

REORGANIZATION AND THE FUTURE OF PEPFAR: IMPLICATIONS OF STATE AND USAID REFORM

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INTRODUCTION & SUMMARY

In March of this year, President Trump issued an “Executive Order on a Comprehensive Plan for Reorganizing the Executive Branch”(1) and Secretary of State Rex Tillerson has made redesign of the State Department and USAID a top priority and recently submitted its redesign proposal to The Office of Management and Budget (OMB). While final plans are still unknown, a variety of organizations have published reports and recommendations on the topic. One area of consideration in these discussions has been whether the statutorily created Office of the Global AIDS Coordinator (OGAC), which oversees and manages the President’s Emergency Plan for AIDS Relief (PEPFAR), should be moved from the State Department to USAID or in other ways be changed from reporting to the Secretary of State as under current law. When created, PEPFAR was intentionally structured in this way to allow it to: have programmatic and budget oversight of the HIV response across multiple implementing agencies with different missions; harness diplomatic, development, and health expertise across the government; and move beyond the usual model of development to address an urgent epidemic with devastating global consequences.

A working group of global health experts and former officials from both Republican and Democratic administrations was convened in November at Georgetown University to consider more fully the risks and opportunities posed by moving OGAC, or changing PEPFAR’s organizational or leadership structure, for the U.S. role in the global fight against HIV/AIDS and global health more generally. This group focused specifically on HIV, but noted there are broader opportunities for improving U.S. global health efforts beyond PEPFAR and the scope of this piece. As part of this discussion, the working group reviewed the history of the creation of PEPFAR and the specific reasons its current structure was chosen. The report below was prepared by the O’Neill Institute for National & Global Health Law based on that consultation.

Since 2003, a bipartisan U.S. leadership effort has chosen to make tackling the global HIV/AIDS crisis a U.S. priority. Championed by the White House across successive administrations and with congressional mandates that cut across partisan lines, PEPFAR has been an unprecedented global health, development, and diplomatic success—investing over \$72 billion to fight a global pandemic virus that has no cure or effective vaccine. The program has ensured 14.5 million people access to life sustaining treatment in countries with the highest HIV rates and—through testing, treatment, and biomedical and structural prevention efforts—is helping turn the tide by dramatically reducing new HIV infections in many countries. Today’s conversations about reaching epidemic control on the way to ending AIDS as a public health threat are only possible, in large part, due to PEPFAR and the unique U.S. partnership with multilaterals and national governments it has created. Yet

progress is incredibly fragile, rapid scale up remains critical, and losing focus could threaten this historic investment and the AIDS response globally.

In this context, the working group noted the profound impact that State and USAID reorganization could have on a program upon which millions of lives rest. While a strong State Department and USAID are critical to the success of PEPFAR, the working group identified many risks, and few benefits, in moving OGAC or changing the lines of reporting away from the Secretary of State, actions that could significantly diminish PEPFAR’s role, disrupt program delivery, undermine human rights connections, and create enormous uncertainty. While the PEPFAR program has evolved substantially in the years since its inception, and the changing HIV pandemic will require this evolution to continue, the core principles in the original design of the program remain a bedrock of programmatic success. Grounded in concrete experience from recent years, working group discussions covered a key set of considerations about what is needed in the AIDS fight in 2018 and beyond which, on balance, argue for maintaining the current PEPFAR structure. They include the:

1. Diplomatic & political mission required to address HIV, which draws on core State Department competencies.
2. Reality that PEPFAR has never been predominantly a development program but instead an interagency effort that harness national security, development, and medical/epidemiologic capacities of USAID, CDC, DOD, and agencies across eight departments.
3. Country level coordination necessary for the complexity of the HIV response, led at the mission-level by U.S. Ambassadors.
4. Indispensable, multifaceted and specific leadership role played by the U.S. in the global HIV response, which is only possible with a sustained, data-driven focus.
5. Political and health diplomacy relationships with other donors, host governments, the Global Fund to Fight AIDS, Tuberculosis and Malaria and other international actors.
6. Necessity of budget authority alongside clear targets to advance the program in the coming years.

