BILL FRIST
TENNESSEE

United States Senate

WASHINGTON, D. C. 20510

February 28, 2000

Ms. Sandra L. Thurman
Director
Office of National AIDS Policy
The White House
Washington, DC

Dear Ms. Thurman:

I want to offer my sincere thanks to you for your expert testimony to the Subcommittee on African Affairs regarding the AIDS crisis in Africa. Your insights and views were extremely helpful, and I look forward to working with you in coming months on meeting our shared goal of combating AIDS on that continent.

With warm regards, I am

Sincerely,

Bill Frist, M.D.
United States Senator

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Testimony of David Satcher, MD, Ph.D. before the
Senate Foreign Relations Subcommittee on African Affairs
Thursday, February 24, 2000

INTRODUCTION

Thank you for the opportunity to come and speak with you as a physician and public health professional on the enormous unfolding global crisis of HIV/AIDS and its impact on Africa. On January 10, 2000, the United Nations Security Council held a meeting focused on health – the first time ever in the history of the Council's 4,000 meetings which date back over a half century. I accompanied Vice President Gore to that meeting as part of his delegation. Never before had a sitting Vice President addressed the Council, not to mention a Surgeon General and Assistant Secretary for Health. Why does the United Nations consider the HIV/AIDS crisis a threat to security? In a word, instability. Not only has this pandemic wiped out soldiers and military personnel, but it has also impacted other professionals such as teachers, businessmen, and laborers who are vital to the future of a nation. HIV/AIDS is a serious public health problem of such magnitude that it threatens the very security of many African countries.

Both the dimensions of this epidemic, and the capacity of existing health care systems to halt its relentless march, demand urgent action to halt the toll of human suffering and loss of life. The attention that this Committee is devoting to the AIDS crisis in Africa is extremely valuable to the creation of new partnerships that can strengthen the global response to HIV/AIDS.

SCOPE OF THE EPIDEMIC

The HIV/AIDS epidemic will soon become the worst epidemic of infectious disease in recorded history. In the 1300s, the bubonic plague decimated the population of Europe with 20 million deaths, and the influenza epidemic of 1918-1919 killed more than 20 million people worldwide. At the end of 1999, 16.3 million people are estimated to have already died from AIDS worldwide and another 33.6 million individuals are living with HIV/AIDS. Without a cure in sight, the toll of AIDS in terms of lives lost is on a rapid rise.

Nowhere has the impact of the epidemic been more severe than in Africa. Of the 33.6 million people living with HIV, an estimated 23.5 million (nearly 70%) are in Africa. An estimated 13.7 million people have died of AIDS in Africa, over 80% of the deaths due to AIDS worldwide. In 1998 in Africa, when 200,000 people died as a result of armed conflict and war, AIDS alone killed 2.2 million people. The progression of this disease in Africa has outpaced all projections. In 1991 the World Health Organization projected that 5 million people would die of AIDS between 1991 and 1999, but half that number now die each year.

In many southern African countries, HIV/AIDS has become an unprecedented emergency, with one in four or five persons (20% - 26%) between the ages of 15 and 49 years living with HIV infection. Women are more heavily affected than men. New information suggests that between 12 and 13 African women are currently infected for every 10 African men; this disparity is greatest among girls aged 15 - 19, who are five or six times more likely to be HIV positive than boys their

own age. The next generation of children of Africa will be doubly burdened by their own HIV infection, or by growing up without the nurture and protection of a parent.

HIV/AIDS also interacts with a number of other infectious diseases, such as tuberculosis and other sexually transmitted diseases. Individuals with immune systems weakened by HIV are more susceptible to infection with TB, and TB is widely prevalent across the African continent. HIV infection is also more easily transmitted in a setting of untreated sexually transmitted diseases. The predominant mode of HIV transmission in Africa is unprotected heterosexual intercourse, highlighting the importance of prevention and early treatment of STDs as an HIV prevention strategy.

THE PUBLIC HEALTH APPROACH

The HIV/AIDS epidemic in Africa, as it has done throughout the world, has shown us the interrelationships of social behaviors, cultural and religious belief systems, and economic and political systems as they influence public health and the delivery of health care and prevention interventions. The traditional approach of public health is to:

- define the problem
- determine the risk factors or causes of the problem
- develop interventions and strategies to address the risk factors or causes, and
- implement interventions and evaluate their effectiveness

We have learned a great deal about the virus which causes HIV/AIDS, and a number of studies are ongoing to examine the specific subtypes of the virus which are most prevalent in Africa. Understanding the pathogenesis of infection, modes of transmission, and parameters of how infections are moving through a population serve as the cornerstone of a public health intervention. These basic science inquiries, and the equally important understanding of the behavioral risk factors and social contexts that facilitate continued spread of the disease, continue to inform the public health response to ending this tragic epidemic.

What is needed to overcome this expanding epidemic is a sustained orchestrated worldwide effort that includes elements of prevention, treatment and ultimately a preventive vaccine. Together, the world community can do this.

PREVENTION

Prevention is our first and best line of investment to end the global HIV/AIDS epidemic. As the world increasingly becomes a global village, an epidemic that continues unchecked in any region will ultimately affect us all. The good news is that we can change the future course of the HIV epidemic through effective actions taken today. Over the last two decades we have learned many things, and there are many examples that demonstrate that the tide of HIV/AIDS can be turned. The challenge is to take this knowledge and support its application systematically, not in isolated communities or a few countries. Bringing prevention efforts up to a scale that can turn

the tide of the HIV epidemic should be among our highest public health priorities.

Achieving the goals of prevention requires a number of elements: the availability of accurate information; the ability to act on that information without fear of stigma or prejudice; and the means to protect oneself from exposure to the virus. With respect to HIV/AIDS, it also means the ability of a mother to protect her unborn or newborn child from exposure to HIV before birth or through breast milk. The ability to screen and treat other sexually transmitted diseases also serves as a primary prevention tool for HIV.

Prevention efforts are most effective when they are grounded at the community level and responsive to the social and cultural contexts in which people live their lives. All too often, stigma and prejudice continue to preclude access to prevention information that can minimize the spread of infection. There are many examples of effective prevention efforts in Africa, as in Uganda – where the whole nation has mobilized to end stigma, urge prevention, and change behavior, with a resulting dramatic drop in the HIV infection rate. In Uganda, the HIV infection rates in certain antenatal clinics have decreased from 30% to 15% as a result of these efforts. Scientists and health professionals from the National Institutes of Health and the Centers for Disease Control and Prevention have worked in partnership with their Ugandan colleagues to evaluate the impact of prevention interventions and support research to develop new prevention tools. In Senegal, the religious and political leadership of the country joined together early in the epidemic to invest in getting prevention messages out, and the result has been one of the lowest HIV infection rates on the continent. These are but a few examples of some successes achieved

on a continent where the epidemic is raging.

TREATMENT

There is also hope for people living with HIV/AIDS to live longer, healthier and more productive lives due to the discovery of new antiretroviral treatments, and effective drugs to treat common opportunistic infections which cause great suffering and early death. The natural course of HIV disease in the United States has seen a great change due to these therapies, with many more adults and children now living longer healthier lives, participating in their communities and the workforce, and parents caring for their children. Our ability to slow the progression of immune dysfunction, and to diagnose, prevent and treat the concurrent opportunistic infections has greatly decreased morbidity and mortality in the developed world.

One of the greatest successes has come in the ability to reduce transmission of HIV from mother to child, through HIV counseling, testing and use of antiretrovirals such as AZT and nevirapine. In the United States, there has been a 72% decline in the number of HIV-infected babies born between 1992-1998 with the use of AZT in the prenatal, labor and delivery, and postpartum period. However this complex regimen is expensive and requires a level of medical infrastructure not available in many areas of the world. The urgency to develop affordable and practical therapeutic interventions for developing countries is profound. In some areas of sub-Saharan Africa, 30 percent or more of pregnant women are infected with HIV, and 25%-35% of their

infants will be born infected. In response to this pressing need, a partnership effort between Uganda and NIH scientists identified a highly effective, safe and inexpensive drug regimen for preventing perinatal HIV transmission. Administration of one oral dose of Nevirapine to a mother at the onset of labor and another dose given to her baby, cut the rate of HIV transmission in half compared with a similar short course of AZT -- for a cost of $4.00 instead of the roughly $800 required for the AZT regimen now recommended in the United States. If widely implemented in developing countries, this intervention potentially could prevent some 300,000 - 400,000 newborns per year from beginning life infected with HIV.

