempts to place "safety nets" in the form of exemptions and waivers of user-fees for health care. From qualitative data in the districts of Mukono and Mbarara, they found that district local governments had little motivation to extend exemptions to their constituents as they were more interested in raising revenue to meet recurrent costs of service provision than in providing equitable access to healthcare. This study concludes that improving health equity through decentralized safety-nets will only be effective if the measures are backed by a national health financing policy, if competing demands for local revenue are resolved, and if there are strict enforcement and supervision provisions at both district and central governments (*Ibid.*). Effective policy responses to the new realities of AIDS treatment will require a well-funded, capable state with goals of health equity.

AID FOR ARVS IN UGANDA

Even though combating AIDS has had domestic support in Uganda, international donors are critical to financing the country's implementation efforts. The increasing level of international interest in Ugandan AIDS policy has had an ambivalent reception in Uganda: More money is flowing into the projects, but the state and, in some cases, its nationals are losing autonomy and decision-making power. Uganda's AIDS success is important to donors, and donors are important to Uganda. Total donor support for all AIDS-related programs from 1989 to 1998 was approximately $180 million – an estimated 70 percent of total expenditures on AIDS in the country (Hogle 2002), and donor funding in 1996 reached a high of 93% of all resources spent on HIV/AIDS (Putzel 2003). Uganda is a recipient country of all three global initiatives, and smaller donors, research and NGO projects abound.[25]

Uganda is one of the most important "showcases" for the US PEPFAR initiative. Museveni's leadership style and outspoken conservatism on social and sexual issues provide fodder to fuel the contemporary American culture wars. As the US Congress and its President generally oppose any spending on condoms or sterile syringes, the prevention efforts under PEPFAR are now known as those that support "the Museveni approach" (Garrett 2004). Indeed, the controversial ABC strategy in Uganda has now been so heavily promoted by its president that "the Museveni approach" signals abstinence as the focus of HIV/AIDS prevention campaigns. Uganda's grant is the largest of the PEPFAR countries, even though it has one of the lowest rates of HIV infection in Africa. Uganda was proposed to receive $95 million in 2004 and $500 million over the next five years. By February 2004, PEPFAR had disbursed $37 million to 20 organizations in Uganda, and funding is pledged for placing 60,000 Ugandans on ARV treatment by 2007.

Simultaneously, the Global Fund has approved over $200 million for Uganda, but the money is caught up in bureaucratic snares and had not reached the ground as of April 2004. The Global Fund's grant is $20 million larger than Uganda's entire health care budget, and aims at sponsoring 33,000 people on ARV treatment (Feuer 2004). However, the Global Fund has been plagued with disbursement delays, including a freeze on $13 million in July 2004 to wait

[25] Some of the organizations providing ARVs in Uganda are Medicins Sans Frontiers (MSF), Centers for Disease Control (CDC), the Rockefeller Foundation, the Bill and Melinda Gates Foundation, the Academic Alliance for Treatment of HIV in Africa, the Uganda Cares Initiative, the Clinton Foundation, Case Western Reserve University, Johns Hopkins University, the Medical Research Council of the UK.

for the procurement plans by Uganda's government to be approved by the Fund's head-quarters in Geneva.

The World Bank's MAP program will loan Uganda $50 million over the next two years, and of this, $3 million is designated for ARV treatment for 6,000 people. After this infrastructural improvement loan, the next installment of MAP funds will be a grant (Feuer 2004). The WHO Representative in Kampala is quoted as applauding the country's initiative to offer free ARVs, noting that "Uganda is one of the countries we are relying on to hit the target of treating three million people worldwide by 2005" (Wendo 2004).

"Sustainability" is a hushed but consistent concern in Uganda. As Alex Godwin Coutinho, executive director of the AIDS Support Organization (TASO) pointed out – by 2007 100,000 Ugandans may be on treatment, but 150,000 more will need it (Feuer 2004). There is also the perception among other areas of the Ministry of Health that HIV/AIDS is getting far more funds than other diseases. For example, one informant stated "the focus on HIV/AIDS has shifted focus from other areas of equal importance" (interview, 28 Jan. 2004). He went on to explain that this was because the allocation of resources is guided by the number of deaths from that disease since this is justifiable politically and economically, but this leaves out many other areas where the numbers are not as obvious such as maternal mortality. Furthermore, "HIV has got a lot of resources and these impact political will, social mobilization, and re-sources at the central, district and community levels – and these are well-run by efficient managers and professionals" (*Ibid.*).

