

Statement on Manager's Substitute, S. 2731 PEPFAR Reauthorization
Senator Tom Coburn, MD
July 14, 2008

PEPFAR's Unique Contribution Has Been Treatment

By any measure, PEPFAR has been a success. We've helped almost 2 million people with AIDS live longer, prevented millions of infections, cared for millions more, and prevented hundreds of thousands of babies born to infected moms from being born with an AIDS death sentence.

PEPFAR was different from all our previous efforts precisely because we treated it like a disease rather than a development problem. We ran it like a medical program and not a foreign aid poverty program. Rather than funding the usual beltway contractors who like to write reports, give advice and convene meetings, we put pills in the hands of doctors, nurses and a legion of community-based healthcare workers riding out to the bush on mopeds with medicine in their backpacks. We treated people with HIV like patients we can save instead of victims. And we told them the truth about where AIDS comes from.

If you go to Nairobi or Soweto or Kampala and ask people what PEPFAR is about, they'll tell you it's about *treatment*. Have we spent billions on prevention? You bet. But ask anyone in Africa what PEPFAR is and they'll say – it's about AIDS *treatment*. It was AIDS *treatment* that was the *innovation* of PEPFAR. We had been funding prevention messages before PEPFAR – though certainly not to the extent as we did after PEPFAR started. But what was new, what was miraculous - what rocked Africa - was the medical *treatment*.

And it has worked. I don't want to make it seem easy. With a tiny staff, the AIDS Coordinator achieved the impossible – what many had said couldn't be done – bringing high-tech medical innovation to the lowest-tech settings on earth. It's still just as hard today as it was then, especially as we start up in new countries.

Treatment Floor is STILL Necessary

The path of least resistance is always the status quo: contractors and “social marketing” and reports and “technical assistance” and “capacity building” and meetings. Without statutory mandates, that path will *always* look more appealing to people who have been asked to do the impossible. That's why PEPFAR reauthorization couldn't retreat on its mandated treatment priority.

Take it out of the law, and despite all the rhetoric and good intentions, it'll *always* be easier to fund something else. Maybe treatment wouldn't have been eliminated, but it would have taken a back seat, maybe by small cuts, by not building new clinics in the harder places, by letting the shortage of doctors become an excuse to not get creative. The commitment to treatment would have eroded over time, and before we knew it, PEPFAR would have become just another failing foreign aid program like so many others.

It doesn't matter what people say their intentions are, because people come and go and promises are hard to keep. What matters is what the law requires, and so it is encouraging to be able to assure the American people today that PEPFAR's unique innovation – cutting edge HIV/AIDS medical care – has been preserved in this bill.

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Good Faith of Negotiators

For that there are a lot of people to thank, starting first with the President and his staff, who first reached out to try to broker this critical compromise. Of course, the bill managers, Chairman Biden and Senator Lugar and their staff were so patient, and so constructive, and deserve all the thanks in the world. They were quick, thorough, honest, and at all times, operated in good faith. Senators Enzi and Burr and their staff were incredible to work with and their commitment to this cause is commendable.

The compromise language has a number of critical features that make it worthy of passage.

The Substitute Restores the Treatment Floor

First, and most important, the compromise restores the critical focus of PEPFAR on medical treatment. The House bill eliminated the provision in current law that required that 55 percent of all funding go to “therapeutic medical care” of people with HIV. The manager’s substitute preserves this focus by requiring that **“more than half”** of the money goes to that medical care. This time, the law will also clarify what was meant by “therapeutic medical care,” so that there is no longer any confusion that this treatment money can be spent on ARV treatment, care for opportunistic infections, and medical monitoring of folks who don’t need ARVs yet.

Prioritizing treatment is not a radical policy – it is the *same* policy we have right here in the U.S. Just this year, we are spending 63 percent of all domestic AIDS funding on treatment, and 14 percent on prevention. Prevention is cheap, so you can still make prevention a big priority without spending nearly the money necessary for treatment.