To maximize the benefits of antiretroviral therapies, their safe and responsible use requires a level of medical care and infrastructure that presents an enormous challenge to the developing world. But first steps can be taken by supporting the development of community-based capacities to diagnose HIV and provide low cost treatment for common opportunistic infections that kill prematurely and cause great suffering. It has been our experience that community-based services, built upon partnerships among existing community institutions, serve as the most effective and sustainable model to provide the net of prevention, health and social services vital to curtailing this devastating epidemic. As the Governments of Africa and their health leaders determine how best to involve communities, determine and address the needs of their people and what their systems can support, the worldwide public health community must stand ready to help.

VACCINE

The importance of developing an effective vaccine for HIV is paramount, as the greatest hope for ending the epidemic lies in this intervention. Vaccines have been the most significant public health intervention to eradicate or curtail the incidence of feared diseases, such as polio, smallpox, diphtheria, tetanus and many others. This Administration has made the development of an HIV vaccine a priority, and my HHS colleagues are working in collaboration with international partners to ensure these products will be effective against the virus strains that are predominant in Africa. A year ago, the first vaccine trial in Africa began in Uganda under the sponsorship of the NIH and carried out by Ugandan investigators. Other Phase II vaccine trials supported by the NIH are also underway in Thailand.

The utility of an HIV vaccine must take into consideration the availability of a health care system that can safely deliver the vaccine to large and often isolated populations. This remains a barrier today to the delivery of many existing vaccines in Africa and developing nations in other parts of the world. Even as we press forward to develop effective vaccines, it is imperative that we not ignore those who are already living with HIV infection. Our experience in this country has shown that developing medical systems of care for already infected persons becomes a critical component of an effective prevention effort.

CONCLUSION

The full dimensions of the unfolding AIDS crisis are becoming better understood. The need to mount an orchestrated, multifaceted and aggressive response is inescapable. Current national/country level AIDS activities in Africa must be expanded dramatically and rapidly to make a substantial impact on the course of the disease. As effective approaches are defined, we need to find ways to support their wide application, working closely with public health leaders on the front lines. Experience from some countries has shown that when governments commit their own political prestige and financial resources, involve broad aspects of society at the community level, and directly confront issues of prejudice and behaviors that hold a high risk of transmission, the rate of new infections can be slowed and communities can begin to develop more durable responses to effectively cope with the HIV epidemic. We have seen over and over again in the Western world the need for a sustained prevention-medical treatment continuum. Developing strategies that are episodic in targeting at risk populations can inevitably lead to high rates of recidivism and a resultant resurgence of new infections.

It is critical we not minimize the human side of this epidemic. The statistics describe a public health crisis that has largely gone unchecked, and do not reflect the extent of human suffering. The extraordinary human toll is evident, the millions of potentials unrealized, the expanding wave of grief that extends beyond the individual, their family and community is self-evident. As part of the Human Family, we will all be feeling the repercussions of this extraordinary human loss for

generations to come. We are committed to look for every opportunity to assist African countries in their continuing efforts to end this epidemic.

International Federation of Pharmaceutical Manufacturers Associations
Fédération Internationale de l'Industrie du Médicament
Federación Internacional de la Industria del Medicamento

AIDS IN AFRICA

Testimony Before the United States Committee on Foreign Relations
Subcommittee on African Affairs

Dr. Harvey E. Bale, Jr.
Director-General
International Federation of
Pharmaceutical Manufacturers Associations (IFPMA)

Senate Dirksen Building, Room 419
February 24, 2000

Introduction

Mr. Chairman and other Members of the Subcommittee: I am the Director-General of the International Federation of Pharmaceutical Manufacturers Associations (IFPMA), based in Geneva, Switzerland, representing the research-based industry in over 55 countries. The Pharmaceutical Research and Manufacturers of America (PhRMA) is one of our important members. We represent our industry before the World Health Organization, the World Trade Organization, the World Bank, the World Intellectual Property Organization and other UN agencies, and the OECD. We are also full partners in the Global Alliance for Vaccines and Immunization (GAVI) and the Medicines for Malaria Venture (MMV).

Our mission is to seek to work with international agencies and national governments to find new ways to bring the therapeutic technologies and know-how of our industry together with efforts to reduce disease burdens. We also address the most important conditions necessary to strengthen the capability of our industry to continue to develop innovative therapies and vaccines: i.e., intellectual property rights, competition-based health care delivery systems, effective product regulatory systems and open information delivery policies for health care professionals and patients.

We are here today to focus on one of the most serious global threats to public health globally and the worst threat to Africans' well being and the economic development of the Sub-Saharan African region. The research-based pharmaceutical industry is strongly

committed to helping people living with AIDS – who wait for better and less costly therapies and, hopefully in the not-too-distant future, a vaccine or vaccines to effectively prevent further HIV infections. I will seek to relate our perspective on this serious problem and to suggest what is needed.

The Seriousness of the HIV/AIDS Pandemic

HIV/AIDS is indeed *the* public health crisis in Africa. Over 34 million people in the world are currently infected with HIV/AIDS, with 95% of them living in developing countries. Most tragically, over 13 million children have lost one or both parents. Two-thirds of those infected live in sub-Saharan Africa, and more than 80 percent of the world's HIV/AIDS deaths have been in this region. HIV/AIDS is now the number one killer in Africa, taking more African lives each year than all the conflicts in the region combined, and HIV-related illnesses are an additional burden on already weakened public health services. According to WHO's 1999 World Health Report, HIV/AIDS has become the disease with the greatest impact on mortality in Africa. Indeed, life expectancy in Africa is declining because of AIDS, and in some places may fall back to 1960s levels, according to Dr Peter Piot, Executive Director of the Joint United Nations Program on HIV/AIDS (UNAIDS). This would mean a drop in expected life spans from 59 years in the early 1990s to just 45 years by 2010. As Dr. Piot recently noted, "AIDS in Africa has become a full-blown development crisis, and is on its way to becoming the single greatest threat to human security on the continent...Few sectors of African society remain untouched by AIDS. The epidemic is wiping out health, social and economic gains that Africa has worked towards for decades." Furthermore, AIDS is decimating the most productive elements of African society. UNDP Administrator Brown declared at the first meeting of the UN Security Council this year that "an extraordinary depletion of the region's human capital is underway. There are estimates that the number of active doctors and teachers in the most affected countries could be reduced by up to a third in the coming years."

Industry's Key Contribution: Searching for Cures

The pharmaceutical companies responsible for the discovery, development and supply of medical products for managing HIV/AIDS are acutely aware of the urgent need to tackle the epidemic in Africa and other parts of the developing world. We are devoted to finding hope for those affected by the tragedy unfolding before us, as literally millions of men, women and children are swept away to untimely deaths by the rising AIDS pandemic. We call upon all parties, national governments and international organizations to take coordinated strong action to fight AIDS. We in industry are prepared to participate in augmenting our contribution to the struggle against AIDS, based on our special expertise and scientific and technical resources.

Industry's primary role in combating HIV/AIDS worldwide is through its unique role in the discovery and development of new vaccines, medicines and treatments for diseases

and disorders. Indeed, it is important to recall that, twenty years ago, AIDS was not yet identified. At that time AIDS was considered untreatable as well as incurable, subjecting those infected with HIV to certain misery and untimely death. Today, there are about 15 antiretrovirals on the global market, with more in the industry's research pipeline. This tremendous advance in treatment is possible thanks to the billions of dollars that the industry has devoted to AIDS medicines and vaccine research, including research into treating opportunistic infections related to AIDS. Today, there are over 100 new AIDS medicines in our industry's R&D pipeline, including **35** new antivirals and **10** vaccines for HIV prevention. Such research will, we hope, one day yield: shorter-course treatments, such as nevirapine from Boehringer-Ingelheim for preventing mother-to-child transmission of HIV; more convenient and tolerable regimens, such as tests of "one-pill-a-day" regimens being tested by various researchers, including Bristol-Myers Squibb; as well as scientific breakthroughs which could open up whole new avenues to fight HIV, such as a recent announcement by Merck scientists that they have found two experimental compounds which were able to obstruct the activity of an enzyme called integrase that plays a critical role when the AIDS virus infects cells. New treatments developed by the pharmaceutical industry and introduced in the last several years – e.g., antiretrovirals (including the protease inhibitors and non-nucleoside reverse transcriptase inhibitors) as well as anti-infectives and antifungals to combat opportunistic infections – have begun to change the pattern of the AIDS epidemic.

