

**Written Testimony**  
**Ambassador-at-Large Deborah L. Birx, M.D.**  
**Coordinator of the United States Government Activities to Combat**  
**HIV/AIDS and**  
**U.S. Special Representative for Global Health Diplomacy**  
**House Foreign Affairs Committee**  
**Subcommittee on Africa, Global Health, Global Human Rights, and**  
**International Organizations**  
**“Global Health Supply Chain Management: Lessons Learned and**  
**Ways Forward”**

**May 17, 2018**

Thank you Chairman Smith, Ranking Member Bass, and other distinguished members of this Subcommittee. I am deeply honored to appear before the House Foreign Affairs Committee and your Subcommittee, which have provided such visionary leadership and remarkable support for the U.S. President’s Emergency Plan for AIDS Relief (PEPFAR) since its inception in 2003.

Today, more than 14 million men, women, and children are alive and we have transformed the global HIV/AIDS pandemic because of the compassion and commitment of the members of this Subcommittee and the full House Foreign Affairs Committee; the bipartisan, bicameral support of your congressional colleagues; the leadership of President George W. Bush, President Barack Obama, and President Trump; and the generosity of the American people. All Americans should be immensely proud of PEPFAR’s achievements – because they are also their achievements.

PEPFAR’s achievements are made possible because of two reasons. First, through our collective, unrelenting focus on outcome and impact results - using data to improve all aspects of HIV prevention and treatment services. And second, through our absolute commitment to using the best of each U.S. government agency to achieve more each year through increased efficiency and effectiveness.

This month, alongside our many partners, we are marking the 15<sup>th</sup> anniversary of PEPFAR’s establishment, which is officially on May 27<sup>th</sup>. With strong bipartisan leadership, the U.S. government, through PEPFAR, now supports lifesaving HIV treatment for more than 14 million people. We have enabled more than 2.2 million babies to be born HIV free to HIV-positive mothers and assist more than 6.4 million orphans, vulnerable children, and their caregivers to ensure the next generation can thrive. We have trained nearly 250,000 new health care workers to deliver HIV and other health services. Our efforts have also reduced new HIV diagnoses by 25-40 percent among adolescent girls and young women in 65 percent of the highest-HIV-burden communities implementing our DREAMS (Determined, Resilient, Empowered,

AIDS-free, Mentored, and Safe) public-private partnership in 10 of the highest-HIV-burden African countries since 2015.

The United States is not only delivering results, but also accelerating our global impact against the HIV/AIDS epidemic, as articulated in the Administration's PEPFAR Strategy for Accelerating HIV/AIDS Epidemic Control (2017-2020). PEPFAR-funded Population-based Health Impact Assessments show that up to 13 high-HIV-burden countries are poised to achieve epidemic control by 2020. PEPFAR's efforts in these 13 countries, in partnership with host-country governments and the international community, will produce a roadmap to reach epidemic control in the more than 50 countries where PEPFAR works. For example, Ethiopia is within months of reaching HIV/AIDS epidemic control and we have been able to reduce U.S. assistance through PEPFAR in the country substantially – from more than \$300 million in FY 2010 down to nearly \$70 million requested in FY 2019 due to this success. Sustaining or maintaining epidemic control into the future will cost much less than what was needed to achieve it.

We have come a long way in the global HIV/AIDS response in the 15 years since PEPFAR began. In 2003, an HIV diagnosis was a death sentence in many countries, and entire families and communities were falling ill. In some African countries, infant mortality doubled, child mortality tripled, and life expectancy dropped by 20 years, with millions of orphans left behind on the continent. At that time, only 50,000 people were on lifesaving HIV treatment in Africa.

A principal factor in PEPFAR's success: we harness the latest data and science to direct resources where the HIV/AIDS epidemic is the largest, the need is highest, and they are most efficiently used to have the greatest impact per each dollar invested. Every quarter we look rigorously at our outcomes and costs in order to continuously improve our work. This commitment to transparency, accountability, and impact is why PEPFAR is often cited as one of the most effective and efficient U.S. foreign assistance programs in history.

