

## An unlikely champion

Was setting up PEPFAR — a massive HIV treatment programme — the best thing that President Bush ever did? **Erika Check Hayden** investigates.

On 1 December 2008, a parade of luminaries appeared on screen in Washington DC to pay video tributes to President George W. Bush on World AIDS day. It was the twilight of his administration, and an obvious time for reflection. But for these people — including former US president Bill Clinton, United Nations secretary-general Ban Ki-moon, rock star Bono and US President-elect Barack Obama — this was not dutiful lip-service. They were heaping praise on Bush's signature programme to fight AIDS, and what many view as his most significant positive achievement of the past eight years.

By the next day though, the compliments had been eclipsed. The front pages of major newspapers were dominated by photos of Obama embracing Hillary Clinton, his pick for Secretary of State. None featured the accolades for Bush, or the new figures showing that his programme — the US President's Emergency Plan For AIDS Relief, or PEPFAR — had put more than two million HIV-positive people on antiretroviral treatments since Bush established it in 2003.

The episode underscores the complicated legacy that Bush has left with his HIV programme, variously praised, criticized and overshadowed. PEPFAR is credited with being the first and largest bilateral foreign-aid programme to try to treat chronic disease on a mass scale, with US\$18.8 billion spent so

far. But it has also been highly controversial because of stipulations on how its funds should be spent. And now, as Obama takes over and with PEPFAR's leadership likely to change, the programme faces a challenging future.

Unlike smallpox or polio, which were brought under control by vaccines that could be administered in a just a few doses, HIV drugs have to be delivered for life. "Once you start people on treatment, you can't stop — you have made a long-term commitment to supporting therapy for these people," says Chris Beyrer, director of the Johns Hopkins Center for Public Health and Human Rights in Baltimore, Maryland. Such therapy could get increasingly expensive as those already on treatment become resistant to their current medications and have to switch to pricey alternatives. And many hope that in addition to covering these drugs, the programme will expand to reach the millions who are still not receiving any treatment at all — a costly scale-up at just the time when the world's economy is in sharp decline and the United States is in a recession. How to sustain this scale-up, says Anthony Fauci, director of the US National Institute of Allergy and Infectious Diseases in Bethesda, Maryland, "is something that I dream about, think about, while I'm eating, sleeping — all the time". For Obama, then, PEPFAR could prove a complicated inheritance.

In 2003, only 400,000 people in poor countries

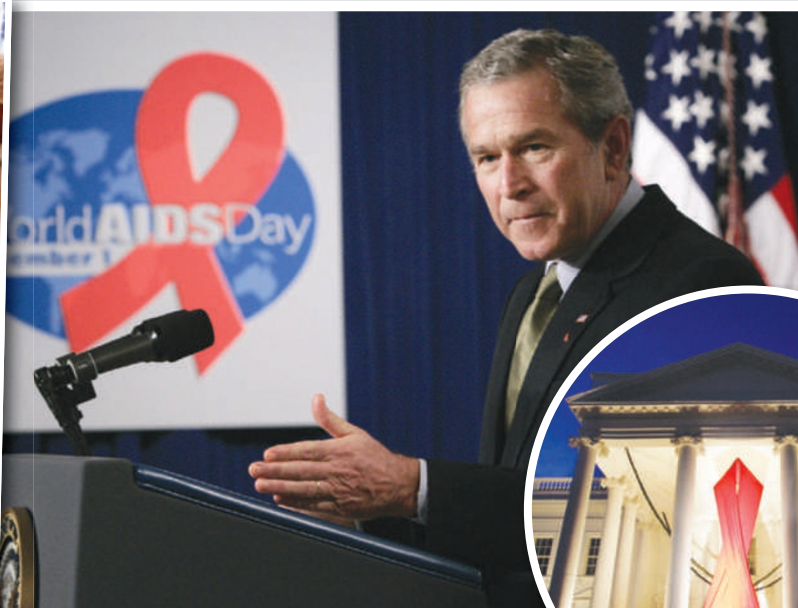
had access to antiretroviral treatment, and the world was spending less than half of what was needed to reach their goals for combating AIDS by 2005, according to the Joint United Nations Programme on HIV/AIDS (UNAIDS). When Bush announced in his January 2003 State of the Union address his intention to create the \$15-billion PEPFAR programme, he "completely changed the landscape", says Peter Piot, founder of UNAIDS. "The most powerful man in the world moved from the 'm' word to the 'b' word — from millions to billions. In that sense, PEPFAR not only brought money, but elevated AIDS issues to one of the big political themes of our time."