Industry R&D can only continue when there is respect for and implementation of protection for intellectual property rights which promote and protect such research. The challenge now is to improve therapies and the search for cures, continue to extend access to these breakthrough medicines to all affected populations, and ultimately to develop an effective vaccine -- or several vaccines. Allowing market incentives to proceed without counterproductive interventions is vitally important in creating an environment favorable for developing new vaccines, treatments and possible cures for HIV and AIDS-related conditions. Drug research and development by the research-based pharmaceutical industry is financed by companies' own internal resources, and on average it takes hundreds of millions of dollars to research, develop and test a new medicine, including treatments for AIDS. It is vital that this research is not hindered by quick-fix solutions such as compulsory licensing, parallel trade and other measures which may sound attractive to some in the short term, but would fatally retard R&D into HIV/AIDS related medicines in the medium and long-term, disappointing the hopes of millions who look for a cure for AIDS. Today, we no longer speak of "incurable diseases" ----- only those diseases for which we have not *yet* developed a cure or vaccine. There are real concerns about access to AIDS medicines in Africa and elsewhere, but this access has little to do with patents, and weakening patents would not -- I repeat, not – significantly improve access for reasons discussed below.

First, many developing countries are not yet TRIPS-compliant and some such countries, such as India, already produce generic copies of patented AIDS drugs. If patents were indeed the problem, large populations within these countries should have easy access to

these copied, generic versions of AZT and other medications; but in India and parts of Africa this is demonstrably not the case.

Second, the cost of a pharmaceutical product is only a small part of the overall AIDS treatment costs, including training, patient diagnostics, treatment supervision and safe drug distribution – elements absolutely essential to ensure the effective use of complex AIDS treatment regimens.

Third, the ex-manufacturer price of drugs in developing countries is often only a small part of the final retail price for consumers due to high import tariffs, taxes and wholesale and retail distribution margins. In America, these mark-ups may add perhaps 40-60% to costs. In Africa, they often add 100-300 % to ex-manufacturer prices.

Fourth, parallel trade and systematic compulsory licensing regimes (which were abandoned by Canada and New Zealand 10 years ago), weaken patent protection, but are claimed as cost saving policy instruments by advocates. Actually, when one observes price differences across national boundaries one is seeing differences in retail prices – which are reflective of many factors including the margins mentioned previously and which do not form a basis for parallel trade. In any case, where parallel trade exists (e.g., within the European Union) evidence shows that the benefits of parallel trade to consumers are small because such trade mainly benefits the parallel traders, not consumers, because the former capture most of the "rents" arising from the differences in ex-manufacturer prices across countries. Some activists promote compulsory licensing as another "solution" to access to AIDS drugs. Such advocates present compulsory licensing as a way to create a more competitive market akin to post-patent generic competition in the United States and a few other industrialized countries. However, as compulsory licensing is a deliberate action by governments, it can lead to a limited number of licenses being issued, with recipients potentially being chosen due to political favors rather than objective criteria. Thus, price benefits may be minimal, while the quality of a copied version may not be equivalent to the original.

Finally, many of the millions of people of Africa earning less than a US dollar a day, and their governments, cannot afford good quality generic versions of AIDS drugs either. Patent-pirated versions appear in Africa, and their prices are often not significantly lower. And there are bottom limits to prices, set by costs; and at these levels the unit costs (especially when the rest of the full costs of a treatment are added in) are well beyond the capability of the poorest patients who need the most help.

Partnerships and New Incentives for R&D

We believe that the AIDS crisis requires a comprehensive, multisectoral response, led by committed governments and intergovernmental institutions – the World Health Organization and the World Bank. We must as a coalition of stakeholders (1) step up educational campaigns to change attitudes and behavior to curb the spread of HIV; (2)

enhance the capacity of health systems to deliver essential medical care to the people living with the disease; and (3) encourage further innovation into new therapies and vaccines while improving access to existing ones in regions such as Africa. We must also recognize that the problem of access to drugs for AIDS and related conditions is one aspect of the broader issue of access to adequate health care generally.

More generally, innovative approaches may be needed to attack disease patterns in the poorest countries. And more resources are required. Fortunately, novel approaches are being explored. For example, UNICEF, WHO, the World Bank and UNAIDS are looking at ways to guarantee a market for vaccines for diseases predominant in developing countries, picking up on an idea of creating a fund (to purchase vaccines) raised initially by Professor Jeffrey Sachs.

The Medicines for Malaria Venture (MMV) is another example of innovative public/private sector partnerships to address the need to develop new medicines for special categories of diseases -- in this case malaria. This public-private sector MMV, designed to develop new antimalarial drugs, is an excellent investment of resources to find new treatments for this widespread disease, which infects millions of people in developing countries, while researchers search for an effective antimalarial vaccine to protect future generations. We would urge the Congress and Administration to financially back the public/private MMV initiative, joining several other countries that have already done so. The financial requirements to contribute positively are relatively small compared to the very large potential benefits that will accrue to millions of malaria-threatened populations in Africa and elsewhere.

Other mechanisms should be explored as well. These include developing policy measures similar in concept to US orphan drug legislation, which includes tax credit and market exclusivity provisions. We note positively the proposal by the Administration to set up a market-based mechanism to support vaccine development for HIV, malaria and tuberculosis. New incentives should not be limited to vaccines, however. Breakthroughs in drug treatments may come more quickly than new vaccines and may provide cures, which would have an important impact on quality of life for those millions already living with these diseases. As with all innovative drugs, the investment in developing new antiretrovirals and researching an HIV vaccine is immense. The continually mutating nature of HIV adds additional complications to the search for more effective treatments as well as possible vaccines or even cures for AIDS. We must accept that, despite the progress being made, bringing an effective treatment, cure or vaccine to market will be a long and demanding process. Despite the large amount of research being conducted into HIV/AIDS, most estimates still reflect a view that a very effective vaccine may still be at least five or more years away.

Industry Partnerships in the Fight Against AIDS and Other Diseases Threatening Africa's Health and Development

Individual companies are working in partnership with the public sector and civil society to fight against AIDS worldwide, particularly in Africa. Such partnerships include the following:

- For over ten years, GlaxoWellcome's "Positive Action" and Merck's "Enhancing Care Initiative" have been offering support to communities for education, training, and social action projects to improve their capacity to deliver care to people in developing countries; GlaxoWellcome also partnered with UNICEF, providing sharply discounted antiretroviral products for projects in the Mother to Child Transmission (MTCT) Program as well as providing its products at substantially discounted prices through the UNAIDS HIV Treatment Access Initiative Pilot Program. GlaxoWellcome has also played a leading role in the Global Business Council on HIV/AIDS, bringing business leaders from many industry sectors together to develop, in cooperation with UNAIDS and NGOs, an effective corporate response to the epidemic.
- Bristol-Myers Squibb (BMS) has committed $100 million for HIV/AIDS Research and Community Outreach in five African Countries under their "Secure The Future™" Program, focusing on women & children in South Africa, Botswana, Namibia, Lesotho and Swaziland. An example of efforts supported by this initiative is a joint study of HIV-1C, a strain of HIV particularly prevalent in Africa, conducted by the Harvard AIDS Institute and the government of Botswana, supported by a US$18.2 million grant from BMS.
- Launched in November 1997, the UNAIDS HIV Drug Access Initiative is designed to develop innovative, effective models to improve access to needed drugs to treat HIV, its opportunistic infections, and sexually transmitted diseases in the developing world. The Initiative seeks to address the many challenges of developing-country drug access, such as lack of medical infrastructure, drug distribution channels, drug supply, professional training, and patient support through facilitating collaboration among pharmaceutical companies, health care providers, national governments, non-governmental organizations, and people living with HIV/AIDS. Pilot projects designed to increase access are underway in Uganda, Vietnam, Chile and the Ivory Coast. Pharmaceutical partners in the UNAIDS Initiative include: GlaxoWellcome, F. Hoffmann-LaRoche, Virco NV, Bristol-Myers-Squibb, Organon Teknika, Merck&Co., and DuPont Pharma.

There are also Industry initiatives in the eradication and prevention of other serious diseases impacting developing countries: AIDS is by no means the only serious threat to the well-being of the poorest developing countries. Often overlooked are the extensive activities of companies contributing their patented or off-patent medicines or technology for specific diseases of poorer countries. These programs were launched and are succeeding because as preconditions governments were required to fully commit to the success of the campaigns. This commitment is critical and offers lessons for the attack against AIDS in Africa and elsewhere. Examples of such company actions include:

- Merck has donated ivermectin free of charge for as long as it is needed to fight

onchocerciasis (river blindness). Key international partners involved with Merck have been the WHO, World Bank and the Carter Center.

