PEPFAR: DRIVING POLICY CHANGE AND ENHANCING GLOBAL COLLABORATION

THE EVOLVING RELATIONSHIP WITH MULTILATERAL ORGANIZATIONS

A REPORT SERIES ON LESSONS LEARNED FROM PEPFAR'S SUCCESS VOLUME 2

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The President's Emergency Plan for AIDS Relief (PEPFAR)

PEPFAR is the largest commitment by a nation to combat a single disease. Launched by President George W. Bush in 2003, it has invested almost \$100 billion to date, both directly and through the Global Fund to Fight AIDS, Tuberculosis, and Malaria and other multilateral institutions. PEPFAR has saved more than 20 million lives over the last 20 years. It has enjoyed overwhelming bipartisan support across four successive administrations, within Congress, and among a diverse array of stakeholders, including civil society and the faith-based community. This series of papers will examine critical lessons learned from PEPFAR and make recommendations for the program's future as well as continued U.S. global engagement.

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THE BUSH INSTITUTE'S PERSPECTIVE

Visionary leadership is critical for tackling seemingly intractable problems. Americans should be proud of how many lives they have saved and changed around the world through their generous contributions via the President's Emergency Plan for AIDS Relief (PEPFAR). At the George W. Bush Institute, we are committed to celebrating and continuing this program and to using our voice to ensure the United States can reap the benefits of the lessons it has learned, for the future of the program and for U.S. global engagement more broadly. We believe PEPFAR is more successful when paired with smart investments in multilateral organizations that share their vision and commitment to data and results. PEPFAR and the Global Fund have been wins for both the countries they serve and for U.S. foreign policy, and Congress and the American people should continue to support their lifesaving work.

Introduction

The cooperation that exists today among PEPFAR; UNAIDS; the Global Fund to Fight AIDS, Tuberculosis, and Malaria; and the World Health Organization (WHO) is the result of strong leadership, hard work, deft diplomacy, and effective use of data.

President George W. Bush always intended PEPFAR to complement multilateral investments. PEPFAR worked closely with UNAIDS from the start to develop the best global strategy, and that enabled optimal implementation of HIV prevention, treatment and care programs in all PEPFAR-supported countries.

But PEPFAR and the Global Fund, the two main financiers of HIV programs, often moved in parallel in their early years – funding programs in the same countries but not sharing plans and programming on the ground. PEPFAR's partnership with the Global Fund has evolved over the past decade, becoming deeper and broader.

Cooperation with the WHO also took years to develop. The WHO now uses real-world data generated by PEPFAR countries to formulate technical recommendations that shape medical and public-health practice in much of the world.

Over time, all four institutions have understood the imperative of acting in concert, and PEPFAR and the Global Fund are delivering more results with the same level of resources.

The transition to controlling the HIV pandemic without a vaccine but with prevention, testing, and effective treatment, created the opportunity for PEPFAR to work in a deeper partnership with communities, United Nations (U.N.) agencies, and the Global Fund.

PEPFAR and UNAIDS

UNAIDS coordinates the efforts and investments of 11 U.N. bodies to confront HIV/AIDS by assisting national governments, other partners, and communities. The WHO was the original U.N. lead on HIV/AIDS,

but the new umbrella institution was created in 1996 following the realization that the pandemic is "not simply a health crisis, but a social and economic crisis whose impact extends to the community, nation, and beyond, in some cases threatening entire [cultures and] economic systems," as stated in UNAIDS' founding documents.

UNAIDS has a multisectoral governing body, the Programme Coordinating Board (PCB). It includes members from civil society, who have equal status with representatives from the U.N. co-sponsors, donors, and rotating delegates from national governments. The U.S. Global AIDS Coordinator, the ambassador who manages PEPFAR, has served as the American representative on the PCB since 2003. For the last quarter century, UNAIDS has played three indispensable roles: 1) ensuring the U.N. system plans and pursues as coherent a strategy as possible on HIV/AIDS, with consistent public messages; 2) advocating for policy reforms and the rights of people who are living with HIV/AIDS (PLHIV) and at risk for acquiring HIV; and, 3) serving as the world's clearinghouse for tracking and analyzing data on the pandemic and modeling its progression.

PEPFAR and UNAIDS began their collaboration by sharing data, something that still ties them closely together. UNAIDS estimates from its annual *AIDS Epidemic Updates* were used to convey urgency and plan President Bush's \$500 million <u>International Mother and Child HIV-Prevention Initiative</u>. Announced in June of 2002, it was the largest bilateral pledge to address HIV/AIDS made by any nation at that time.