Each of these elements is explored in greater detail below. Taken together they suggest that the core structures of the U.S. whole-of-government approach to global HIV/AIDS, including the unique accountability mechanisms surrounding the Office of the Global AIDS Coordinator, should be reinforced rather than re-organized.

HISTORY OF THE PEPFAR STRUCTURE

PEPFAR was created by the George W. Bush Administration in 2003 to address the widening global HIV crisis through an unprecedented 5 year, \$15 billion effort that replaced more limited efforts by the U.S. government before it. Announced by President Bush and authorized in the United States Leadership Against HIV/AIDS, Tuberculosis, and Malaria Act of 2003, the PEPFAR program was structured to facilitate a “whole of government” response to the AIDS crisis with a global AIDS coordinator position created at the State Department with the rank of Ambassador to manage the multiple interlocking streams of work across agencies.

The Leadership Act creating PEPFAR amended U.S. law with the language,

“There shall be established within the Department of State in the immediate office of the Secretary of State a Coordinator of United States Government Activities to Combat HIV/AIDS Globally, who shall be appointed by the President, by and with the advice and consent of the Senate. The Coordinator shall report directly to the Secretary.”

The vast majority of PEPFAR funds are appropriated to the State Department and then disbursed to implementing agencies—largely USAID and the Centers for Disease Control and Prevention (CDC)—for programming. The U.S. Global AIDS Coordinator, based at The State Department, is charged with coordinating the AIDS response across eight agencies to ensure these and all U.S. funds to fight global AIDS are managed for greatest impact.

PEPFAR agencies include

- Department of State (DoS)
- U.S. Agency for International Development (USAID)
- Department of Defense (DoD)
- Department of Commerce (DoC)
- Department of Labor (DoL)
- Department of Health and Human Services (HHS, CDC, NIH, FDA)
- Peace Corps
- Department of the Treasury



Photo: Sarah Day Smith

THE CREATION OF PEPFAR MARKED A DEPARTURE FROM PRIOR WAYS OF ORGANIZING AND IMPLEMENTING U.S. GLOBAL HEALTH AND DEVELOPMENT EFFORTS AND THERE WERE SEVERAL REASONS A NEW DIRECTION WAS TAKEN:

- **A global infectious pandemic requiring support of unprecedented magnitude required a different approach**, incorporating elements of traditional development programs alongside complex epidemic response techniques. The work of rapidly establishing high quality HIV testing and treatment programs, building disease surveillance systems, securing supply chains of lifesaving commodities, and supporting programming across national militaries and communities, required a different model for using aid dollars.
 - **Strong U.S. leadership** was needed to move from a fragmented, inadequate response to global AIDS to an emergency response capable of tackling a major global health threat. Importantly, this leadership was represented by an Ambassador-level coordinator at a Cabinet-level agency in Washington able to hold Ambassadors accountable for the whole-of-government effort in countries. Moreover, this structure would allow for the coordination and oversight by a non-implementing entity of multiple budget lines across several implementing agencies.
 - **The whole-of-government effort across multiple implementing agencies imagined bringing the best minds and capacities together**—this required cooperation where it had not always succeeded in the past. Most prominently, this effort focused on USAID and CDC but a variety of agencies were also given roles in PEPFAR: The National Institutes for Health provides the research support that has revolutionized AIDS medicine, the Food and Drug Administration ensures effective and safe antiretroviral medicines are procured, and HHS's Health Resources and Services Administration builds education and training programs. The Department of Defense engages host country militaries, the Peace Corps leverages U.S. volunteers, the Department of Commerce builds public-private partnerships, and Department of the Treasury works with ministries of finance to improve financial planning and accountability. In this context the State Department represented a Cabinet-level department with significant experience and capacity for coordination and global health diplomacy at both Washington and country-level, where Ambassadors and U.S. embassies around the world manage the U.S. presence.
 - **Diplomacy** was identified from the start as a critical component to this new approach. Mobilizing U.S. Ambassadors, Embassy teams and State Department resources for securing high level political support in both implementing countries and among other donor countries was central to PEPFAR's success. As Ambassador-at-Large inside the State Department, the U.S. Global AIDS Coordinator is placed to coincide with the chain of command for U.S. chiefs of mission, who receive instructions and evaluation only from State. This was meant to allow PEPFAR to work with Ambassadors to both direct country-level staff and ensure that the overall PEPFAR mission is effectively adapted at the country level.
 - **National security concerns** were also key to the motivation and thinking since the program needed to address HIV spread in militaries, which had high prevalence and transmission rates, and neglect of AIDS was increasingly being identified as a major risk to stability and U.S. economic and security interests.
 - **New partners from universities to faith based groups** were an important part of the new emergency response, and engaging them effectively required mobilizing expertise at multiple agencies, particularly HHS and USAID, and reaching out through networks beyond traditional development organizations.
- These drove the innovative structure created for PEPFAR—designed to elevate the U.S. response to HIV and make a whole-of-government effort reflect the U.S. decision to take on a leading role in the global fight against AIDS. All of them are still relevant today.