- SmithKline Beecham and Merck are donating albendazole and ivermectin (two antiparasitic drugs for lymphatic filariasis, LF) free of charge for use in countries where LF in endemic. This also done with support of WHO and other agencies.
- GlaxoWellcome is donating an antimalarial combination drug (Malarone) free of charge to the public sector in malaria-endemic countries for treatment of cases which are resistant to standard first-line treatments.
- To help in WHO's global fight to eradicate polio, Aventis Pasteur has donated 50 million doses of oral polio vaccine to cover the vaccine needs for National Immunization Days scheduled in five conflict affected areas in Africa in 2000-2002. Countries to be covered are Angola, Liberia, Sierra Leone, Somalia and South Sudan.
- Pfizer is donating the oral antibiotic azithromycin to combat trachoma in 5 developing countries (Morocco, Ghana, Mali, Tanzania and Vietnam) in collaboration with the Edna McConnell Clark Foundation.
- Recently, Aventis Pharma donated the patent rights on life-saving eflornithine to WHO to treat African trypanosomiasis (sleeping sickness). This concluded a 15-year old public/private sector collaboration between Hoechst Marion Roussel and WHO, during which the development of the drug and its approval by drug authorities were finalized. The partnership in the effort to ensure efficient distribution of this drug includes WHO, Aventis Pharma and NGOs.
- Hoffmann-La Roche has conducted the "Sight & Life Program" dedicated to the prevention of xerophthalmia and other adverse effects of vitamin A deficiency that impairs the health of children in numerous developing countries. In this initiative, Hoffmann-La Roche donates vitamin A in many countries in Africa, Asia and Latin America, as well as educational materials.

There are other industry-wide efforts to improve health worldwide in partnership with the public sector including:

- The new Medicines for Malaria Venture (MMV), started in partnership between WHO, pharmaceutical industry and other parties has been established to stimulate the discovery and development of new treatments for this wide-spread disease. We are seeking to develop a new antimalarial therapy every 5 years beginning in this decade. We do not preclude, indeed we hope, that a new malaria vaccine might also come from the MMV or separately.
- The IFPMA and its vaccine company members are in full partnership in the Global Alliance for Vaccines and Immunization (GAVI). Through the Alliance, member partners will address ways to accelerate the development and introduction of new vaccines specifically needed by developing countries. The vaccine industry members of the IFPMA will, in cooperation with their GAVI partners, work to ensure accessibility to the vaccines and other related elements that are necessary for the immunization of all the world's children, with a particular focus on poor populations and countries.

- The WHO/CEO Roundtable process involves not only a yearly meeting between the Director-General of WHO and CEOs of IFPMA companies, but also WHO/industry working groups on issues relating to research&development, drug quality and access to drugs. For example, the WHO/CEO Roundtable process supports the "Malaria Pathfinder" initiative, which is a joint WHO/industry program examining ways to sustainably improve antimalarial access and rational use at the household level (in some cases, at the district level) as measured by improvements in rapid procurement and dispensing of appropriate treatments. A joint communiqué on the most recent meeting of the WHO/CEO Roundtable is available on the IFPMA and WHO web sites: (http://www.ifpma.org and http://www.who.int/medicines/).

Barriers to Access to Health Care

It must be recognized that only a committed effort by national governments can be effective in fighting AIDS, as the spread of AIDS is very much linked to poverty and underdevelopment which make people more vulnerable to becoming infected with HIV. Furthermore, there are several barriers to access to health care, barriers which industry can play only a limited role in overcoming. Indeed, the manufacturers' cost of pharmaceutical products is small in comparison to the overall distribution costs required to reach populations affected by AIDS or even to the retail price paid by the end consumer.

Understanding barriers to access is extremely important because they would make even free-of-charge antiretrovirals (ARVs) impossible for people living with AIDS in Africa to access regularly and effectively, making treatment useless and even possibly dangerous. Indeed, inappropriate use of these powerful drugs can and has resulted in strains of HIV developing which are resistant to all known treatments, making our search for a cure even more difficult. Also, due to the complexity of ARV regimens and the possible toxic side effects of these powerful drugs, appropriate medical support and careful monitoring is a vital part of using ARVs. According to UNAIDS and WHO, certain services and facilities must be in place before considering the use of antiretrovirals in any situation:

- Access to functioning and affordable health services and support networks into which ARV treatments can be integrated so that the treatments are provided effectively;
- Information and training on safe and effective use of ARVs for health professionals in a position to prescribe ARVs;
- Capacity to diagnose HIV infection and to diagnose and treat concomitant illnesses;
- Assurance of an adequate supply of **quality** drugs;
- Sufficient resources should be identified to pay for treatment on a long term basis; patients must be aware that treatment is "for life";
- Functioning laboratory services for monitoring, including routine hematological and biochemical tests to detect toxicities, must be available;

- Access to voluntary HIV counseling and testing (VCT) and follow-up counseling services should be assured, including counseling people living with HIV/AIDS on the necessity of adherence to treatment.

The barriers to access detailed below make it very difficult and even impossible to create the infrastructure described above which is so vital for the effective use of antiretrovirals and other medications for treating AIDS and related conditions. Therefore, examining access to AIDS health care from a broader perspective will help policy-makers focus their attention on reforms in the areas likely to have the greatest impact. .

Military, Social and Political Issues

- Military spending priorities: The existence of international and civil wars in many developing countries increase peoples' vulnerability to HIV-infection and prevent people living with AIDS from being treated. Even in countries where there are no wars or external threats, governments give a higher priority to spending money on "defense" than on healthcare, including AIDS.
- Lack of priority due to political cynicism: Effective treatments are being offered by companies (often at substantial discounts) and cheaper therapies are becoming available. Yet, in some countries, groundless excuses for not increasing spending on AIDS treatments, such as an alleged excessive toxicity of antiretroviral AIDS drugs, have been made. These excuses mask the basic cynicism that some governments have concerning treating poor people living with AIDS or in preventing mother-to-child transmission of AIDS. A very recent article in the African press quoted a government official from the region as saying that trying to prevent mother-to-child transmission in impoverished areas would only shift the cause of mortality later on. In other words, the government that this official serves is making policy based on the cynical observation that poverty and malnutrition could lead to the same result as HIV in the motherless and impoverished child.
- Tolerance of corruption: In countries where official corruption is prevalent, health care access is impeded through the pilferage and diversion of products and services, with the poorest elements of society being harmed the most.
- Inefficiency and wastage: UNAIDS has found that, although the World Bank and other international agencies make money available for AIDS projects in Africa, much of it goes unspent because of bureaucratic complexities and other problems;
- Literacy and language barriers: If the patient is illiterate and/or does not understand the language used by the health care providers, then they will have difficulty in accessing care;
- Minority (including ethnic or gender) groups may experience discriminatory attitudes from health care providers. Illegal immigrants may fear discovery or be not entitled to full access to health care facilities, thus hindering their access to care;
- Stigma: the stigma attached to being HIV-positive in many cultures has led to ostracization, abandonment, violence and even murder of people living with HIV. In light of these dangers, people will refuse to be tested for their HIV status and, if they

do discover that they have HIV, they will be afraid to seek appropriate treatment due to the possible repercussions if others were to find out their status.

Financial Hurdles

- The shortage of financial resources in the poorer developing countries is the most important barrier to access to health care, including medicines, in these countries. International aid agencies, as well as industrialized countries, often play an important role in financing health care infrastructure in the poorest developing countries.
- In many countries in Africa and elsewhere, governments require patients to 'co-pay' for therapy costs (including diagnostics, training, health care infrastructure, etc.), ranging from $35 to hundreds of dollars per month. Clearly few can afford such payments; so that less than 1% of HIV infected patients receive such therapy. (In comparison, in Brazil a much higher percentage of infected persons receive therapy; but Brazil is aided by World Bank funds.)
- Many countries due to insufficient resources can provide not even rudimentary health care. For example, annual spending on health in some African countries is under US$4 per capita. This lack of spending can also result from governments not setting health care services, including care for people living with HIV/AIDS, as a high enough priority in determining the use of national resources.
- Inadequate purchasing power for medicines and a lack of an adequate number of medical professionals and hospital facilities to deliver health care result from this lack of adequate financial resources.

Physical Infrastructure Barriers

Lack of physical access to health care facilities or personnel is another major barrier to access in developing countries. There are several factors leading to such inadequate access:

- Adequate clean food and water is needed. Therapy for HIV/AIDS requires healthy food intake in some relation to the time of drug ingestion as well as access to clean water. Both are often missing in the developing world.
- Inadequate health care facilities to meet the needs of a growing population due to insufficient public and private resources.
- Insufficient transportation infrastructure to permit access to medical care providers for much of the population.
- Unequal distribution of health care facilities that may be concentrated in densely populated urban areas, leaving wider, rural areas without adequate coverage.