UNAIDS' numbers on HIV-infected pregnant women, extrapolated from sentinel surveillance in prenatal clinics, particularly influenced the selection of the initiative's 14 focus countries in sub-Saharan Africa and the Caribbean. Further analysis of these data over the next six months helped convince President Bush to increase his financial commitment 30-fold by launching PEPFAR, which originally targeted the same 14 nations.

UNAIDS modeling used in the early years of the pandemic to project the number of HIV and AIDS cases turned out to have some limitations, including overestimating the burden of the disease in some countries. However, close collaboration between the data teams at PEPFAR and the Global Fund produced important refinements in the statistical information available about the pandemic.

PEPFAR began collecting data from treatment and testing sites in almost real time, creating a clear picture of who is acquiring HIV and where (including "hotspots") as well as how many infected people start and stay on lifesaving antiretroviral drugs (ARVs). This information, triangulated against PEPFAR's Population-based HIV-Impact Assessments and other surveys, allows UNAIDS to calculate more accurately the number of annual new and total infections (by country and worldwide), how many people are on ARV treatment, and how healthy they are. There is also better information on the development of drug resistance and side effects. Policymakers use these open and accessible data in real time to guide decision-making and improve outcomes and impact, and citizens can hold both host governments and PEPFAR accountable for results.

More reliable numbers have permitted PEPFAR and UNAIDS to forge a crucial partnership to advocate for more, and smarter, investment in the campaign against HIV/AIDS. Public support from inaugural UNAIDS Executive Director Dr. Peter Piot after the announcement of PEPFAR helped give the idea more credibility, since even some within the U.S. government had questioned publicly whether treatment for HIV was feasible in less-developed countries.

The relationship between PEPFAR and UNAIDS deepened in the intervening years, especially as the next leader of UNAIDS, Michel Sidibé, joined with U.S. ambassadors to urge African heads of state to implement crucial policy changes to expand access to testing and treatment for HIV. UNAIDS also began to harness the energy and profile of African first ladies to reduce stigma around HIV/AIDS and encourage women to take charge of their health and that of their families. By 2011, with encouragement from PEPFAR, the PCB had sketched out the first vision for approaching the pandemic that went beyond an emergency response. Called the "Three Zeros" (for zero new infections, zero AIDS-related deaths, and zero discrimination), the strategy reflected the hope that the first decade of PEPFAR's results had provided. In the same year, PEPFAR and UNAIDS spearheaded the Global Plan toward the Elimination of New HIV Infections among Children and Keeping Their Mothers Alive, which called for reducing transmission of the virus to infants by 90% and reducing AIDS-related maternal deaths by 50% in the 22 highest-burden countries.

Today, PEPFAR and UNAIDS remain united in their conviction that aggressive steps at the national and community level can actually bring the entire HIV pandemic under control, not just continue to save individual lives. Evidence from programs in the field funded by PEPFAR and the Global Fund gave the UNAIDS PCB the confidence to adopt three clear, ambitious goals in 2013 meant to help governments, civil society, and communities focus their efforts: at least 90% of all PLHIV should know their HIV status; at least 90% of all people with diagnosed HIV should receive ARV treatment and continue it; and at least 90% of all people on ARV therapy should have undetectable levels of the virus in their blood. Later ratified by the U.N. General Assembly in a political declaration adopted in 2016, exceeding these "90-90-90 targets" has been the centerpiece of PEPFAR's annual Country Operational Plans (COPs) for almost a decade.

PEPFAR and the WHO

The WHO is the U.N. specialized agency charged with protecting and advancing human health and well-being. Founded in 1948 and headed by an elected Director-General, the organization responds to the governments of its 193 member states through an executive board and the annual World Health Assembly (WHA). Six separately elected Regional Directors manage the WHO's 150 country offices around the world. While the WHO does not run programs that provide direct medical care, it exerts great influence by issuing technical or "normative" guidance, which ministries of health in developing countries take as authoritative and often adopt automatically as national policy. To make its recommendations, the organization engages outside physicians and academics in a series of expert committees, a slow and deliberative process.

One of the most important areas of interaction between PEPFAR and the WHO has been around drugs, diagnostic tests, and other supplies. The WHO Prequalification Programme, which covers medicines, vaccines, diagnostics, medical devices, and tools to control pests that transmit diseases to people, officially establishes standards for the procurement of health products by the elements of the U.N. System, including the World Bank. However, many national governments that do not have their own regulatory agencies have decided to accept WHO prequalification as the only process by which drugs, laboratory tests, and other health-related goods may receive approval to be bought and sold in their countries. Large nongovernmental and humanitarian organizations often follow suit. As a result, the WHO is the gatekeeper for entry into the market of health products in much of the world.