Coordination between donors and the government has been an obstacle for actually getting donor-financed ARVs to patients. For example, as late at early 2004, Dr. Mayanja-Kizza, head of Dept. of Medicine, Mulago and Academic Alliance, explained that the World Bank's MAP funds were in the country but not released because of lack of a national policy, and the Global Fund monies were not yet in-country (interview, 16 Jan. 2004). A representative from another NGO approved to receive MAP funding in February 2003, noted that they had not seen any funding at all and in response to their inquiries, had been told that MAP in Uganda was ex-periencing a "case flow crisis" (interview, 26 Jan. 2004). While aid is clearly flowing to Uganda to support President Museveni's claim for free ARVs for those in need, it is actually the governance of international trade that limits the coverage of cost-saving generic drugs, limiting the supposed roll-out to more recipients.

TRADE OF ARVS IN UGANDA

Ugandans seeking ARV care are caught up in the "public-private mix-up" where access to government facilities, fee-for-service private clinics, retail drug outlets and research projects with free ARVs become intertwined in the lives of individuals, families and communities (Whyte et al. 2004). AIDS is one of few diseases without alternative older off-patent generic treatment versions and all ARVs on the market are under patent protection in Uganda[26]. For other diseases like malaria and tuberculosis some products that are old enough to be off-patent and cheap are used as first line treatment, even though they may not be as effective as newer drugs (interview, pharmacist, Ministry of Health, 6 Oct. 2003). Because ARVs have only been on the global market since the mid-1980s, all products are still under patents, and branded products dominate the market. However, some products especially from India have been entering the market in generic versions since 2000. With the Doha Declaration allowing developing countries to import generic products under compulsory license, there is scope for much more competition on the ARV market. In Uganda the result of generic competition has already been a dramatic decrease in the prices on anti-retroviral treatment.

Before the Drug Access Initiative was launched in 1999, treatment cost $12,000 per year. In 1999 prices fell to $7,200 per year. One year later in 2000 with the Accelerated Access Initiative prices went further down to $1,000 for one year treatment. Later the same year, generics were introduced at $480 per year. In 2002, the price of generics had gone down to $31 for a month or $372 per year. The number of people on medication has risen accordingly: from less than 1,000 in 1999 to more than 10,000 in 2002 (Oxfam 2002, WHO 2003, JCRC 2002). The costs of ARVs in Kampala in January 2004 per patient per month ranged from $25-$60 for generics to $86-$560 for brands.

Three types of payment schemes are currently operating in Uganda. According to UNAIDS (2004) between 5,000 and 10,000 people are taking ARVs in Uganda on their own expense. As late as early 2004, 80% of patients were still paying for ARVs out of their own pockets. A second modality that functions relatively well for the employed elites is a company subsidy policy whereby over 15 companies have agreed to offer partial subsidies to their employees for

[26] Uganda is a member of the African Regional Industrial Property Organization (ARIPO) which means that patent applications are handled regionally and patents are granted for all the members (interview, registrars office Kampala, 30 Sept. 2003).

the costs associated with ARV care.[27] Most paying clients for ARVs are men, while more women receive free treatment through donor-funded projects.

Buying ARVs can be done from several sources. The main access is to go to one of the 25 governmentally approved treatment centers where the patients are sure to get counseling and testing facilities. About half the patients do this. The drugs coming into these clinics are all imported by private organizations or companies as the national governmental health authorities have not yet gone into import and distribution of ARVs. The main provider is Medical Access, an NGO formed in a collaboration between UNAIDS and the patent holding global pharmaceutical companies. Since 1998 Medical Access has imported branded ARVs on a not-for-profit basis to Uganda. Since the South African court case, the prices on branded ARVs have gone down due to pressure from the civil society and competition from other sources. One of the official treatment centers, the Joint Clinical Research Center (JCRC), started importing generic ARVs in 2000 and the price for this treatment was down to $25 for one month treatment in December 2003 (interview, JCRC doctor, 30 Oct. 2003).