FORM AND FUNCTION FOR PEPFAR'S CONTEMPORARY TASK: HALTING AN INFECTIOUS DISEASE

The PEPFAR program has been singularly successful at a monumental task—halting and reversing a global pandemic virus that has no cure or effective vaccine. Today the epidemic stands at an exciting but tenuous stage. Major investments are paying off with falling new infections and deaths as treatment and prevention services reach tipping-point levels—with new technologies and new evidence, the HIV response is succeeding in PEPFAR countries and new HIV infections and AIDS deaths both falling significantly. But progress is incredibly fragile and failure to continue strategically could result in HIV resurgence.

“In the field of infectious disease where you have a dynamic situation and a complex response, when you start to intervene and turn it around you cannot slow the intervention until you have it truly knocked down. All infectious diseases will revert and come back, we have seen through multiple experiences over the years. We cannot stop until its over. And AIDS is not over.”

—Dr. Anthony Fauci

Director of NIAID, December 1, 2017

According to the most recent data released by the program, to date it has directly and indirectly supported lifesaving antiretroviral treatment for approximately 14.5 million people, 15.2 million voluntary medical male circumcisions, and last year supported 85.5 million HIV tests.⁽²⁾ An estimated 2.2 million infants have been born HIV-free to mothers living with HIV through effective prevention efforts. External evaluations have confirmed that millions of lives have been saved by the program. ^(3–5) Recent reports show that PEPFAR-supported countries including Swaziland, Malawi, Zimbabwe, Zambia and others have seen rapid reductions in new HIV infections—reaching toward a milestone of epidemiologic control on their way to halting HIV.^(6,7) PEPFAR has continued to innovate in programming along with scientific advance and evidence. For example, the DREAMS initiative responded to clear evidence that girls and young women in sub-Saharan Africa were at

disproportionate risk of HIV yet programs were not effectively reducing this risk. As the initiative has scaled up a combination of structural interventions, according to preliminary data, many of these districts are showing 25-40% decline in new HIV diagnoses among adolescent girls and young women 15-24.⁽²⁾

The structure and programmatic management of PEPFAR has evolved substantially since the program began. What started as an emergency response has grown into a sustained attack on the crisis that HIV continues to represent in key countries where PEPFAR is most active. Where PEPFAR initially airlifted billions of dollars worth of brand-name antiretroviral medicines, today PEPFAR has instead built expertise and structured its funding around a partnership with Global Fund and national governments to procure low-cost generic drugs quality-tested by the U.S. FDA's tentative approval process through coordinated, if not consolidated, national supply chains. PEPFAR's initial singular focus on program inputs—like people on treatment or numbers reached with HIV outreach activities—has shifted to collection and use of multifaceted data (e.g. outputs, outcomes, expenditures, and service quality) at increasing granular levels to achieve the greatest impact. PEPFAR staff in the field are increasingly responsible for managing funded partners toward overall results including reductions in new HIV infections, ultimately judged through high-quality epidemiologic studies like the Population-based HIV Impact Assessments (PHIA). A recent re-organization of staffing at the headquarters level has moved from subject-specific working groups to inter-agency “Epidemic Control Teams” that collectively manage work in a set of countries with a similar epidemiologic and programmatic profile.

PHIA Studies

Recent studies in many PEPFAR countries have shown rapid declines in new HIV infections and progress toward the global goals that 90% of all people living with HIV know their status, 90% of those are accessing treatment, and 90% of those are virally suppressed.

