The Save Lives First Act of 2008: Preserving a Life-saving Legacy STATEMENT FOR THE RECORD: Senator Tom Coburn, MD

Tragic History, Miraculous Turnaround

Five years ago, Africa was in crisis and in despair. HIV/AIDS was decimating whole communities. Some countries, such as Botswana, were literally on a path to extinction, with rates of HIV infection among pregnant women in some locations reaching as high as 40 and even 50 percent.ⁱ In South Africa, while a third of pregnant woman were infected with the virus, the country's political leaders were actually denying that AIDS was caused by HIV infection, an ominous sign that little help was on the way for the over 4 million South Africans (over 10 percent of the population) dying of AIDS.ⁱⁱ

In 2003, if a woman in sub-Saharan Africa was infected with HIV, the familiar story was all too oftrepeated. She would very likely watch her husband die first, and then her youngest children would also become infected either at birth or through breastfeeding, as she languished under her own death sentence. Within a short time, her children would be orphans, left to fend for themselves in the streets and slums of Nairobi, or Soweto, often getting sick with their own HIV infections and dying alone, without food or shelter or medicine.

The sheer numbers at the time were staggering. The disease affected well over 20 million people in sub-Saharan Africa by the year 2000,ⁱⁱⁱ roughly equivalent to the total number of American children under 6 years old.^{iv} The problem seemed overwhelming, indeed hopeless.

What was the world doing to stop the carnage? Were there armies of doctors sweeping in with the miracle drugs that had been saving lives in America and other rich countries for nearly a decade? No. The U.S. was spending under \$200 million a year on HIV/AIDS overseas, mostly on report-writing, some condom marketing, and "capacity-building" programs that never actually used any of the capacity supposedly built and that had no measurable impact on the devouring epidemic.

Treatment was the demand of most global health activists of the day. An indignant group gathered in South Africa in 2002. "While a necessary component of the response to HIV/AIDS, prevention will never be enough," insisted Winston Zulu of the Network of Zambian People Living with HIV/AIDS (NZP+). "When will the world wake up to the fact that the 16 million Africans that have already died of HIV/AIDS? This is only the beginning if we continue down the prevention-only path. This movement will make treatment, which we all know strengthens prevention efforts, our priority demand."^v Domestic and international chapters of ACT-UP and others were heckling U.S. officials at international health conferences, demanding antiretroviral treatment for people with HIV/AIDS in the developing world, especially in Africa.

And then something remarkable happened. On a cold January night in Washington, D.C., far from the overcrowded, underequipped clinics of Africa, an American president made a promise – a 15 billion promise to provide treatment to millions of Africans, within five years.

Anti-retroviral drugs can extend life for many years. And the cost of those drugs has dropped from \$12,000 a year to under \$300 a year -- which places a tremendous possibility within our grasp. Ladies and gentlemen, seldom has history offered a greater opportunity to do so much for so many...tonight I propose the Emergency Plan for AIDS Relief -- a work of mercy beyond all current international efforts to help the people of Africa. This comprehensive plan will prevent 7 million new AIDS infections, treat at least 2

million people with life-extending drugs, and provide humane care for millions of people suffering from AIDS, and for children orphaned by AIDS.

-President George W. Bush, State of the Union Address, Jan. 28, 2003.

Glimmers of hope ignited around the world that night, as the U.S. policy *against* providing treatment in a foreign aid program came to an abrupt and inspiring end. The Congress took up the challenge, and passed a bill a few months later that was ground-breaking, a seismic shift in current policy and funding levels. The first and perhaps most dramatic policy shift was the statutory requirement that over half, a full 55 percent of all \$15 billion dollars of the program's funding be spent on life-saving medical treatment for people with HIV/AIDS.

People said it couldn't be done. The naysayers said that Africans would not be able to adhere to complex drug regimens. They said that there simply wasn't the capacity to absorb all those dollars and build new clinics and expand hospital wings. They said people wouldn't come from miles around to get tested and treated. We wouldn't be able to use mopeds and bicycles to deliver drugs to the rural hinterlands. There weren't enough doctors. There wasn't sufficient logistic ability to store so many drugs. These arguments are being repeated today. They were uninspired and uninformed in 2003 and they still are today. The President's Emergency Plan for AIDS Relief (PEPFAR) has proven them all wrong.

Since PEPFAR started, over 1.4 million people who would either be dead or dying today have received life-saving antiretroviral treatment. That's millions of children who didn't become orphans. Millions of parents who get to see their children grow up. Millions of moms whose babies were protected from infection. Countless communities across the plains and prairies, streets and slums of Africa and the Caribbean, where hope has taken a foothold. Where once stigma and despair kept people from even getting tested, people now come out by the thousands on HIV testing days in Kampala and elsewhere.