Bad Micro-Economic Policies

- Protectionism: Many governments protect their local insurance and pharmaceutical companies from foreign competition, making local insurance and pharmaceutical costs higher than they should be. Tariffs imposed on imported pharmaceuticals raise

drug cost margins to patients. In developing countries, the final price to a consumer is often 3-5 times the price received by the manufacturer, whereas in developed countries, the ratio is often less than twice the manufacturer's level.

- Non-competitive distribution networks: Protected wholesale and other distributors can artificially raise distribution margins, making drug costs in developing countries high – perhaps even higher than in some developed countries.
- Poor Intellectual Property Protection: The lack of adequate and effectively enforceable intellectual property rights hurts access to health care and pharmaceuticals by eliminating incentives for research and development of new products in at least two ways:

  (1) local firms in countries with good scientific infrastructure devote resources to copying (often without regard to Good Manufacturing Practices (GMP)) instead of focusing on research into diseases prevalent locally; and

  (2) countries which allow international patent exhaustion (i.e., parallel trade) discourage local pharmaceutical investment and the offer of companies to supply the local market on terms that local patients and governments would find more advantageous.
- Price Controls: Governments may look at price controls as one solution to access. However, price controls tend to damage incentives for research and development industry, they can also negatively affect the development of a GMP-based local generics industry. Furthermore, price controls destroy competition and usually evolve from being limits on price increases (or 'ceilings') to becoming fixed price 'floors' preventing consumers from enjoying benefits of market competition. One need only look at comparisons in changes in post-patent prices between Europe, where price controls exist, and the United States.

Informational Gaps

- People may fail to access health care due to a lack of information about the need to treat diseases such as tuberculosis, hepatitis, or hypertension.
- Patients may not know how or where to access health care (particularly in the cases of minorities or immigrants).
- Self-medication by poorly informed patients may lead to ineffective drug utilization.
- Poorly informed physicians in developing countries often treat illnesses such as diarrhea inappropriately with antibiotics or they may not always be aware of the most cost-effective therapy.
- There is often the lack of information about the quality of generic products. In most developing countries, providers and patients prefer brand name products because they are unsure of the origin, safety and reliability of generic products.
- Lack of adequate training for inspectors and regulators regarding pharmaceutical product quality issues hinders people's access to quality health care. Such insufficient training allows substandard and counterfeit drugs to enter national markets, which endangers the population's health, engenders uncertainty about the effectiveness of treatments, and often crowds quality out of the market.

- Gray-market or illegal workers not contributing to the national tax system may be excluded from the social and workers health insurance system of their country of residence.

Cost and Price Issues

How important are price and cost issues? We firmly believe that they are secondary or tertiary problems in Africa compared to those discussed above. Some have charged that patents for pharmaceutical products reduce access to these products. This focus on patents (and prices) ignores the complexity of the access to healthcare issue and prevents policy-makers from considering real solutions to this issue. This is recognized by patient groups and public-sector decision-makers alike. For example, the European Coalition of Positive People publicly stated with regard to HIV/AIDS drugs recently that focusing on patent protection and pricing is "simplistic and fails to take into account the serious practical problems that need to be addressed..." Drugs could be free and still not be appropriately used without adequate health care systems. In fact, they would rapidly become ineffective. The cost of drugs to patients in Africa is determined principally by distribution, infrastructure, training and other factors discussed above. The issues of patents and prices of AIDS drugs are not the key issues.

Approaching the access issue solely through debates over price is not only simplistic, as noted above, but also factually incorrect. Patents do not, in fact, have an influence on access to the drugs, which the population in developing countries actually consumes. These are primarily off-patent drugs; for example, almost all of the products on the WHO Essential Drug List are off-patent. Furthermore, many developing countries do not currently have TRIPS-compliant intellectual property legislation and the poorest of these countries will not be required to implement such legislation until 2005, perhaps even later if they apply for a longer transition period. Therefore, access to the drugs for which this population is looking is *not* inhibited by patent protection. Indeed, developing countries without effective patent protection have already started producing their own versions of patented AIDS products, including India and Brazil.

An additional indication that prices are not the major barrier to access to drugs is shown by the experiences of several companies when they instituted the programs (mentioned specifically above) to donate their products for free or at dramatically reduced prices. Drugs that had been offered at a zero price could not find their way to patients until the barriers and issues were addressed that constituted the real obstacles. The targeted populations could only receive the drugs they needed after national governments and international agencies undertook concrete actions to ameliorate these barriers to access.

One would expect that, if intellectual property protection were really a barrier to access that some claim that it is, there should be no problem for the population of these countries to obtain drugs at "affordable" prices. However, the evidence shows otherwise: Again, why is it that in India -- where patent protection is not required by TRIPS and where unprotected copies of AIDS drugs (patented in Europe and elsewhere) are available from

a number of local producers –that there is a drug access problem and the AIDS epidemic is reaching alarming proportions?

Accepting the alleged, but spurious, links between intellectual property rights, prices, and access to pharmaceuticals could lead political decision-makers to institute policies such as parallel trade and compulsory licensing, which destroy the basis upon which further scientific progress is based: intellectual property rights. By threatening to take away the fruits of innovative companies' labor, the advocates of compulsory licensing and other attacks on intellectual property rights are driving research-based companies away from working on diseases particularly affecting developing countries. If there are to be cures and vaccines for diseases and conditions that are currently incurable or untreatable, further research must be protected and encouraged. After all, before one can realistically talk about gaining access to drugs and vaccines, these substances first need to be discovered, developed, tested and registered, a costly process taking years to accomplish. Without protection, companies simply cannot devote the huge resources (literally hundreds of millions of dollars) necessary for bringing new products to market.

V. Conclusions and Recommendations

Industry, which has much experience -- not only in developing the drugs available today to patients everywhere and in developing the drugs and vaccines in the pipeline for tomorrow's use – but also in health care delivery systems experience which can be brought to the table if asked to do so – firmly insists that there are a number of key elements to resolving the AIDS crisis. They are:

1) Partnerships among public institutions and with the private sector is the only effective route. Recognize that no single solution will solve this problem. We in industry are working on more effective therapies and vaccines, but delivery will be a critical problem and this involves several key issues, including the following:

2) Political commitment and concrete actions by countries affected to prevent the spread of AIDS and to treat those affected. Raising AIDS awareness and as a priority is vital. Prevention through education must be a high priority. Regarding funding, as UNAIDS' Executive Director has noted, pumping money into a country where AIDS is a low priority will not end the epidemic. "If a country does not recognize that it has an AIDS problem, then it is not willing to take on the tough questions," Dr Piot said. "Outside support for something that can only be solved from the inside will not work." Figures in 1997 show that international aid paid for the bulk of the millions spent on AIDS prevention in Africa in 1997. Uganda accounted for much of the money that the African countries spent. National priorities in Africa need to be shifted away from arms and weapons towards healthcare, including AIDS care, if this epidemic is to be fought effectively.

3) International funding is needed to meet the crisis: Bridging the cost gap, in the case of drugs and future vaccines, between costs and prices of AIDS products and what people in poorer countries can afford will need new international financial support.

4) Infrastructure and distribution improvements: So much of current drug supplies are wasted. Why is it that the price paid by a patient for quality AIDS and other drugs in parts of Africa and other developing countries is three to five or more times the price received by the manufacturer – because of the level of taxes, tariffs, monopolistic distribution systems, etc. -- so that if you were to cut the manufacturers' price by, say, 50%, patients would not significantly benefit; and then if you counted in the cost of the health support services needed for AIDS treatments, a drug price reduction may not reduce overall costs of delivery at all.

5) Serious Partnerships: Our companies have been working with UNAIDS and countries on the pilot projects by supplying medicines and expertise in their use. Industry knows that it must contribute in this extraordinary crisis. But true partnership is required, not one-way partnership. For example, not all countries have responded positively to mother-to-child program offers of medicines, even at discounted prices. It seems that some countries prefer to use legalistic approaches to undermine patents instead of working together with industry. Partnership means we all must be committed. As a sign of the seriousness which the industry gives to partnership efforts, IFPMA and major pharmaceutical companies have represented the research-based pharmaceutical industry in deliberations of the International Partnership Against AIDS in Africa organized by UNAIDS, most recently in New York at a meeting convened by UN Secretary-General Kofi Annan. This partnership brings together stakeholders in this issue, including donor countries, NGOs, the private sector and the African countries themselves. It is our hope that this dialogue will create effective and practical ways for all of us to work together to fight the AIDS menace.