	% of PLHIV who know their status	% of those accessing treatment	% of those virally suppressed
Malawi	72.7%	88.6%	90.8%
Zimbabwe	74.2%	86.8%	86.5%
Zambia	67.3%	85.4%	89.2%
Swaziland	84.7%	87.4%	91.9%
Lesotho	77.2%	90.2%	88.3%

A key example of the evaluation of PEPFAR's form and function can be seen in the Country Operational Planning (COP) Process. From a time when country-level PEPFAR “plans” were little more than a confidential list of contracts and budgets (often running hundreds of pages), the COP has evolved into a publicly available strategy driven by programmatic data that is

transparent.⁽⁸⁾ A wide range of stakeholders are now engaged in this process—from national government and international experts to civil society and communities using PEPFAR programs—in what has quickly become the most inclusive and transparent planning process of any U.S. foreign aid program.

These changes over the last 15 years reflect a form and function that is different than when the program started—shifts enabled by the core structure of PEPFAR as a collaboration across eight departments with centralized planning but decentralized responsibility designed to engage the particular expertise of different agencies. Aimed at ending the public health crisis of HIV, this central coordination function and laser focus on the epidemic have proven to be critical.

BENEFITS AND RISKS OF MOVING THE OFFICE OF GLOBAL AIDS COORDINATOR

The U.S. has chosen to take a leadership role in the global fight against HIV—with particular focus on a key set of countries primarily, but not entirely, in Sub-Saharan Africa. As noted above, the 2003 law authorizing PEPFAR statutorily created its current structure. Shifting PEPFAR’s management structure, therefore, would not only require a change in current law, it could have a significant impact on the U.S. role in the global AIDS response. Members of the working group reviewed the various public reports, publications and recommendations that have come out recently with respect to State and USAID redesign. Most say little about global health overall—which is a significant missed opportunity given the important global health programs at USAID. However, most of the reports have recommended moving the Office of the Global AIDS Coordinator to fall under USAID. **Previous analyses, however, have not included substantial input from the global health community or experts in PEPFAR’s operations. Such a change would have profound impact and carries significant risks for a program in which the U.S. has invested \$72 billion and upon which millions of lives rest.**

Public recommendations for restructuring the State Department and USAID as a whole have been based on perceptions of fragmented authority, inefficiencies at headquarters and country level, ambiguity in the roles of the State Department and USAID, and the need to elevate the power and position of USAID administrator. Some of these concerns apply to PEPFAR, though as noted in various oversight reports significant attention to these issues has been paid in recent years.^(5,9)

Working group members considered these points as well as a number of broader issues about how best to accomplish the U.S. mission on HIV/AIDS. Grounded in concrete experience from recent years, working group discussions covered a key set of considerations that, on balance, argue for maintaining

the U.S. global AIDS coordinator at the State Department, even as efforts to increase harmonization and impact are pursued. Specifically, the following critical aspects of the U.S. global AIDS response were identified:

1. THE HIV HAS A DIPLOMATIC & POLITICAL MISSION: The HIV pandemic, since its earliest years, has represented a significant global political challenge alongside medical and development challenges. Addressing all three components effectively is crucial. Political leaders in many countries with significant HIV epidemics (notably including the U.S.) have resisted talking about and effectively addressing HIV, which has undermined public messaging, distorted policy, and diverted resources needed in the response. Human rights concerns are inextricably linked to the epidemiology of HIV, with implications for access to HIV treatment, services for key populations, and sufficient domestic investment in the AIDS response. Diplomacy has always been a core competency of the State Department and thus a necessary component to effectively addressing HIV through PEPFAR. Indeed, by making the HIV response a diplomatic priority, the U.S. has multiplied the impact of taxpayer dollars and accomplished far more than traditional aid alone has made possible.⁽¹⁰⁾ Meanwhile, the diplomatic capacity of the U.S. has been critical to driving other donor countries to make and keep their own commitments on HIV funding to ensure the U.S. is not going it alone—supporting contributions to the Global Fund to Fight AIDS, TB, and Malaria and synergistic funding through other national bilateral programs. However, the State Department is not a program implementer and having independent entities in USAID and CDC, focused on program delivery a step apart from the diplomatic mission, has been key to deploying effective interventions to fight HIV.