Thirdly, for those few people in donor programs who are getting free ARV treatment, other problems are relevant to look at. By only providing free treatment for poor people compromises compliance as their priorities can be more basic than ARV treatment. At the JCRC some patients explained how they sometimes sell their free treatment on the streets in periods where they needed money for food or other expenses for their children[28]. Higher income patients, who do not qualify for these programs, are willing to buy the medicine, as long as it is cheaper than in the pharmacies. This potentially contributes to the increasing resistance to treatment as the patient may share it with the purchaser[29]. Furthermore, such choices reinforce the need for providing access for greater percentages of the infected population who need the drugs. For those paying from their own pocket, compliance can be difficult as well. After taking the ARVs for a period, the patient starts feeling better, then it is tempting to stop treatment in order to be able to pay other expenses. After a while the patient feels worse and will start taking ARVs again. While patients may have information about risking resistance, the

[27] These were Bank of Uganda, Standard Chartered Bank, Coca Cola, Citibank, World Bank, Shell Uganda, Total Uganda, Nile Breweries, American Embassy, National Housing Corporation, UN Agencies, GTZ, The New Vision, Medical Research Council Project.

[28] Informal interviews during participant observation, JCRC, 30 Oct. 2003.

[29] In some programs the patients have to take one dose in the clinic and get a package for the rest of the week, therefore neither the patient nor the buyer take the full cure and resistance could develop in both (interview, physician, Oct. 2 2003).

monthly cost may still outweigh rational drug use. While the cost of drugs has declined to make them within the range of an employed civil servant, most Ugandans are still below this income category.

JCRC in Kampala is the biggest provider of ARVs in Uganda and exists as a cost-recovery programme. An official from USAID characterized JCRC as providing "mover and shaker capacity building for the government" (interview, 27 Jan. 2004). As a governmental research institution JCRC has developed to be the leading AIDS treatment institute in the country providing both branded versions and generic versions to the clients. Most patients are paying for their treatment and few are sponsored by different donor programs. Over 60% of Ugandans paying for drugs purchase them at JCRC (interview, Dr. Cissy Kityo, 12 Sept. 2004). In 2002 almost half of the ARV patients used the generic triple combination, Triomune, and the other half used the branded combination of the same products D4T, 3TC and EFV (JCRC 2002). By December 2003 JCRC had 6,000 persons in ARV treatment in their clinics in Kampala and five other major towns (interview, JCRC doctor, 30 Oct. 2003). Recently, JCRC has been a major recipient of PEPFAR funding to allow them to expand from service provision in 7 sites to reach 22 sites.

Another way to get ARVs is to buy from the private importers. There are five private importers of ARVs in Uganda: two are selling branded products from Europe and the US and three are selling generic copies from India. The two selling branded products import the same products as Medical Access Initiative. They engage in similar pricing strategies to be competitive which keeps the Ugandan prices on branded products lower than in many other countries. The importers sell in their private pharmacies to patients from private clinics and others, preferably with prescriptions, but not always. Private importers work as agents for the manufacturing companies who put restrictions on prices but also assist in marketing by providing information for potential customers and doctors. For the wealthy people who have access to this type of treatment, it can provide a way of maintaining some degree of privacy regarding their illness (see also Whyte et al. 2004).

The private importers of generics have based their business on private networks in India. All three of them sell the products to hospitals, clinics etc. and in their own pharmacies. In one pharmacy visited, they provide ARVs to about 3,000 people regularly and most of their imports are sold over the counter directly to the patients. One Kampala pharmacy owner explained:

> I also treat people here. They come and get the medicine at the counter but we do not have the laboratorial stuff to test and all that. This is done by the doctors before they write the prescription…sometimes the doctors do not know how to combine the ARVs in combination therapies and prescribe combinations that are dangerous. In such cases, I give them different products than their doctors prescribe' (*interview, pharmacist, 11 Oct. 2003)*

That health workers and pharmacists prescribe ARVs incorrectly was recognized by the head of JCRC during the recent August 2004 counterfeit scandal in Kampala. The Ugandan government stopped the distribution of ARVs in two Kampala pharmacies that had been licensed to sell them because of claims that fake drugs were being sold in real ARV bottles (Mascolini 2004).

The importers of generic ARVs face more competition as their market is expanding and more foreign generic producers are entering the market through local agents. Meanwhile, they also face more insecurity as the products are, in fact, illegal to import, sell and distribute in Uganda due to the patent legislation. With the large tenders coming up from the money from PEPFAR and The Global Fund, the patent holders are expected to claim their rights anytime. So far, there have been no compulsory licenses granted on pharmaceutical products. There is only an informal agreement between the industry and the government in which the global companies agree to close their eyes to illegal generic imports and will continue to do so '…as long as the number is this small' (interview, pharmacy manager, 27 Sept. 2003).