### Stormy start

The programme was dogged by controversy from the outset. Bush became interested in putting together a large AIDS programme partly because the disease was becoming a big issue among Republican leaders and some of his conservative supporters. Yet some of those same supporters balked at the prospect of supplying condoms, and with it the implicit endorsement of premarital sex. They found a compromise in a public-health approach called ABC — Abstinence, Be faithful, Correct and consistent condom use — that had been credited with helping to cut HIV prevalence in Uganda. When lawmakers enacted the legislation that enabled PEPFAR, they dictated that

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one-third of the 20% spent on prevention must be used for abstinence education programmes. They also required organizations who would receive aid from PEPFAR to pledge their opposition to prostitution — ruling out support for any group trying to reach out to sex workers. And none of the money could go to groups that support abortion, under the ‘gag’ rule enacted by Bush on his first day in office.

“It’s probably true that PEPFAR never would have gotten through Congress had it not been for these political compromises,” says Lawrence Gostin, faculty director of the O’Neill Institute for National and Global Health Law at Georgetown University in Washington DC. But for many activists, these compromises confirmed their suspicions that PEPFAR was little more than a ploy to curry favour for the United States abroad after its internationally unpopular invasion of Iraq. If that was the intention, it backfired, says Thomas Coates, director of the Program in Global Health at the David Geffen School of Medicine at the University of California, Los Angeles. “The directives made the United States look ridiculous to the world,” he says. “It was like, ‘There they go again — being generous on the one hand and then earmarking these moral dictates on the other.’”

The taint of moral hypocrisy deepened when Randall Tobias, the first head of PEPFAR, who left in 2006, resigned from government a year later after being linked to a prostitution ring. Tobias, a former chief executive of the pharmaceutical company Eli Lilly, had publicly questioned the effectiveness of condoms and the reliability of generic drugs. He was replaced at PEPFAR by Mark Dybul, an intense young

doctor who specialized in infectious disease and who had helped to work out the nuts and bolts of the PEPFAR programme with Fauci. Dybul was seen as being more in touch with the reality of AIDS. “As a gay man who lived through the epidemic, he had a professional and personal connection to it in a way that Tobias didn’t have,” says long-time activist Gregg Gonsalves, now with the International Treatment & Preparedness Coalition in New Haven, Connecticut. “He helped to give [PEPFAR] a more clinical focus and strip it of some of its ideology.”

By 2008, PEPFAR was estimated to have prevented infection in 240,000 babies born to HIV infected mothers and provided health care to 9.7 million people, on top of the two million receiving antiretroviral treatment. The programme targets 15 of the most stricken “focus countries” in Africa, Asia and the Caribbean. In addition to providing an overwhelming sum of money, PEPFAR also seems to have succeeded in setting and meeting targets from the outset, establishing a type of accountability that is often missing from aid efforts. “The PEPFAR strategy was to make sure that promises were kept, and that was new in international health,” Gostin says.

Yet the controversy surrounding PEPFAR never let up. In 2006, a study<sup>2</sup> commissioned by the World Health Organization (WHO) found “little evidence of the effectiveness of abstinence-only programmes in developing countries”. And in Uganda, critics say, restrictions on PEPFAR-funded organizations compelled the groups to place too much focus on abstinence and too little on condoms, helping to trigger a resurgence of the epidemic. PEPFAR

officials counter that they always promoted the ABC strategy as a whole. “Our policy was never abstinence only,” Dybul says, “anyone who read any of our documents could see that — we supplied more than 2 billion condoms.”

### Poaching partners

The abstinence provisions aren’t the only source of contention. Some have alleged that PEPFAR is poaching scarce workers from countries’ own health programmes. Others complain that by focusing resources on AIDS alone, the programme neglects other, equally vital aspects of the health system, such as childhood vaccinations or other infectious diseases. PEPFAR was also criticized for introducing its own process for approving generic drugs, meaning that drugs bought with PEPFAR money were mostly expensive brand-name ones. But some PEPFAR beneficiaries have said that such policies were possible to work around. Agnes Binagwaho, former head of Rwanda’s AIDS-control commission, says that her country purchased cheap generic drugs with money from other donors, such as the Global Fund to Fight AIDS, Tuberculosis and Malaria and the World Bank. Rwanda used some of its \$30 million from PEPFAR when it needed to purchase brand-name drugs to treat patients who had developed resistance to their original treatments. “There are so many needs, there is always something else the money can be used for,” Binagwaho says.