6) One of the most critical elements of a global strategy is fostering continued innovation through academic and industrial R&D. The industry has responded to the need for AIDS medicines and has spent billions of dollars to make current treatments available; but we are not there yet. We do not yet have a cure. We do not have a vaccine. We are working on them. Over 100 new medicines are in the industry's development pipeline, including second-generation protease inhibitors, new drugs for opportunistic infections and vaccines against HIV. But without a strong patent system we would not have these medicines today or in the future. Attacking patents on AIDS medicines would means causing industrial R&D to shift away from AIDS research to more research on heart disease, cancer, depression, etc. The only winner in a strategy to weaken patents is the industrial copier or parallel trader, and the loser is the AIDS patient worldwide who is waiting for help.

One caveat must be raised here. We cannot, in addressing the AIDS crisis, neglect the importance of addressing other serious threats to the health of Africa and other poor regions of the world. Malaria, TB, hepatitis, respiratory ailments and other diseases may become equal dangers in the future. I urge the Congress and Administration to support public-private initiatives such as the Medicines for Malaria Venture and the Global Alliance for Vaccines and Immunization. Let's also explore new vehicles for developing new vaccines and drugs taking the tax credit and market exclusivity aspects of the US Orphan Drug legislation as examples of possible approaches that may be needed in addition to traditional patent protection.

In closing, I want to convey the desire of the R&D pharmaceutical industry that IFPMA represents to work more with countries, WHO, UNAIDS and other parties on this most serious matter for Africa. With resolve and with positive partnerships, we believe that we all can make a real difference.

Testimony by

Sandra Thurman
Director, Office of National AIDS Policy

Before the

Senate Committee on Foreign Relations
Subcommittee on African Affairs

February 24, 2000

Mr. Chairman and other members of this Subcommittee and Full Committee, I am delighted to be with you today to talk about the global AIDS pandemic – with a special focus on AIDS in Africa. Your interest in addressing this crisis is very much appreciated – and desperately needed.

We have heard your colleagues and our Surgeon General lay out a vivid picture of the scope of this tragedy – particularly as it relates to the public health crisis. I would like to use my time with you to talk about its impact on the stability of families, communities and nations. I would like to share with you some of my experiences with the faces behind these shocking facts. And I would like to outline for you some key components of our enhanced Administration response to this global pandemic.

By any and every measure – AIDS is a plague of Biblical proportion. And it is claiming more lives in Africa than in all of the wars waging on the continent combined. But unlike other wars – it is women and children that are increasingly caught in the crossfire of this relentless epidemic.

In Africa, an entire generation of children is in jeopardy. Already, in several sub-Saharan African countries, between one-fifth and one-third of all children have already been orphaned by AIDS. And the worst is yet to come. Within the next decade, more than 40 million children in Africa will have lost one or both parents to AIDS. 40 million. That is about the same number as all children in the United States living east of the Mississippi River. Or taken another way, it is almost the same number as all children in

public school in this country. Left unchecked, this tragedy will continue to escalate for at least another 30 years.

In just a few short years, AIDS has wiped out decades of hard work and steady progress in improving the lives and health of families throughout the developing world – infant mortality is doubling, child mortality is tripling, and life expectancy is plummeting by twenty years or more.

AIDS is not just a health issue; it is an economic issue, a fundamental development issue and a security and stability issue.

AIDS is having a dramatic effect on productivity, trade and investment – striking down workers in their prime, driving up the cost of doing business, and driving down GNP. Professionals have been hit particularly hard in sub-Saharan Africa, including civil servants, engineers, teachers, miners, and military personnel. In Malawi and Zambia, more than 30% of teachers are HIV positive. Some mining firms in South Africa are reporting that nearly half of their workers are already infected. And many businesses are hiring at least two workers for every one skilled job, assuming that one will die from AIDS.

According to the *Economist* magazine, recent studies have found that AIDS is seriously eroding the economies of many of our partner nations. In Namibia, AIDS cost the country almost 8% of its GNP in 1996. By 2005, Kenya's GNP will be over 14% smaller than it would have been without AIDS.

Similarly, in Tanzania, The World Bank has predicted that its GNP will be 15% to 25% lower as a result of AIDS. The South African government has estimated that this epidemic costs the country 1% of its GNP each year, a situation that will only worsen without strong intervention.

AIDS is also effecting stability in the region. As you all know, the UN Security Council recently held a day-long meeting on HIV/AIDS. This historic event highlighted the growing awareness that AIDS is a security threat that requires a global mobilization. This reality was also addressed in a report recently released by the National Intelligence Council. The Report draws several very disturbing conclusions including the following:

- The epidemic is far worse than predicted.
- Development of an effective global surveillance and response system is at least a decade or more away.
- The economic costs of infectious diseases – especially HIV/AIDS – are already significant and could reduce GDP by as much as 20% or more by 2010 in some sub-Saharan countries.
- Some of the hardest hit countries in sub-Saharan Africa – and possibly later in South and South-East Asia – will face a demographic upheaval as HIV/AIDS and associated diseases reduce human life expectancy by as much as 30 years and kill as many as a quarter of their populations over a decade or less, producing a huge orphan cohort.

- Nearly 42 million children in 27 countries will lose one or both parents to AIDS by 2010; 19 of the hardest hit countries will be in sub-Saharan Africa.
- The relationship between disease and political instability is indirect but real.

The prevalence of HIV in the armed forces of many African countries is already staggeringly high. The *Economist* has estimated the HIV prevalence in the Congo range at 50% to 80%. Other recent reports have projected that the South African military and police are also heavily impacted by HIV. Moreover, as these troops participate in an increasing number of regional interventions and peacekeeping operations, the epidemic is likely to spread.

Extremely high levels of HIV infection among senior officers could lead to rapid turnover in those positions. In countries where the military plays a central or strong role in government, such rapid turnover could weaken the central government's authority. For those countries in political transition, this kind of instability could slow or even reverse the transition process. This is a dynamic that deserves serious attention not only in Africa, but also in the Newly Independent States of the Former Soviet Union, and in India where AIDS is intensifying its deadly grip.

The South African Institute for Security Studies has also linked the growing number of children orphaned by AIDS to future increases in crime and civil unrest. The assumption is that as the number of disaffected, troubled, and under-educated young

people increases, many sub-Saharan African countries may face serious threats to their social stability. Without appropriate intervention, many of the 2 million children projected to be orphaned by AIDS in South Africa alone will raise themselves on the streets, often turning to crime, drugs, commercial sex, and gangs to survive. This seriously affects stability and promotes the spread of HIV among these highly vulnerable young people.

Yet my message to you today is not one of hopelessness and desolation. On the contrary, I hope to share with you a sense of optimism. For amidst all of this tragedy, there is hope. Amidst this terrible crisis, there is opportunity: the opportunity for us – working together – to empower women, to protect children, and to support families and communities throughout the world in our shared struggle against AIDS.

It is important to remember that what we are talking about today is not numbers but names, not facts and figures but faces and families. Let me tell you the story of one inspirational grandmother I met in a small village outside of Masaka, Uganda.

Bernadette has lost 10 of her 11 adult children to AIDS. Today, at age 70, she is caring for her 35 grandchildren. With loans from a village banking system, she has begun growing sweet potatoes, beans, and maize, raising goats and pigs, and trading in sugar and cooking oil.

With the money she earns, she is now able to send 15 of her grandchildren to school, provide modest treatment for the 5 who are HIV+, and begin construction on a house

big enough to sleep them all. In her spare time, she participates in an organization called "United Women's Effort to Save Orphans" – founded by the first lady of Uganda, Mrs. Museveni – linking in solidarity thousands of women allied in the same great struggle.

And these women are not alone. From the young people doing street theater in Lusaka to educate their peers about HIV to the support groups in Soweto providing home and community based care for people living with AIDS – communities are mobilizing and creating ripples of hope.

These are the faces of children and families living in a world with AIDS. And their spirit, their determination, and their resilience lead us on.

The good news is, we know what works. With our partners in Africa we have developed useful knowledge and effective tools. Together, we have designed model programs and proven that they work. And today, we know how to stem the rising tide of new infections, how to provide basic care to those who are sick, and how to mobilize communities to support the growing number of children orphaned by AIDS. Uganda has demonstrated that with strong political commitment and sustained nationwide programs, HIV prevalence can be cut in half. And Senegal has shown that HIV can be stopped in its tracks and prevalence can be kept low. But there is more, much more that needs to be done if we are to bring these successes to scale.

The United States has been engaged in the fight against AIDS here at home since the early 1980s. But increasingly we have come to realize that when it comes to AIDS – both the crisis and the opportunity have no borders. We have much to learn from the experiences of other nations, countries, and the suffering of citizens in our global village touches and affects us all.