PEPFAR is a comprehensive program, investing heavily in prevention and care as well as treatment. However, the majority of the funds have been spent on treatment. The true nature of PEPFAR, the appeal of the program, the miracle that has raised millions from the dead is the program's commitment to lifesaving antiretroviral treatment. If you ask Africans what PEPFAR is, they'll tell you it's about AIDS treatment. It is the treatment component of PEPFAR that has made it the most successful U.S. humanitarian effort in history because it has literally saved the lives of millions, preserved families and communities, and rescued countless babies from being born with an AIDS death sentence.

Five years later, the American people stand at a crossroads. PEPFAR is expiring and the true test of our commitment to life-saving treatment is before us. We have a choice. Will we lose heart? Will we lose our focus? Will we allow a program that was ambitious, inspiring, targeted and tangibly and measurably effective at saving lives become diluted, vague, ill-defined and lose its life-saving impact? Will we allow partisanship and competing priorities and even some good intentions cloud and subvert the long-term success of PEPFAR? Will we turn PEPFAR into just another bloated, unmeasured and unmeasurable foreign aid program with no accountability and no real impact, a program that tries to do too much and accomplishes too little? As funding increases and rhetoric builds, will we, in this moment of testing, betray our historic commitment to Africa and the lives of millions of its inhabitants?

It is embarrassing to admit that we find ourselves on a direct path to that shameful outcome. The once loud and indignant voices demanding treatment for Africans have found other priorities, it would seem. Inexplicably and inexcusably, the House and Senate PEPFAR reauthorization bills, negotiated with the approval of the Administration, reverse what was undoubtedly the most important element of PEPFAR –

the requirement that the majority of funding be spent on HIV/AIDS treatment. What's more, the bills more than triple PEPFAR funding, but only increase treatment targets by 50 percent. Despite their \$50 billion price-tags, the House-passed bill and the Senate committee-reported bill would only add an additional one million people, of the many more millions in need, to the treatment rolls over the next five years. It seems that, after five years focusing on helping people with HIV/AIDS, the focus of the program under these proposed reauthorizations would shift to helping the foreign aid "industrial complex" of USAID contractors based in the U.S. and European capitals. The proposed reauthorization bills would prioritize literally *every* possible development cause *except* HIV diagnosis and treatment.

The Save Lives First Act

It is this glaring policy reversal that is the impetus for S. 2749, the "Save Lives First Act of 2008." The bill reinstates the current policy requiring at least 55 percent of funding to go to life-saving medical treatment for people infected with HIV/AIDS. It also allocates a small percentage of funding for the critical diagnostic screening that must be ramped up dramatically if we are to locate and treat every infected person in the countries where PEPFAR operates. Finally, the bill acknowledges that every baby infected with HIV by her mother during birth or breastfeeding is a largely preventable tragedy. The bill would target baby AIDS for complete elimination with 100% coverage with the medical protocols that prevent almost all instances of mother-to-child HIV transmission.

Although we have grave concerns about many other policies in the House and Senate reauthorization bills, including the prevention policy, the expansion of funding to rich countries, the "mission creep" that diverts funding from high-priority HIV/AIDS programs to lower-priority development programs, and others, we chose to focus in the Save Lives First Act on the critical problem of the House and Senate bills' betrayal of the President's and the 108th Congress' historic commitment to life-saving HIV/AIDS treatment.

There is no question that PEPFAR has been the most successful foreign aid program since the Marshall Plan. The structural reason for its success is that it approaches and addresses AIDS for what it is -a viral epidemic. Though much may have changed in the past four years, this simple fact has not, and will not, change.

The Mechanics of Treatment

Regardless of location, demography, mode of transmission, and so forth, the basic method of combating an epidemic, any epidemic, is the same: find the infected, provide them care, and help them prevent transmission to others. There are 33 million people living with HIV, and only they can prevent the transmission of the disease.^{vi} If we find the people with HIV, we could not only treat them, but yes, prevent new infections as well. That's why treatment and testing are critical to prevention efforts. They are not the whole story – behavior change programs are needed – but diagnosis and treatment are two of the foundations of disease control. What's more, prevention through education is far less costly than treatment. Uganda's success in the 1990s proved that with the proper message and political leadership, behavior change that reduces transmission rates dramatically can be achieved fairly inexpensively. The current PEPFAR program and its original authorizing legislation are appropriately structured on this foundation of diagnosis, treatment and successful prevention.