The ‘B’ part of ABC — be faithful — has also received some credit. Interest in how to encourage people to change their sexual behaviour is growing throughout the world, led by public-health researchers such as Edward Green, director of the AIDS Prevention Research Project at the Harvard Center for Population

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— Thomas Coates

S. BENGALI/MCT/NEWS.COM; C. DHARAPAK/AP; R. EDMONDS/AP





#### US lawmakers dictated that one-third of HIV prevention funds be used to promote abstinence.

and Development Studies in Cambridge, Massachusetts. Green and others argue<sup>3</sup> that AIDS spreads more slowly in regions where people are encouraged to favour monogamous relationships — even if they are serial relationships — over multiple concurrent long-term sexual relationships. The theory is that the virus will spread more quickly between multiple partners in the acute infectious stage. And Green, who has been an adviser to PEPFAR, says that the organization has been in the vanguard here by advancing the idea that people need to change their behaviour in ways more radical than the wider use of condoms. “PEPFAR is the only major donor that has promoted this,” he says.

#### Congressional credit

Three influential reports released since 2006 — two by the non-partisan US Government Accountability Office<sup>4,5</sup> and one by the US Institute of Medicine<sup>6</sup> — have praised the programme's results, but faulted its spending directives for lessening the initiative's potential impact. And in July 2008, Congress finally responded, stripping PEPFAR of the abstinence provision during the programme's required re-authorization.

The new law authorized \$48 billion in new PEPFAR spending over the next five years — more than three times the original sum and a massive affirmation of the initiative's success. It still asks countries to explain themselves if they spend less than half of their prevention funds on abstinence and fidelity projects, but critics hope that this will not restrict distribution of the money. It also includes provisions that seem to counter other arguments against PEPFAR, setting tar-

gets to train 140,000 health workers, link AIDS and nutrition programmes and authorize \$5 billion for malaria and \$4 billion for tuberculosis.

The challenge now is to build on PEPFAR's success. Programme officials acknowledge that the people they have reached so far may be the ‘low-hanging fruit’ — those that can travel to clinics, for example. Many more live a long way from roads or services and will be difficult to reach. The WHO estimates that two-thirds of the nearly 10 million people who need treatment in developing countries still have no access to it. There is also a rising chorus of calls for PEPFAR to expand its remit



As head of Bush's HIV programme, Mark Dybul (right) was credited with giving it a clinical focus.

beyond HIV and begin providing services such as maternal care, clean water, basic sanitation and food. Some even want it to be folded into a new US department of international development with a broader portfolio. “No matter what we do with PEPFAR, it will still ignore many of the fundamental things we need,” says Gostin.

But such broad ambitions seem unlikely to be realized. Tight financial times leave no room for Obama to start bold new initiatives in global health, and some worry that Congress won't even appropriate the \$48 billion authorized for PEPFAR. Who will lead the programme also remains uncertain. Observers say that Dybul's strong defence of the ABC initiative may have doomed his chances of staying on under Obama, and several people have been rumoured as potential replacements. Among the most prominent names is Jim Yong Kim, director of the François-Xavier Bagnoud Center for Health and Human Rights at Harvard School of Public Health in Boston, Massachusetts.

Whoever takes over, observers anticipate that the programme will improve under the Obama administration, and that many of the problematic aspects, such as the prostitution pledge and the anti-family planning bent, will be eliminated. “The good stuff will be salvaged, the bad stuff will be thrown out and PEPFAR will emerge a very different beast,” predicts Stephen Lewis, co-director of the advocacy group AIDS-Free World, based in Boston.

Even as the beast it is, the PEPFAR legacy continues to win Bush a level of regard that was only rarely voiced during his administration. “I can't stand him,” Gonsalves says, “but Bush has done something unprecedented.” And for Fauci, the praise is most apparent in the places where HIV is hitting the hardest. “If you go to Africa,” he says, “into villages where PEPFAR has had a major impact, people look at you and say, ‘Thank you, and thank God for the United States of America.’” ■

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