The Substitute Restores an Ambitious Target - Linked to Funding

The original law had the 55 percent allocation, but it also had an ambitious target of treating 2 million people with antiretroviral treatment. The House-passed reauthorization only targeted 3 million people on treatment – a pretty underwhelming figure that meant adding only 1 million more to the PEPFAR treatment rolls. That 1 million would mean a 50% increase in results, while funding was more than tripling in the bill. Some have argued that this funding includes a lot of other things besides AIDS and so you can’t make that comparison. That’s just not true. The original bill included malaria, TB and the Global Fund as well, so it is an apples-to-apples comparison to say that the funding for AIDS, TB, malaria and the Global Fund was \$15 billion the first time and is \$50 billion this time. That’s a lot of money, and the targets for what we expect to achieve with that money must go up at the same rate the funding goes up.

The compromise language appropriately links the target number to appropriations. As the funding goes up from current funding, the treatment target has to go up by the same percentage above the current goal of 2 million people. That means that if all the money authorized in this bill is appropriated, the number of people treated will exceed more than 5 million. Those extra millions of lives saved are a major accomplishment of the Senate bill.

Target Also Linked to Cost Decreases

However, the formula doesn’t end there. Treatment costs per patient right now are pretty high – about \$1,000 per patient. Since drugs are as low as \$80 or at most around \$200 per person,

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we're talking a good 80 percent of treatment costs that are not being spent on direct medical care. That 80 percent represents overhead and infrastructure which should be reduced over time as more efficiencies are built in. To account for that, the compromise language also requires that the target number for treatment *increases* by the same percent that cost-per-patient *decreases* over time. This ensures that cost savings are reinvested right back into treatment rather than diverted to other activities.

Substitute Protects PEPFAR Patients from Substandard Drugs

Another key element of the compromise is the protection of PEPFAR patients from substandard medicines.

From the earliest days of PEPFAR, there were some calling for the U.S. to buy cheap, copycat drugs for PEPFAR patients, including drugs weren't approved by the FDA or any other rigorous regulatory body of any country. These are drugs we would never wish on our domestic patients here in the U.S. This is no abstract threat. Today, under the Orwellian-named "quality assurance" process at the Global Fund, American dollars may be used to purchase drugs that have met no standard except that they have put an application in for WHO prequalification. They don't even have to have received that prequalification – just the application makes them eligible for Global Fund support.

When this conflict first arose shortly after PEPFAR was first authorized, the President rightly insisted that we would not treat African AIDS patients like lab rats or guinea pigs. We would treat them with the same standards we treat American patients – they would only receive drugs with FDA approval. To help expedite the approval of some international products that were likely safe and effective but had not been through the FDA process, the President established an emergency review process to speed up approval while still ensuring that PEPFAR patients get the same standard of care we expect for our domestic patients. Since then, the activists and others have generally agreed that all appropriate, safe and effective drugs made it through this new process with proper speed.

In direct contradiction of this more moral approach, the House bill took bilateral PEPFAR programs down the same scary path that the Global Fund has gone – it required that PEPFAR purchase the *cheapest* drugs available on the world market, without requiring any standard of safety and efficacy. Under such a provision, African patients would have been treated worse than lab rats – receiving drugs that the U.S. would never have purchased through Medicaid, Medicare and Ryan White Care Act.

The bill managers are to be commended for modifying this provision in their substitute to require that drugs purchased by PEPFAR have FDA approval or its equivalent in other developed countries, such as the EU or Switzerland. We can all breathe a little easier as we seek to put 5 million people on ARVs. We want those 5 million to thrive as long as possible on first-line drugs before they experience treatment failure, and after that, it's all the more important that the quality of their 2nd and 3rd line drugs is secure. You shouldn't be relegated to unsafe drugs just because you're poor and living in Africa. Setting rigorous standards for drug quality is the right thing to do and I'm pleased the substitute does that.

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The Substitute Resolves Most Concerns

There are quite a few other improvements in the substitute that the managers and the President helped to broker, but I won't take any more time. Suffice it to say that most of my outstanding concerns have been met through our negotiations and I am confident that PEPFAR's success in the future is no longer in jeopardy.

PEPFAR wasn't "broken." It didn't need "fixing." It just needed reauthorization. The manager's substitute does that, and I am confident that lives that are going to be saved because of the good faith of the bill managers, the President and my other colleagues who were part of these negotiations.