Uganda does not have to comply with the TRIPs Agreement until 2016 for pharmaceuticals, but the industrial property law that also covers patents has been in a process of revision for the last three years. Initially, this reform was assisted by the USAID program for technical assistance through a consultant to help in rewriting the law in compliance with the TRIPs Agreement. However, this USAID consultant had earlier been working with the pharmaceutical companies in the US and was accused of taking US corporate interests more seriously than the public health needs of Ugandans. Because of this, civil society organizations engaged in a law reform process helping to implement the TRIPs Agreement in a way that will protect public health in Uganda. This has slowed the implementation down a lot.

Local organizations are working to make the terms of international trade beneficial for Ugandan public health interests. The Ugandan Coalition on Access to Essential Medicines was formed in 1996 to supervise the implementation of the TRIPs Agreement in Uganda. It is a coalition of 25 NGOs working on public health issues in the country, including access to

ARVs, and granting of compulsory licenses. Although the organization recognizes that access involves more than just patents, they argue that paying four times the minimum price will not make it any easier to build an appropriate health sector to monitor the medicines. On the contrary, the government and donors should make sure to get cheap medicines in order to get more ARVs and meet other infrastructural needs (interview, HEPS, 30 Sept. 2003). A lawyer working for the coalition explained "…developing countries have a fear of lawsuits. That is why they will not engage in compulsory licensing. They do not have the capacity and knowledge to run a case against one of the big players on the world market and they will fear getting a bad reputation or to be put on the Special 301" (interview, 1 Oct. 2003).

There are many obstacles for any government to grant a compulsory license and declare a "national emergency" or "circumstance of extreme urgency". The Ugandan case shows that it is not clear what will happen to other trade or aid relations. The worst-case scenario is that the donor and trading partners will interpret such a declaration as a government failure. More likely, a large number of lawsuits will be filed to establish precedence on how far the provisions can be used. While this is normal procedure, for developing countries the legal burden is particularly onerous and one for which they are note likely to be well-prepared. Developing country representations in Geneva are small and the resources necessary to hire specialist lawyers on intellectual property are great. There is a good reason to be afraid to end up in the US Special 301, as the list has two different categories and ending up in the worst one can lead to a US boycott of your products. India, Brazil, and Thailand have all been on this list because they were producing and distributing generics for their national markets.

Uganda has a limited capacity for harvesting the gains from the WTO negotiations as communication flows slowly from the delegations to the relevant ministries. With a representation of two people in Geneva following and participating in all the ongoing negotiations and two people working on WTO issues in the Ministry of Tourism, Trade and Industry in Kampala it is difficult to transform relevant trade agreements into the everyday political life in Uganda (interview, Ministry of Tourism, Trade and Industry, 7 Oct. 03). In case of the TRIPs Agreement and access to medicine a strong relationship between the people working with WTO in the Ministry of Tourism, Trade and Industry, the Ministry of Health, The Uganda AIDS Commission and the Ministry of Law is needed. Such a relationship does not exist but would be necessary in order to pass the relevant information on WTO to the Ministry of Law; then to implement the provisions in the patent law of Uganda; and finally, to pass relevant information to the Ministry of Health in order to make use of these (interview, Solicitor General, 12

Nov. 2003). So far the Ministry of Health has not engaged in patent law issues (interview, Law Reform Commission, 7 Oct. 2003).[30]

Because Uganda does not have the manufacturing capabilities for producing ARVs,[31] the Doha Declaration could help to officially legalize their importation from countries like India or Brazil. While these products are already available in the market, from a WTO perspective they are illegal. Moreover, generic ARVs are allowed due to an informal mutual understanding between the patent holders and the Ugandan government (UNAIDS 2004). This understanding holds as long as the quantities are relatively small, for the time being only about 25,000 Ugandans access ARVs. However, it will not be sustainable if the medicine is to be provided for all those who need it, estimated 120,000 in 2004, and far more in the future. Thus, even though there is ground for granting compulsory licenses in the patent laws of Uganda, it has not yet been used. The civil society organizations working in this area give the impression that Uganda has a tendency to support the US in trade negotiations. Along this line, the president is not supportive. As explained by his advisor, Museveni finds that compulsory licenses are infringing private property rights and expresses it the following way: "you should not eat the seeds for next season" (interview, president advisor on HIV/AIDS, 12 Nov. 2003).

[30] When talking with the different officials, the lack of communication is obvious. In the Ministry of Health there was an impression that there is already a compulsory license on ARVs and in the Ministry of Law the impression was that generics were not in the market. Talking with the doctors importing the generic ARVs, they claim that there is no patent law on medicines in Uganda. (interviews with ministerial officials Sept. – Dec. 2003)

[31] In spite of claims to the contrary in the Ugandan press, there are no plans of producing ARVs in Uganda. The pharmaceutical sector is not ready to engage in ARVs; production is expensive and there is no indication that national producers would be able to compete with imported ARVs as the market is relatively small and they will have to import all intermediates.