USING DIPLOMACY TO SUPPORT SCIENCE-BASED POLICIES

Recently, U.S. Ambassadors and embassy officials in many countries engaged directly with national political leaders to move toward change to a “Test and Start” treatment policy rather than waiting to treat until people living with HIV were sick and immune compromised—a policy that was required to reach needed levels of treatment coverage. In many countries this required not just discussions on the technical merits but negotiations at the political level about how this policy change would be timed, paid for, and sustained amidst new challenges it presented. While earlier policy shifts often took many years, PEPFAR’s health diplomacy effort moved this policy change in most countries within 12 months—saving PEPFAR funds in the medium term and helping achieve the treatment scale up announced this year on World AIDS Day by the PEPFAR program.

2. INTERAGENCY CAPACITIES TO HALT AN INFECTIOUS DISEASE:

Insofar as the AIDS response is as much a medical and epidemiologic challenge as it is a development challenge, both HHS and USAID are critical to PEPFAR's continued ability to drive progress. Even as the two agencies have merged some capacities, today CDC is responsible for programming roughly 45% of PEPFAR funds (and a far higher percent of programming funds) and plays a critical part in supporting in-county capacity and partnerships with government health officials. This is a key complement to USAID, the lead development agency of the U.S. government, which brings strength in supporting community systems and addressing social and economic drivers of HIV.

3. COUNTRY LEVEL COORDINATION: A particular area of concern in thinking about improving the function of State and foreign aid comes at the country level—where interactions with key partners including foreign governments, international agencies, NGOs, and the public must be harmonized to ensure effective programming. Here the role of U.S. Ambassadors and the U.S. Embassy mission has been decisive. As noted in the IOM evaluation of PEPFAR, strong leadership from the chief of mission in valuing and facilitating positive interagency collaboration has been the single most important factor in this area.⁽⁵⁾ Meanwhile, with the many other key actors engaged in HIV at the country level, State Department capacity to navigate the politics of coordination has helped overcome roadblocks and increased accountability on all sides.

4. AN INDISPENSABLE AND COMPLEX GLOBAL ROLE: The bill authorizing PEPFAR, titled the “global leadership” act, creates an independent structure focused on the global AIDS response that is unique and upon which the international AIDS response has come to depend. On the U.S. side, a data-driven effort that combines medical and development approaches to defeat a global infectious pandemic requires strategic focus given the complexity of the response—which necessitates tasks ranging from epidemiologic modeling to pharmacovigilance, from training nurses to building new cadres of peer mentors, from expanding the use of condoms to getting young people into a primary health system for the first time. Globally, the Global AIDS Coordinator has come to play a critical role in the architecture of the AIDS response beyond simply the funding provided. The metrics, data, and systems OGAC has built alongside UNAIDS and Global Fund are baked into how the AIDS response judges progress and the world relies on the content of U.S. diplomatic leadership to drive progress. Pulling back on the focus PEPFAR has enabled before the epidemic is controlled would undermine 15 years of work.

5. INTERFACE WITH THE GLOBAL FUND AND INTERNATIONAL ACTORS (G7, G20): The Global Fund to Fight AIDS, TB, and Malaria, which was created through diplomacy at the United Nations General Assembly and G8 meetings in 2001, is inextricably linked to the success of PEPFAR—with synergies in every PEPFAR supported country that have built the

response. At a global level, State Department diplomacy is critical to moving funds and supporting policy initiatives across regional and national governments and organizations. At the national level, the coordinated Ambassador-led HIV response is critical to ensuring the Global Fund and PEPFAR are synergistic rather than duplicative.

6. BUDGET AUTHORITY AND CLEAR TARGETS: PEPFAR's high-level mission is not complete. Key to the progress thus far, however, has been budget authority with the flexibility to move funds as required to tackle the epidemic alongside clear targets and accountability. Setting those targets as a collaborative exercise between the administration and Congress has enabled prioritization that is, today, bearing fruit as the program's focus on achieving and reporting against clear goals has driven much of its success. It is vital that the relevant Congressional committees maintain this budget authority and that the U.S. Global AIDS Coordinator remain accountable at the political level of a Presidentially-appointed, Senate confirmed Ambassador-at-Large to ensure not only that targets are set but that they are accurately accounted for.