So what are the mechanics of treating people? First, you must diagnose those who are infected. That is why this bill designates specific funding for performing rapid tests, and sets testing target goals. If we

test 1 billion people over the next 5 years, we will discover the vast majority of all those living with HIV. However, experience shows that people will not get tested, no matter how much they may want to, without an incentive to know their status. It cannot be disputed that people known to be HIV positive suffer enormous stigma and discrimination throughout the world, and therefore need an incentive strong enough to overcome this.

The incentive is treatment. If people know that, should they be found to be HIV positive, there is hope and health in their future, they will have an incentive to get tested. The promise of a longer and healthier life is necessary to overcome the stigma (and, in a self-reinforcing loop, the presence of treatment, and the effect of people literally returning from the dead, goes a long way to reduce HIV stigma). That is one of the reasons why the Save Lives First Act maintains the 55 percent allocation of PEPFAR funding for treatment, and seeks to increase the number of people treated proportionally to the increase in overall funding.

The AIDS drug nevirapine, which costs only \$4 per treatment, can dramatically reduce the likelihood that a newborn will become infected with HIV. Yet a new U.N. report delivers the news that only a quarter of HIV-positive pregnant women in poorer countries are receiving the medication needed to prevent baby AIDS. Furthermore, the number of AIDS orphans in poorer countries continues to increase, and in sub-Saharan Africa an estimated 12.1 million children in 2007 had lost one or both parents to HIV.^{vii}

Can Treatment Be Part of a Prevention Strategy?

By sticking to the fundamental disease control methods of testing and treatment, new infections are prevented. First, we have seen here in the U.S. that people who know their HIV status are less likely to engage in risky behavior – they seek to protect themselves and their partners. The Centers for Disease Control and Prevention (CDC) reports that the 25 percent of Americans who don't know their HIV status transmit 50-75 percent of new infections.^{viii} What's more, a recent study has suggested that increased testing in the U.S. reduced infection.^{ix} Further, people who are receiving treatment have less of the virus in them, and are less infectious. There is increasing evidence documenting this phenomenon.^x Behavior change programs targeted to the general population, most of whom are uninfected, may help reduce infection rates to a point, but it is hard to think of a more *direct* preventive measure than rendering an HIV positive person less infectious and less likely to infect others.

Therefore, claims that the bill does not address prevention are simply untrue. First, billions and billions of dollars not dedicated to treatment and testing are available for prevention in the House and Senate bills. After spending 55 percent of the \$50 billion in the bills on lifesaving treatment, there will still be \$27.5 billion left over from which prevention programs could be funded, dramatically more programs than under the current, \$15 billion program. Second, and to an important extent, testing and treatment *are* part of an effective prevention approach.

In addition, some have claimed that the Save Lives First Act significantly increases costs, anywhere from \$13 - \$17 billion. These claims miss the point of the Save Lives First Act – which is not to *add to* costs, but to *prioritize* how authorized funds are spent. As the attached treatment cost analysis shows, the total dollar amount for all drugs, test kits, and prevention-of-mother-to-child-transmission materials needed to meet the goals in the bill is just over \$11 billion (using conservative assumptions about costs that are likely to be lower in reality due to government discounts). A reauthorization bill containing \$50 billion plus numerous "such sums" authorities, such as the bills under current consideration in the House and Senate, would contain sufficient money to meet these goals as well as procure the infrastructure necessary

to deliver these drugs and diagnostic tests. These costs are not added *on top* of the proposed reauthorization spending levels, as some have claimed. Rather, the Save Lives First Act takes the first 55 percent of all funding in any reauthorization bill – whatever the ultimate amount of funding turns out to be – \$30 billion, \$50 billion or more (as is actually likely given the current appropriations frenzy in the Congress) – and directs it to treatment costs. If meeting the heroic targets in our bill – adding 5 million new people to treatment (in addition to the 2 million already in treatment), conducting a billion HIV tests, and saving babies from being infected by their moms – ends up costing more than 55 percent of PEPFAR funding, we challenge any critic to think of a better use of funds. However, as the attached chart demonstrates, there will be plenty of money in a \$50 billion bill left for prevention and care after meeting the requirements of the Save Lives First Act.