In the early years of the HIV/AIDS pandemic, access to medicines was a major concern. Branded ARVs were expensive, few alternatives proven safe and effective were available, the market for both was small because few national governments or donors were funding treatment programs, and the WHO Prequalification Programme was slow. To maximize the safety of patients, PEPFAR was buying only drugs

that had received approval from the U.S. Food and Drug Administration (FDA), and the Global Fund restricted its purchases of medicines to those accepted by a so-called stringent regulatory authority (like the FDA) or prequalified by the WHO.

Former WHO Director-General J.W. Lee (in office from 2004 to 2006) recognized the urgency of confronting the HIV/AIDS pandemic and was an early champion of rapidly expanding access to ARV treatment. As a result, the WHO published guidelines in 2003 that recommended a small number of cheaper combination drugs for treating HIV in developing countries and encouraged their swift introduction, while PEPFAR emphasized the use of medicines that were the standard of care in the United States. Meanwhile, the WHA was engaged in unproductive debates around drug patents, a subject not within the jurisdiction of the WHO.

The Bush Administration decided to pursue a free-market solution to the challenge of making ARVs more available and affordable. Secretary of Health and Human Services Tommy Thompson and his team came up with a novel use of the authority of the FDA to permit the manufacturers of generic versions of ARVs to apply for tentative approval for their products well before the patents or marketing restrictions on the original drugs were due to expire. Upon approval, PEPFAR and the Global Fund could purchase these products right away for use outside the United States, and the companies also could assure their investors that their formulations would have access to the lucrative U.S. market in the future. PEPFAR convinced Lee that the WHO should immediately consider as prequalified any drug that received tentative approval from the FDA, which meant that it would be eligible for purchase and use around the world almost right away. The results have been incredible: More than 200 ARV formulations from firms around the globe have received FDA tentative approval, as detailed by the U.S. Food and Drug Administration's PEPFAR Database, and the average annual price of the most-recommended first-line combination therapies for HIV in low- and lower-middle-income countries has fallen to under \$100 from well over \$1,000, according to UNAIDS' 2021 Global AIDS Update.

PEPFAR's engagement with the WHO on the selection, quality, and safety of ARVs and other products has been constant and intensive. Because of the granular data PEPFAR produces from following millions of patients at thousands of sites, the program has been at the forefront of pushing the WHO to refine its treatment guidelines to start HIV-positive clients, including pregnant women, on treatment sooner. When evidence generated by PEPFAR's programs indicated that some of the components of the drug cocktails recommended by the WHO were toxic and contributing to resistance by the virus, U.S. government doctors on WHO's expert committees helped forge a new set of recommendations. Replacing an older drug, nevirapine, with the newer dolutegravir is creating better outcomes for PLHIV around the world and ensuring treatment options will remain effective for longer. Finally, PEPFAR's innovative adaptations before and during the COVID-19 pandemic convinced the WHO to endorse multimonth prescriptions for ARVs, a move that saves time and money for clients, providers, donors, and governments without compromising safety.

PEPFAR also worked with the WHO to create clear guidance for doctors, nurses, and laboratories on what they needed to do to expand access to HIV treatment. Beginning in 2007, a formal WHO/PEPFAR collaboration standardized operational and clinical guidelines and patient-monitoring systems for HIV prevention and care at primary health clinics. This effort produced a template operation manual and accompanying tools that governments and other partners could adapt as they trained staff at more sites to welcome patients with the virus, treat them, and track their progress. PEPFAR also collaborated with the WHO on recommendations for task shifting, under which nurses, technicians, and community health workers safely assume some duties once reserved for doctors, an efficiency that allows clinics and hospitals to care for more clients.

In a similar way, collaboration between PEPFAR, WHO, UNAIDS, and communities advanced the acceptance of voluntary male medical circumcision (VMMC) as a key part of the comprehensive package to prevent infection risk and the transmission of HIV in sub-Saharan Africa. Clinical trials funded by the U.S. National Institutes of Health and pilot programs supported by PEPFAR provided much of the evidence needed to allow the WHO to issue guidance in favor of VMMC as a prevention method in 2007. Since then, PEPFAR consistently has been the largest funder of VMMC and other primary prevention services in the world.