PEPFAR in-country teams assess populations and geographies, design interventions, and set targets aimed at accelerating epidemic control based on the clarity provided by the data. This allows the program, in partnership with governments and communities, to focus services, stop or improve the activities that are not having the desired outcomes, and expand those activities that are reaching essential groups. To enhance the systematic gathering, analysis, synthesis, and interpretation of program data for routinely measuring progress, PEPFAR has a robust set of Monitoring, Evaluation, and Reporting program indicators that collect site-level programmatic results by age (in five-year age bands), sex, and, in some cases, key population for each person receiving PEPFAR-supported services, which are reviewed at least quarterly.

In addition to using data to target our efforts toward saving and improving the lives of millions of people living with and affected by HIV/AIDS, PEPFAR has invested to enhance surveillance and health information systems as well as laboratories that are critical to effective and efficient health care delivery. In 2017 alone, through PEPFAR's

Country and Regional Operational Plans (COPs/ROPs), we invested nearly \$600 million in horizontal, above-site health system strengthening investments. This includes nearly \$100 million to enhance laboratory systems and almost \$70 million to strengthen supply chains.

Over the past 15 years, through these types of health systems strengthening investments, PEPFAR has enhanced global health security, accelerating the progress toward a world more secure from the threat of infectious diseases by improving the global capacity to prevent, detect, and respond to new and existing risks. PEPFAR's investments in countries with sizable HIV/AIDS burdens have also bolstered their ability to swiftly address Ebola, avian flu, cholera, and other outbreaks, which ultimately protects American lives and America's national security.

Through harnessing the whole-of-government approach, PEPFAR has been able to bring the most effective, state of the art antiretroviral agents, diagnostic and monitoring commodities to the most resource limited settings utilizing the brilliant research from the U.S. National Institutes of Health, the strength of the U.S. Food and Drug Administration, and working effectively with manufacturers translating science to patients in record time.

PEPFAR has invested toward building and supporting a strong, reliable, and secure supply chain to serve the more than 50 countries where we work. A high-performing supply chain is the lifeblood of our efforts. We must ensure that the right commodities reach the right people, in the right places, and at the right time. This requires effective and efficient commodity forecasting, procurement, and delivery – including tracking every product all the way down to the site-level where it is provided to the patient. PEPFAR has invested billions since 2003 on strengthening the supply chain - providing technical assistance to Government and non-Governmental Supply chains, building infrastructure, and funding hundreds of fulltime U.S. government personnel in-country and with host governments. Collectively, we have worked together to achieve amazing progress and we remain committed to bringing the most effective medications to those that need it.

This is why I am deeply concerned about the recent supply chain challenges that bring us here today. Suffice it is to say, there are a number of things that have not gone well in this regard. Some of these have been fixed but others still need to be urgently addressed. Everyone who is involved in the supply chain at all levels must feel a strong sense of accountability to get our supply chain on the right track. We need it so we can successfully and sustainably deliver the essential lifesaving treatment and other commodities for the mothers, fathers, sisters, brothers, daughters, and sons who we are so privileged to serve. They deserve nothing less than our best, and we can do better. After PEPFAR's significant investment as well as our substantial U.S. government in-country and technical support, we should not be at this place in this moment.

In light of these serious supply chain shortcomings, I have instituted strengthened headquarters oversight on all PEPFAR-supported commodities. This includes – but is

not limited to – monthly antiretroviral medication (ARV) risk reporting; approval of the Emergency Commodity Fund to address potential, or existing, stock outs; approval over the procurement of any legacy ARVs using funds approved in PEPFAR 2017 or 2018 Country Operational Plans; and sharing of commodities-related data between PEPFAR, USAID, and the Global Fund to Fight AIDS, Tuberculosis, and Malaria. Further, I have initiated rigorous PEPFAR-wide partner management to increase performance and efficiency.