Conclusions: Aid to AIDS or Trade for AIDS?

As access to ARVs is becoming recognized as an important part of combating HIV/AIDS in developing countries, governance conflicts become more significant. Access to ARVs requires life long commitments from the national health policies, donors and patients. Still, ARVs are only accessible to 2% of the adults who need it in Africa. Engaging in ARVs is different from other health programs, as thus far there is no cure for AIDS, and developing country health systems are not experienced in treatment of chronic diseases. The governance challenges in large-scale ARV provision are not justification for a lack of engagement by the international community or by national or local activists. However, they do call for more attentive analysis of the realities of "scaling up" and for evaluation that goes beyond simply numbers of patients receiving pharmaceuticals.

The Ugandan government promises universal access to ARVs for everyone who needs them, yet it is unclear how this access will actually be realized. On the World AIDS Day 2003, President Museveni announced that "we need to treat 150,000 people in a year. The ones who have got the virus are 1.2 million now. Now, out of that maybe only 150,000 may be sick enough to need drugs. Now if you are to take the present level of $150 per person per month that would work out something like 600 billion dollars" (cit. Museveni, The Monitor, 01-12-2003). International aid has been flowing into the country for the purchase of drugs and for constructing what many hope will be health delivery systems sufficient to handle them. Yet, donors who provide ARVs must only guarantee to fund them for five years, and individuals will need these interventions and their requisite monitoring for life. The Ugandan government is counting on drug costs dropping even further - but how realistic is this expectation of even lower prices? The global governance of trade suggests that it may be unrealistic to expect that prices will drop so significantly as to make these regimes sustainable without ongoing international aid support. The proposed scale-up will have unknown effects on the relationship between international donors and drug companies, and the terms of formal and informal agreements may shift as donors become the biggest buyers of ARVs in developing countries. It also holds potentially detrimental implications for local governance as more money and more players crowd the field offering incentives for ARV programs.

Provision of ARVS has played a special role in recent national governance of Uganda. Museveni has very successfully used the possibility of providing life-saving drugs for so many of his citizens as a distraction from the overall lack of government-provided health care. At the time when Museveni is experiencing the most civil unrest in his nearly two decade rule and his

regime is under strong internal opposition calling for change and political pluralism, this influx of drugs is also an influx of political capital. Now, Museveni is equipped by international donors with the possibility of taking credit for saving the lives of millions of Ugandans, but what will this relationship mean for Ugandan autonomy? Will major donors like the US conitue to fund Museveni's efforts for AIDS treatment even as he continues to violate many of the existing preconditions of "good governance" in the political sphere? Indeed, as Museveni has already been accused by critics of governing for the interests of the US and the UK more than those of regular Ugandans, the stakes of such a cozy relationship with donors over ARVs are politically volatile. Competition over spoils can also pit different sections of the government against each other as funds are held back from certain areas while being allocated inequitably to others. At a recent Makerere University seminar workshop on ARVs in Uganda, one District Health Officer asked the other participants the bold question: "Whom are you addressing—the international community or Ugandans?"

Museveni's regime has been characterized by Tripp (2004) as "semi-authoritarian," and perhaps ARVs can also be described as semi-authoritarian technologies. Their influx into Uganda can contribute to a particular political outcome due to the kind of technologies they are. For example, treatment with ARVS requires stability of both individuals and communities. Their high cost makes them valuable commodities for consumption, trade, or as political spoils. Also, the global importance patient adherence justifies international concern with the intimate behavior of Ugandans' pill-taking. If "they" do not adhere to the regime, then "we," the global community will suffer the consequences of more virulent strands of HIV.

Many of the ARV discussions neglect the foundational discourses of development – poverty, inequality, health equity – yet a physician from JCRC reminds us that these are pivotal: "The main problem with compliance has been not having enough money to pay for more drugs" (Kityo 2004). In spite of the political discourse of equality in treatment, the realities of funding suggest the difficult choices will be made from the level of policy to that of individual. In the words of one Ugandan physician, "Would a physician ignore your own family? Who decides? Doctors? Lawyers? The bigshots or the village peasant?" (presentation, 24 Jan 2004, Physicians for Human Rights Conference, Kampala). Thus, global governance of trade and of aid will both shape and rely on individuals in charge of "implementation" which must be examined outside the sanitizing context of development discourse.

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