The current alternative to this approach, as embodied by the House and Senate bills containing *no money* dedicated to testing and treatment – is that <u>millions of people will die</u> for lack of treatment. In addition, the vast majority of people with HIV will remain ignorant of their status, and will continue to unknowingly infect others, continuing the cycle that led to the devastating epidemic we now face. Letting people die, and keeping people ignorant of their status, is not the way to end this epidemic. We recognize this truth here in the U.S., where we spend <u>11 percent annually on prevention, but 67 percent on treatment</u> out of a total budget of \$23.3 billion spent on AIDS domestically.^{xi}

The U.S. Role in the Donor Community

Some have argued that a heroic American commitment to testing and treatment such as the targets in the Save Lives First Act will discourage other donors from supporting diagnosis and treatment. The truth is that other donors have yet to demonstrate substantial commitment to bilateral treatment programs. Most other donors prefer to fund treatment through their contributions to the Global Fund to Fight HIV/AIDS, Tuberculosis and Malaria, a multilateral organization affiliated with the United Nations, to which the U.S. is the largest (by far) contributor. That is what the Global Fund is for – to create efficiencies of scale and allow smaller donors to contribute to those more efficient programs rather than reinventing the wheel and starting up their own bilateral programs. When other donors do invest in bilateral efforts, it is almost always on the prevention side – funding needle exchanges for drug users, condom and "empowerment" programs for prostitutes, and other prevention efforts in Africa, Asia and eastern Europe, usually based on behavior change programs. This is all the more reason why one donor, the U.S., needs to focus on diagnosis and treatment – the rest of the donor community is not as committed to these programs compared to other approaches. But let's say that other donors want to support treatment - great! We welcome their participation. There is so much to do - between 7 and 8.4 million people still need treatment today.^{xii} PEPFAR certainly can't treat everyone in a given year, and will have to rely on the efforts of others going forward, if we want to bring hope to everyone affected by this dreadful disease.

We are proud of PEPFAR and the millions of miracles it has created already in its first four years of operation. The American people can look at PEPFAR and, unlike what they'll find with most government programs, they can see measurable and tangible results in the faces of the millions saved and cared for with U.S. funding. PEPFAR isn't "broken," and it doesn't require "fixing" in its reauthorization – it's a stunning success. The burden of proof is on those who want to radically change PEPFAR policies, not on those of us who want to preserve them. We look forward to working with the President and House and Senate leaders to ensure that PEPFAR continues its successful, miraculous, life-saving track record.

Bertha, a 23-year old PEPFAR treatment client in Tanzania speaks for millions when she says, "If it is not these ARVs, I think I was dead long time ago because I use and I am still using these drugs. Now I can do anything. I'm healthy and I'm strong."^{xiii}

ⁱ UNAIDS Botswana Epidemiological Fact Sheet, 2006,

http://www.who.int/GlobalAtlas/predefinedReports/EFS2006/EFS_PDFs/EFS2006_BW.pdf

http://data.unaids.org/pub/GlobalReport/2006/2006 GR CH02 en.pdf

^{iv} U.S. Census Bureau. <u>http://factfinder.census.gov/servlet/STTable?_bm=y&-geo_id=01000US&-</u>

<u>qr_name=ACS_2006_EST_G00_S0901&-ds_name=ACS_2006_EST_G00_&-redoLog=false</u>

^v Health GAP Press release, 26 August 2002. <u>http://www.healthgap.org/press_releases/02/082202_PTM_PR_LAUNCH.html</u> ^{vi} UNAIDS AIDS Epidemic Update, December 2007.

vii UNICEF/UNAIDS/WHO 2008. Children and AIDS: Second Stocktaking Report, April, 2008

^{ix} Pinkerton SD et al. *Infections prevented by increasing HIV serostatus awareness in the United States, 2001 to 2004.* J Acquir Immune Defic Syndr 47: 354 – 357, 2008.

^x Bulletin des Médecins Suisses, 89 (5), 2008

^{xi} "AIDS Funding for Federal Government Programs: FY1981-FY2008" Congressional Research Service Report #RL30731, updated March 8, 2008.

^{xii} WHO/UNAIDS Towards Universal Access: Scaling Up Priority HIV/AIDS Interventions in the Health Sector, Progress Report, April 2007

xiii PEPFAR Documentary, "Saving Lives Creating Hope", 2008.

ⁱⁱ Reuter's NewMedia. April 19, 2000. "Scientists Call S. Africa's AIDS Policy Idiotic".

ⁱⁱⁱ UNAIDS. 2006 Report on the Global AIDS Epidemic.

^{viii} Marks G, Crepaz N, Janssen RS. Estimating sexual transmission of HIV from persons aware and unaware that they are infected with the virus in the USA. AIDS 2006;20:1447-50.