Moving forward, PEPFAR now tracks and analyzes its results and partner performance data down to the site level at least on a quarterly basis as opposed to previous practice, which was annually or semiannually. We can now identify and address emerging problems earlier, allowing for more rapid course-correction before these problems become big ones. Our partner performance and our programmatic outcomes and impact are critical to the successful functioning of the supply chain and the absolute predictability of supplies. No one wants to be down to their last test when a pregnant woman comes through the door; in such a situation, every clinic, district hospital and community site of service begins to slow down their outreach and testing to ensure adequate supplies. With the breadth and depth of our investment over the years, we should expect nothing less than a highly functioning and sustainable supply chain.

We are not only collecting our results and partner performance data every quarter, but also sharing it with the public. Last month we reached a new transparency milestone by publicly releasing program results and implementing partner performance for more than 40,000 PEPFAR-supported facilities spanning all of our 35 country and regional programs. By putting all of these data online, we hope that everyone will be more empowered to effectively and sustainably control the epidemic.

One of the most important tasks that our programs and our supply chain must soon navigate is the transition to new and more effective antiretroviral regimens based on Dolutegravir (DTG), a new integrase inhibitor. Dolutegravir is cheaper, better tolerated for the patient, and leads to improved results including faster viral suppression. There is a virtuous circle created by DTG's low side effect profile, which makes adherence easier. It also offers easier adherence and fewer side effects for most of the population, although a full analysis of the safety in pregnant women is still being explored. The transition to DTG will mean a more rapid adoption of differentiated care and more models of community care. It will be critical to utilize and move rapidly to regimens that are more effective and better tolerated, especially as we start treatment on clients who are early in the progression of the disease and still feeling well, to ensure people stay on their treatment. We need a supply chain supplier that is nimble and proactive.

Due to faster viral suppression, ART prevention benefits are also felt quicker with the use of DTG. The drug's wide applicability – including for patients currently on second-line regimens – simplifies supply chain regimes. It also creates very low resistance, which should allay concerns that the increase number of people on ART could lead to the rise of drug-resistant strains of HIV.

In our 2018 PEPFAR Country Operational Plans, which I approved last month for 22 countries, we worked with each of them to develop a transition plan to Dolutegravir, Lamivudine and Tenofovir Disoproxil Fumarate (TLD), including the utilization of so-called “legacy ARVs” to prevent stocks out as this transition takes place. Taken together, these transition plans have allowed us to develop a global forecasting tool to ensure that future TLD demand does not outpace product supply. This positions our supply chain to account in advance for manufacturing lead times and product availability, and to establish delivery timelines that support effective and efficient program performance. It allows us to be proactive and obtain the best prices.

In addition to transitioning to new and more effective commodities, PEPFAR is also working to lower the costs of other purchases, most notably the cost of laboratory reagents. For example, PEPFAR has achieved impressive reductions in the cost of viral load tests, in some cases from \$40 per test to as low as \$15. Further future reductions are possible. In addition, with fewer clinic visits, fewer laboratory tests are needed as PEPFAR works hard to eliminate unnecessary tests. In fact, with Test and Start, CD4 counts are no longer necessary to determine the initiation of ART. PEPFAR is scaling back support to CD4 testing, which is generally needed in fewer cases, freeing up resources for the expansion of viral load monitoring to ensure clients remain virally suppressed.

Together, we are closer than ever to ending AIDS and decreasing the future costs of addressing the pandemic because of effective and focused programming. What once seemed impossible is now possible – controlling and ultimately ending the AIDS epidemic as a public health threat. But this will only happen if we all constantly hold ourselves accountable to not only do more but also do it better.

Chairman Smith, Ranking Member Bass, and other distinguished members of this Subcommittee, thank you for the opportunity to appear before you today. We are once again profoundly grateful for the ongoing support and engagement of the House Foreign Affairs Committee and this Subcommittee for PEPFAR’s work.

Thank you. I look forward to your questions.