Collaborations by the President's Malaria Initiative (PMI) Have Yielded Similar Positive Results

As with PEPFAR and HIV, technical and scientific leadership and data from PMI have been critical to improving global guidance on malaria:

- Successive U.S. Global Malaria Coordinators have provided invaluable direction, both in public and behind the scenes, to shape the evolution of the Roll Back Malaria partnership.
- Evidence produced by programs funded by PMI (and the Global Fund) prodded the WHO to
 prequalify and recommend additional pesticides and types of bed nets that protect families from
 malaria-carrying mosquitoes.
- PMI, the Global Fund, and the WHO now share more data than ever on the malaria parasite's development of resistance to insecticides and on the circulation of substandard and counterfeit malaria medicines.
- PMI, the Global Fund, the Bill and Melinda Gates Foundation, and the WHO collaborate on policy revisions and recommendations, such as the guidance put out by WHO during the COVID-19 pandemic to deal with treating malaria in the face of COVID-19.

According to a <u>report</u> by Friends of the Global Fight, together the Global Fund and PMI are responsible for over two-thirds of all financing for programs and policies on malaria around the world. Also mirroring PEPFAR's experience, collaboration between PMI and the Global Fund has improved greatly after an uneven beginning. Earlier in the Global Fund's life, successive U.S. Malaria Coordinators had to deal with crises in the implementation of the Global Fund's grants at the country level. Incorrect forecasts, mismanagement within ministries, or procurement delays meant that PMI had to step in on multiple occasions to cover shortages of bed nets or prevent stock-outs of antimalarial drugs.

Today, PMI, the Global Fund, and the Gates Foundation synchronize their supply-chain and financial data in harmonized categories under an memorandum of understanding (MoU), to ensure better delivery of commodities over time and to assist in planning globally and at the country level. This cooperation extends to innovation: The Gates Foundation finances novel therapies and interventions, PMI often field tests and brings them to scale, and the Global Fund buys them later in their lifecycle.

Mutually reinforcing investments from both PMI and the Global Fund produce better results because of their closely calibrated partnership:

- PMI and the Global Fund conduct yearly planning exercises with host governments, including reviews of PMI's national-level Malaria Operational Plans.
- The Global Fund provides its grants primarily to ministries of health, to which PMI's programs offer technical support.

- In many countries, PMI and the Global Fund divide responsibility for buying medicines and test kits while co-funding the procurement of bed nets.
- National governments, PMI, the Global Fund, and the Gates Foundation share data in country to improve performance over time

Here are two examples of what this collaboration looks like in the field:

- PMI and the Global Fund launched the first joint cross-border campaign to distribute bed nets at the same time in Senegal and Gambia to support the Malaria Elimination Initiative Agreement between the two countries.
- In the Democratic Republic of Congo, PMI spearheaded the signature of an MoU with the Global Fund, other donors, and the Ministry of Health to allow for the rapid exchange, borrowing, or redistribution of bed nets, tests, and antimalarial medicines between them and their partners to cover more people and avoid stock-outs

PEPFAR and the Global Fund

President Bush <u>announced</u> a founding contribution of \$200 million to an institution that did not yet exist, "a global fund to fight AIDS, tuberculosis, and malaria," on May 11, 2001. Flanked by a bipartisan group of members of Congress in the White House Rose Garden, the president said the U.S. government would support the idea as long as the new fund did the following:

- 1. Organized itself as a public-private partnership of governments, private corporations, foundations, faith-based groups and nongovernmental organizations.
- 2. Promoted an integrated approach that emphasized prevention in a continuum of treatment and care.
- 3. Focused on best practices proven to work in the field.
- 4. Financed only proposals reviewed for effectiveness by medical and public health experts to create "scientific accountability to ensure results."
- 5. Respected intellectual-property rights as a spur to research and development on lifesaving medicines.

More than 20 years later, the architecture and policies of the Global Fund still reflect the bottom-line principles articulated by President Bush and Republicans and Democrats through 10 sessions of Congress. The Global Fund has become an indispensable partner for PEPFAR. The United States remains the largest donor to the Global Fund, having contributed \$26 billion over two decades, according to a report from the Kaiser Family Foundation, and President Biden made clear his intention to pledge \$6 billion more for the Global Fund's Seventh Replenishment period, which covers its 2023-2025 funding cycle, in his February 2022 budget request to Congress. American contributions to the Global Fund are limited under U.S. law to no more than one third of the total given by other donors.