The United States has been the leader in the battle against AIDS. The Administration has taken an active role in sounding the alarm on the AIDS crisis in Africa, and in ensuring that the United States supports African efforts to combat this deadly disease.

Since 1986, this nation has contributed over $1 billion to the global fight against AIDS. More than 50% of those funds have been used to address the epidemic in sub-Saharan Africa. Overall, nearly half of all of the development assistance devoted to HIV care and prevention in the developing world has come from the US. The United States has also been the leading supporter of the Joint United Nations Programme on HIV/AIDS – UNAIDS – contributing more than 25% of its budget.

It is a strong record of engagement and one of which we can be proud, but unfortunately it has not kept pace with this terrible pandemic. We have done much, but there remains much more that the United States and other developed nations can and must do.

During the past year and a half I have made four trips to eight African countries. Together with members and staff from both parties and chambers we went to witness

firsthand both the tragedies and triumphs of AIDS in Africa. In response to the findings of these trips, the Administration requested and the Congress appropriated an additional $100 million in FY2000 to enhance our global AIDS efforts.

This new initiative provides for a series of steps to increase US leadership through support for some of the extraordinary community-based programs currently being funded through USAID and to provide much needed technical assistance to developing nations struggling to respond to the needs of their people infected and affected by AIDS. This effort more than doubles our funding for programs of prevention and care in Africa, and challenges our G8 and other partners to increase their efforts as well. This initiative is a significant increase in the US government's investment in the global battle against AIDS and it begins to reflect the magnitude of this rapidly escalating pandemic.

The initiative focuses on four key areas:

- **Prevention**. Specifically, we hope to implement a variety of prevention and stigma reduction strategies, especially for women and youth, including: HIV education, engagement of political, religious, and civic leaders, voluntary counseling and testing, interventions to reduce mother-to-child transmission, and enhanced training and technical assistance programs.
- **Home and community-based care**. This will help create and enhance counseling and support systems, and help clinics and home health workers provide basic medical care (including treatment for related illnesses like STDs and TB).

- **Care of children orphaned by AIDS**. We hope to improve our ability to assist families and communities in caring for their orphaned children through nutritional assistance, education, training, health, and counseling support, in coordination with micro-enterprise programs.
- **Infrastructure**. These funds will help to increase the capacity for the effective delivery of essential services through governments, NGOs, and the private sector. We also need to enhance surveillance systems so that we can better track the epidemic and target HIV prevention efforts.

Some of the other key components of this initiative include an increase in our efforts to include the AIDS epidemic in our foreign policy dialogue, both to encourage and support political leadership in hardest hit countries and to promote an increased response by our developed nation partners. We are also taking steps to increase our coordination with the private sector and the many non-governmental organizations working in Africa, including religious organizations.

You will find a more complete description of this initiative – both the problems and solutions – in the report released by the Administration last summer. I have submitted a copy to this Subcommittee and would like to request that it be included in the record as part of my remarks.

While this new initiative greatly strengthens the foundation of a comprehensive response to the pandemic, UNAIDS has estimated that it will take $1 billion to establish an effective HIV prevention program in sub-Saharan Africa. Currently all donors

combined are contributing less than $350 million to that end. In addition, UNAIDS estimates that it will take a minimum of $1 billion to begin to deliver even the most basic care and treatment to people with AIDS in the region. We have not even begun to scratch the surface when it comes to delivering treatment.

In the face of such tremendous need, the Administration has requested, in the President's 2001 Budget submission, an additional $100 million increase to enhance and expand our efforts to combat AIDS in Africa and around the world. These funds will enable us to bolster our efforts already underway at USAID and CDC, and to expand our approach to include the Departments of Labor and Defense for efforts to address HIV/AIDS transmission in the workplace and in the military.

Let me repeat, however, that the United States cannot and should not do this alone. This crisis will require engagement from all segments of all societies working together. Every bi-lateral donor, every international lending agency, the corporate community, the foundation community, the religious community and every African government must do their part to provide the leadership and resources necessary to turn the tide. It can be done.

The bottom line is this: We have no vaccine or cure in sight, and we are at the beginning of a global pandemic, not the end. What we see in Africa today, frankly, is just the tip of the iceberg. As goes Africa, so will go India and the Newly Independent States of the Former Soviet Union. There must be a sense of urgency to work together with our partners in Africa and around the world to learn from the experiences there and

to share the successes and avoid the failures in countries now standing on the brink of disaster. Millions of lives – perhaps hundreds of millions of lives – hang in the balance.

We look forward to working closely with each and every one of you, and are so grateful that this issue is receiving the broad-based bipartisan support it deserves. AIDS is not a democratic or republican issue – it is a devastating human tragedy that cries out to all of us for help.

We are one world – and in many ways – Africa's destiny is our destiny. There is hope on the horizon – but that hope will only be realized if we take constructive action together. Today, let us commit to seize this opportunity. And let me conclude by thanking this Subcommittee for its interest in this issue, and offer my continued assistance as you seek ways to respond to this terrible tragedy. As Archbishop Tutu said: "If we wage this holy war together – we will win."

Thank you.

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Before the

Senate Committee on Foreign Relations
Subcommittee on Africa

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In Africa, an entire generation of children is in jeopardy. Already, in several sub-Saharan African countries, between one-fifth and one-third of all children have already been orphaned by AIDS. And the worst is yet to come. Within the next decade, more than 40 million children will have lost one or both parents to AIDS. 40 million. That is about the same number as all children in the United States living east of the Mississippi River. Or taken another way, it is almost the same number as all children in public

school in this country. Left unchecked, this tragedy will continue to escalate for at least another 30 years.

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AIDS is not just a health issue; it is an economic issue, a fundamental development issue and a security and stability issue.

AIDS is having a dramatic effect on productivity, trade and investment – striking down workers in their prime, driving up the cost of doing business, and driving down GNP. Professionals have been hit particularly hard in sub-Saharan Africa, including civil servants, engineers, teachers, miners, and military personnel. In Malawi and Zambia, more than 30% of teachers are HIV positive. Some mining firms in South Africa are reporting that nearly half of their workers are already infected. And many businesses are hiring at least two workers for every one skilled job, assuming that one will die from AIDS.

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country almost 8% of its GNP in 1996. By 2005, Kenya's GNP will be over 14% smaller than it would have been without AIDS.

Similarly, in Tanzania, The World Bank has predicted that its GNP will be 15 to 25% lower as a result of AIDS. The South African government has estimated that this epidemic costs the country 1% of its GNP each year, a situation that will only worsen without strong intervention.

AIDS is also effecting stability in the region. As you all know, the UN Security Council recently held a day-long meeting on HIV/AIDS, at which the Vice President spoke. This historic event highlighted the growing awareness that AIDS is a security threat that requires a global mobilization. This reality was also addressed in a report recently released by the National Intelligence Council. The Report draws several very disturbing conclusions including the following:

- Development of an effective global surveillance and response system is at least a decade or more away.
- The economic costs of infectious diseases—especially HIV/AIDS –are already significant and could reduce GDP by as much as 20 percent or more in by 2010 in some sub-Saharan countries.
- Some of the hardest hit countries in sub-Saharan Africa—and possibly later in South and South East Asia—will face a demographic upheaval as HIV/AIDS and associated diseases reduce human life expectancy by as much as 30 years and kill as many as a quarter of their

populations over a decade or less, producing a huge orphan cohort. Nearly 42 million children in 27 countries will lose one or both parents to AIDS by 2010; 19 of the hardest hit countries will be in sub-Saharan Africa.

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The prevalence of HIV in the armed forces of many African countries is already staggeringly high. The *Economist* has estimated the HIV prevalence in the Congo range at 50 to 80%. Other recent reports have projected that the South African military and police are also heavily impacted by HIV. Moreover, as these troops participate in an increasing number of regional interventions and peacekeeping operations, the epidemic is likely to spread.

Extremely high levels of HIV infection among senior officers could lead to rapid turnover in those positions. In countries where the military plays a central or strong role in government, such rapid turnover could weaken the central government's authority. For those countries in political transition, this kind of instability could slow or even reverse the transition process. This is a dynamic that deserves serious attention not only in Africa, but also in the Newly Independent States of the Former Soviet Union, and in India where AIDS is intensifying its deadly grip.

The South African Institute for Security Studies has also linked the growing number of children orphaned by AIDS to future increases in crime and civil unrest. The assumption is that as the number of disaffected, troubled, and under-educated young people increases, many sub-Saharan African countries may face serious threats to their social stability. Without appropriate intervention, many of the 2 million children projected to be orphaned by AIDS in South Africa alone will raise themselves on the streets, often turning to crime, drugs, commercial sex, and gangs to survive. This seriously effects stability and promotes the spread of HIV among these highly vulnerable young people.