Photo: Sarah Day Smith

CONTINUING EVOLUTION OF PEPFAR

HIV remains a global pandemic in need of a locally-informed epidemic-driven response. The PEPFAR program has evolved substantially in the nearly 15 years since its inception, even as core principles in the design of the program have remained a bedrock of programmatic success. The argument here is not one of perpetual stasis in for PEPFAR. Indeed, as the epidemic evolves there is continued need for the program to do so as well.

There are also important ways in which the lessons of PEPFAR can help strengthen other U.S. global health programs. The working group focused on HIV but notes that, without moving OGAC, there are many opportunities to increase the efficacy, impact, and prominence of other global health programs inside USAID, HHS and elsewhere through increased investment and strategic alignment across government. There are also multiple opportunities for learning and coordination with PEPFAR—as programs like pink ribbon-red ribbon have shown on cancer and the SEARCH study have shown with non-communicable diseases.^(11,12) However, such efforts are not predicated on moving OGAC and, in fact, such a move could de-stabilize the U.S. global HIV response which itself could have negative impacts on other U.S. global health efforts.

Working group members described a variety of ways in which PEPFAR can continue to evolve to enhance its effectiveness and to link and coordinate with other health and development programs. Yet these do not require—and could well be undercut—by a change in where the Global AIDS Coordinator is housed or to whom s/he reports. For example, the Country Operational Planning process has increasingly become a meaningful mechanism for cross agency dialogue and coordination inside and outside the U.S. government and in coming years could be better used to increase synergies between U.S. global health programs. Focusing on continuing to build it out as a platform for governing a multi-nodal high-profile global health initiative could have significant benefit to the PEPFAR program and to U.S. leadership—increasing transparency and accountability of the program and as a test model for future efforts to build aid efficacy. PEPFAR's growing data hub is another example of an innovation that could actually improve coordination as it focuses all agencies (and the public) on the same set of outcomes and measures of success—reducing friction over competing measures, data systems, and accountability points.

Meanwhile, PEPFAR stakeholders can be better tapped to translate lessons learned and evidence of what is working well for use in other global health programs, without migrating PEPFAR's structure. Focusing on areas like this to deepen impact and continuing to improve management for interagency and international coordination is likely to bear the greatest fruits for leaders at the State Department and USAID. Lastly, while a variety of oversight reports have documented the challenges of coordination, information sharing, and fragmented authority that have come with managing a program across multiple agencies (13,5,14,9), management reforms in recent years ranging from professionalizing in-country PEPFAR coordinators to the new Epidemic Control Teams have been implemented to address these challenges. While more work needs to be done, overall, working group members reported that collaboration in many countries has substantially improved in the last few years as the program and management structures have matured.

Moreover, the working group found little to suggest that moving the OGAC would improve inter-agency coordination or address inherent conflicts stemming from the need of multiple U.S. agencies to engage with different host government ministries. Instead, there is significant concern that doing so could exacerbate underlying tensions. Instead, focusing on opportunities to maximize effective management using new spaces and tools like PEPFAR Country Operational Planning processes is likely to be far more important to the program.

CONCLUSION

The U.S. global AIDS response through PEPFAR, as well as the Global Fund, have succeeded because of continuous White House leadership across administrations, bipartisan congressional mandates that have supported the program across ideological lines even in periods of hyper-partisanship, and the empowered authority of the U.S. Global AIDS Coordinator. Clear targets along with the support of an exceptional coalition of implementers, advocates, industry, the faith community, and foundations has helped build a government response with a unique record of active learning—evolving new approaches to implement science, engage stakeholders in planning, and achieve evidence-based efficiencies.

Proposals to move the Office of the Global AIDS Coordinator have not sufficiently recognized the unique character of this program or how important the current structure is to PEPFAR's success. Today the AIDS response is at a critical juncture—impact against the epidemic is both inspiring and fragile. Interrupting the structures of accountability that make U.S. global AIDS programs uniquely effective just when we need clearer-than-ever focus would be a mistake.



Photo: Joan Lewa

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