Incorporated as a Swiss nonprofit foundation in early 2002, the Global Fund is not a U.N. agency but an independent financier of programs to combat the three diseases in more than 150 countries (including through regional grants). Like UNAIDS, the Global Fund's governance structure includes civil society, donors, and representatives of partner governments, but also has a dedicated seat for private companies. Since 2005, the U.S. Global AIDS Coordinator has served as a member of the Global Fund's Board of Directors. Leaders from PEPFAR have chaired and participated in the board's major committees as well.

At the national level, the Global Fund replicates its hybrid structure through public-private Country Coordinating Mechanisms (CCMs), which submit applications for financing to the Global Fund and oversee the implementation of the Global Fund's grants. Independent experts on a technical review panel (TRP) assess each funding proposal for "technical merit and strategic focus." The TRP and the Global Fund's staff (called the Secretariat) have stayed true to President Bush's call to prioritize best practices in carrying out an

integrated approach aimed at preventing the three diseases and treating and caring for people affected by them.

Nevertheless, in the early years of the Global Fund, coordination with PEPFAR was not optimal. Friction occurred because the Global Fund's Board

[Bilateral investments are] not a substitute for further U.S. contributions to the Global Fund.

- President George W. Bush

June 2002, during a speech promoting his new mother and child HIV prevention initiative

approved groups of grants, which sometimes included proposals to be carried out in countries deemed by the United States to be state sponsors of terrorism. The Global Fund's grant-making schedule, based on periodic open competitions called rounds, did not align with the annual planning processes established by the U.S. government's Global AIDS Coordinators. The uncertainty of the Global Fund's proposal timelines, coupled with long delays in signing approved grants, meant that CCMs asked the Global Fund and PEPFAR to finance the same (or very similar) activities. These overlaps often did not become apparent for some time, particularly when they involved the procurement of drugs and other supplies.

Beginning under U.S. Global AIDS Coordinator Dr. Mark Dybul, later elected as Executive Director of the Global Fund in 2012, the relationship between PEPFAR and the Global Fund matured into a deep data-driven partnership. The institutions established a new, symbiotic way of working together, one that intertwines investments in many countries to form cohesive programs instead of disparate grants. Both the Global Fund and PEPFAR jointly planned with countries and communities and worked to eliminate duplications on the ground – and still do. U.S. Global AIDS Coordinators Dr.

Close Cooperation with the Global Fund's Inspector General Safeguards U.S. Taxpayers' Investments

PEPFAR, PMI, and U.S. government inspectors general have worked with the Office of the Inspector General (OIG) of the Global Fund for 20 years to attack corruption and mismanagement. An independent branch of the Global Fund's Secretariat founded in 2005 at the insistence of the U.S. government, the OIG has helped uncover a number of schemes intended to defraud donors and divert drugs and supplies onto the black market. Because PEPFAR, PMI, and the Global Fund all use contributions from U.S. taxpayers to purchase and distribute many of the same products, the OIG and the Inspector General of the U.S. Agency for International Development share information and even pursue joint investigations under an MoU.

Deborah Birx and Dr. Eric Goosby refined this model even further, and the connections between PEPFAR and the Global Fund are visible and continuous:

- PEPFAR and the Global Fund in 2017 established an ongoing resource alignment collaboration through which they share harmonized financial data so that both sides have full visibility into their investments and those of partner governments.
- The Global Fund now participates in PEPFAR's annual planning conferences, which bring community representatives and advocacy organizations to the table along with government officials so that they can chart the course of their country's response to HIV together.

- PEPFAR includes the Global Fund in quarterly programmatic reviews in each country, during which both sides assess each other's plans in detail and staff members from each organization meet regularly on progress. PEPFAR has created and funded the position of Global Fund Liaison at the U.S. embassy in each country in which both the U.S. government and the Global Fund have a substantial portfolio of grants in HIV, tuberculosis, and malaria.
- Through constant communication, the Liaisons and PEPFAR in-country teams ensure there is no overlap or duplication of on-the-ground programming with the Global Fund.

In most countries, PEPFAR has worked out a specific division of labor with the Global Fund and has expanded complementary programming to match the Global Fund's investments. In large countries in sub-Saharan Africa, for example, the Global Fund's HIV grants purchase first-line ARVs, while PEPFAR

PEPFAR teams must seek to ensure PEPFAR, partner country, and Global Fund resources strategically align to maximize impact.