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Bernadette has lost 10 of her 11 adult children to AIDS. Today, at age 70, she is caring for her 35 grandchildren. With loans from a village banking system, she has begun

growing sweet potatoes, beans, and maize, raising goats and pigs, and trading in sugar and cooking oil.

With the money she earns, she is now able to send 15 of her grandchildren to school, provide modest treatment for the 5 who are HIV+, and begin construction on a house big enough to sleep them all. In her spare time, she participates in an organization called "United Women's Effort to Save Orphans" -- founded by the first lady of Uganda, Mrs. Museveni -- linking in solidarity thousands of women allied in the same great struggle.

And these women are not alone. From the young people doing street theater in Lusaka to educate their peers about HIV to the support groups in Soweto providing home and community based care for people living with AIDS -- communities are mobilizing and creating ripples of hope.

These are the faces of children and families living in a world with AIDS. And their spirit, their determination, and their resilience lead us on.

The good news is, we know what works. With our partners in Africa we have developed useful knowledge and effective tools. Together, we have designed model programs and proven that they work. And today, we know how to stem the rising tide of new infections, how to provide basic care to those who are sick, and how to mobilize communities to support the growing number of children orphaned by AIDS. Uganda

has demonstrated that with strong political commitment and sustained nationwide programs, HIV prevalence can be cut in half. And Senegal has shown that HIV can be stopped in its tracks and prevalence can be kept low. But there is more, much more that needs to be done if we are to bring these successes to scale.

The United States has been engaged in the fight against AIDS here at home since the early 1980s. But increasingly we have come to realize that when it comes to AIDS – both the crisis and the opportunity have no borders. We have much to learn from the experiences of other nations, countries, and the suffering of citizens in our global village touches and affects us all.

The United States has been the leader in the battle against AIDS. The Administration has taken an active role in sounding the alarm on the AIDS crisis in Africa, and in ensuring that the United States supports African efforts to combat this deadly disease.

Since 1986, this nation has contributed over $1 billion to the global fight against AIDS. More than 50% of those funds have been used to address the epidemic in sub-Saharan Africa. Overall, nearly half of all of the development assistance devoted to HIV care and prevention in the developing world has come from the US. The United States has also been the leading supporter of the United Nation's Joint Program on AIDS—UNAIDS—contributing more than 25% of its budget.

It is a strong record of engagement and one of which we can be proud, but unfortunately it has not kept pace with this terrible pandemic. We have done much, but there remains much more that the United States and other developed nations can and must do.

During the past year and a half I have made four trips to eight African countries. Together with members and staff from both parties and chambers we went to witness firsthand both the tragedies and triumphs of AIDS in Africa. In response to the findings of these trips, the Administration requested and the Congress appropriated an additional $100 million in FY2000 to enhance our global AIDS efforts.

This new initiative provides for a series of steps to increase US leadership through support for some of the extraordinary community-based programs currently being funded through USAID and to provide much needed technical assistance to developing nations struggling to respond to the needs of their people infected and affected by AIDS. This effort more than doubles our funding for programs of prevention and care in Africa, and challenges our G8 and other partners to increase their efforts, as well. This initiative is a significant increase in the US government's investment in the global battle against AIDS and it begins to reflect the magnitude of this rapidly escalating pandemic.

The Initiative focuses on four key areas:

- **Prevention**. Specifically, we hope to implement a variety of prevention and stigma reduction strategies, especially for women and youth, including: HIV

education, engagement of political, religious, and civic leaders, voluntary counseling and testing, interventions to reduce mother-to-child transmission, and enhanced training and technical assistance programs.

- **Home and community-based care**. This will help create and enhance counseling and support systems, and help clinics and home health workers provide basic medical care (including treatment for related illnesses like STDs and TB)
- **Care of children orphaned by AIDS**. We hope to improve our ability to assist families and communities in caring for their orphaned children through nutritional assistance, education, training, health, and counseling support, in coordination with micro-enterprise programs.
- **Infrastructure**. These funds will help to increase the capacity for the effective delivery of essential services through governments, NGOs, and the private sector. We also need to enhance surveillance systems so that we can better track the epidemic and target HIV prevention efforts.

Some of the other key components of this initiative include an increase in our efforts to include the AIDS epidemic in our foreign policy dialogue, both to encourage and support political leadership in hardest hit countries and to promote an increased response by our developed nation partners. We are also taking steps to increase our coordination with the private sector and the many non-governmental organizations working in Africa, including religious organizations.

You will find a more complete description of this initiative – both the problems and solutions - in the report released by the Administration last summer. I have submitted a copy to this Subcommittee and would like to request that it be included in the record as part of my remarks.

While this new Initiative greatly strengthens the foundation of a comprehensive response to the pandemic, UNAIDS has estimated that it will take $1 billion to establish an effective HIV prevention program in sub-Saharan Africa. Currently all donors combined are contributing less than $350 million to that end. In addition, UNAIDS estimates that it will take a minimum of $1 billion to begin to deliver even the most basic care and treatment to people with AIDS in the region. We have not even begun to scratch the surface when it comes to delivering treatment.

In the face of such tremendous need, the Administration has asked the Congress to appropriate an additional $100 million increase to enhance and expand our efforts to combat AIDS in Africa and around the world. These funds will enable us to bolster our efforts already underway at USAID and CDC, and to expand our approach to include the Departments of Labor and Defense.

Let me repeat however, that the United States cannot and should not do this alone. This crisis will require engagement from all segments of all societies working together. Every bi-lateral donor, every international lending agency, the corporate community, the foundation community, the religious community and every African government must do

their part to provide the leadership and resources necessary to turn the tide. It can be done.

The bottom line is this: We have no vaccine or cure in sight, and we are at the beginning of a global pandemic, not the end. What we see in Africa today, frankly, is just the tip of the iceberg. As goes Africa, so will go India and the Newly Independent States of the Former Soviet Union. There must be a sense of urgency to work together with our partners in Africa and around the world to learn from the experiences there and to share the successes and avoid the failures in countries now standing on brink of disaster. Millions of lives...perhaps hundreds of millions of lives hang in the balance.

We look forward to working closely with each and every one you and are so grateful that this issue is receiving the broad-based bipartisan support it deserves. AIDS is not a democratic or republican issue – it is a devastating human tragedy that cries out to all of us for help.

We are one world – and in many ways – Africa's destiny is our destiny. There is hope on the horizon -- but that hope will only be realized if we take constructive action together. Today, let us commit to seize this opportunity. And let me conclude by thanking this Subcommittee for its interest in this issue, and offer my continued assistance as you seek ways to respond to this terrible tragedy. As Archbishop Tutu said: "If we wage this holy war together – we will win."

Thank you.

United States Senate

Office of Senator Bill Frist

Facsimile Sheet

To: Sandy

Office:

Date:

Fax Number:

Regarding:

Number Of Pages:
(including this cover)

From: Michael Miller

Phone Number:

Notes: Hard copy to follow in the mail. Look forward to your testimony. Regards,

Michael

For immediate delivery
If there is a problem with this transmission, please call (202)224-3344

BILL FRIST
TENNESSEE

COMMITTEES:
Commerce, Science, and Transportation
Budget
Health, Education, Labor, and Pensions
Foreign Relations

United States Senate

WASHINGTON, DC 20510

February 15, 2000

Ms. Sandra L. Thruman
Director
Office of National AIDS Policy
The White House
Washington, D.C.

Dear Ms. Thruman:

On February 24, at 2:30 PM, in 419 Dirksen Senate Office Building, I will chair a hearing of the United States Senate Committee on Foreign Relations Subcommittee on African Affairs regarding AIDS in Africa. On behalf of the Committee, I respectfully request that you present your expert testimony.

The Committee is especially interested in the Administration's overall strategy to address the HIV/AIDS crisis in Africa. Specifically, we would like your assessment of the effects on the economic viability of the continent; the best prospects for combating the disease in the global economic environment; the consequent priorities and decisions on spending, and whether current U.S. and multilateral efforts maximize potential; and the issues surrounding retro viral drugs and the prospects for a vaccine.

Your position as the President's advisor will be an especially valuable element for the Congress as we begin to consider new and additional strategies to address what will certainly be the greatest policy and humanitarian challenge for the United States on the continent. The United States can be a powerful force for positive change in Africa, and the nature of our response can be the difference between life and death for millions. I look forward to working with you on this critical issue, and I am grateful for the assistance you will give us in our progress toward our shared goals.

With warm regards, I am

Sincerely,

Bill Frist, M.D.
United States Senator

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