 <u>Guidance</u> for PEPFAR's Country and Regional Operational Plans for 2022

buys more complicated drugs, trains health workers, and supports the delivery of care and treatment; some of these arrangements are formalized in MoUs. PEPFAR also has learned from the Global Fund's CCMs to increase and improve its community engagement. Here are two examples of what this collaboration looks like in the field:

- In South Africa, the Global Fund focuses its grants in rural zones, while PEPFAR's investments assist in cities and their surrounding townships.
- In Ethiopia, PEPFAR and the Global Fund have operated for 15 years under an MoU that creates clear roles and responsibilities.

The closer relationships between PEPFAR and the Global Fund forged over the last decade have made each of them more efficient and together more effective. Some concrete benefits of the collaboration include the following:

- PEPFAR and the Global Fund have seen a dramatic increase in results as both programs have been able to expand the number of people on ARV treatment despite flat budgets. (See Figures 1 and 2.)
- PEPFAR has increased prevention programming across the board in sub-Saharan Africa, including
 a dramatic expansion of VMMC and the launching of DREAMS, not only in response to data, but
 because the Global Fund began absorbing more of the cost of buying first-line ARVs.
- PEPFAR and the Global Fund have improved equity by promoting the realignment of funding and programming to all parts of the countries in which they work.
- PEPFAR, the Global Fund, and their partners, including government ministries, use open, accessible, and accurate information in real time to guide decision-making and improve outcomes and impact.
 - This culture of data allows citizens to hold host governments and donors accountable for results.
- The Global Fund and PEPFAR can speak with one voice to press the WHO to issue the right policy guidance and then drive its rapid adoption at the country level.
 - The policy and implementation changes PEPFAR and the Global Fund have successfully championed have been essential to increase access and transparency and improve performance.

Figure 1: PEPFAR expands prevention and treatment services on a flat budget: Number of people receiving care doubles in five years and the number of VMMCs quadrupled

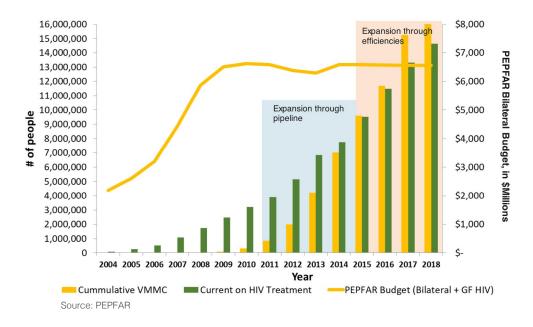
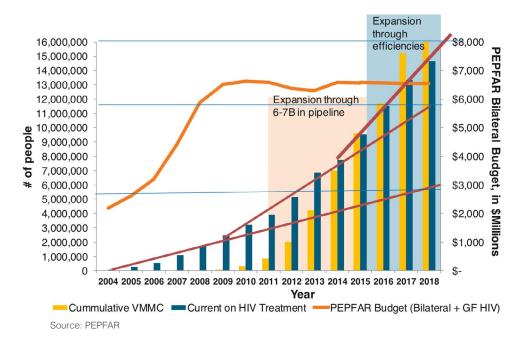


Figure 2: PEPFAR: Remarkable expansion of prevention and treatment services with flat budget since 2010



Recommendations to Enhance This Collaboration

Programs financed by the Global Fund and PEPFAR have been strengthened by the organizations' expanded and focused partnership. This intimate collaboration has improved results dramatically, increased accountability on the ground, and used continuous input from local communities to serve clients better. A symbiotic relationship with UNAIDS and an improved dialogue with the WHO driven by U.S. technical and scientific expertise complements implementation by PEPFAR in the field. Moving forward, we offer the following recommendations:

U.S. Global AIDS Coordinator:

The U.S. Global AIDS Coordinator should continue to serve as the U.S. representative on the Board of the Global Fund.

PFPFAR:

PEPFAR should urgently publish a list of the most important changes UNAIDS and the WHO could make to their guidance and recommendations to improve HIV/AIDS programs in the field. PEPFAR, UNAIDS, and the WHO should also continue to share data to support the uptake and implementation of the changes.

PEPFAR should renew and extend its resource alignment collaboration with the Global Fund for another five years.

PEPFAR should continue to plan jointly with communities and host governments, in deep partnership with the Global Fund, to ensure maximum impact for all dollars expended.

PEPFAR and its implementing agencies in the U.S. government should continue to prioritize their partnership with the Office of the Inspector General of the Global Fund to safeguard U.S. taxpayer funds and the well-being of beneficiaries.



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