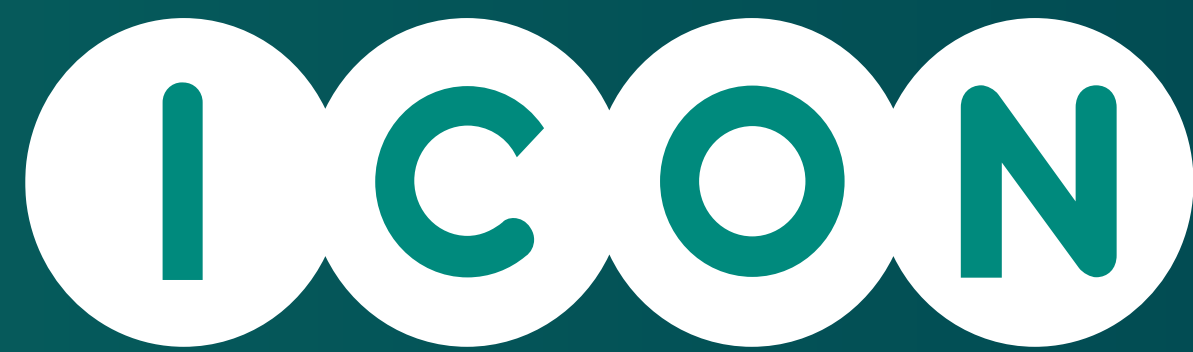


Implications of Recent U.S. Policy Changes on Evidence Generation Requirements for Enabling Access to Medicines and Vaccines in Low- and Middle-Income Countries



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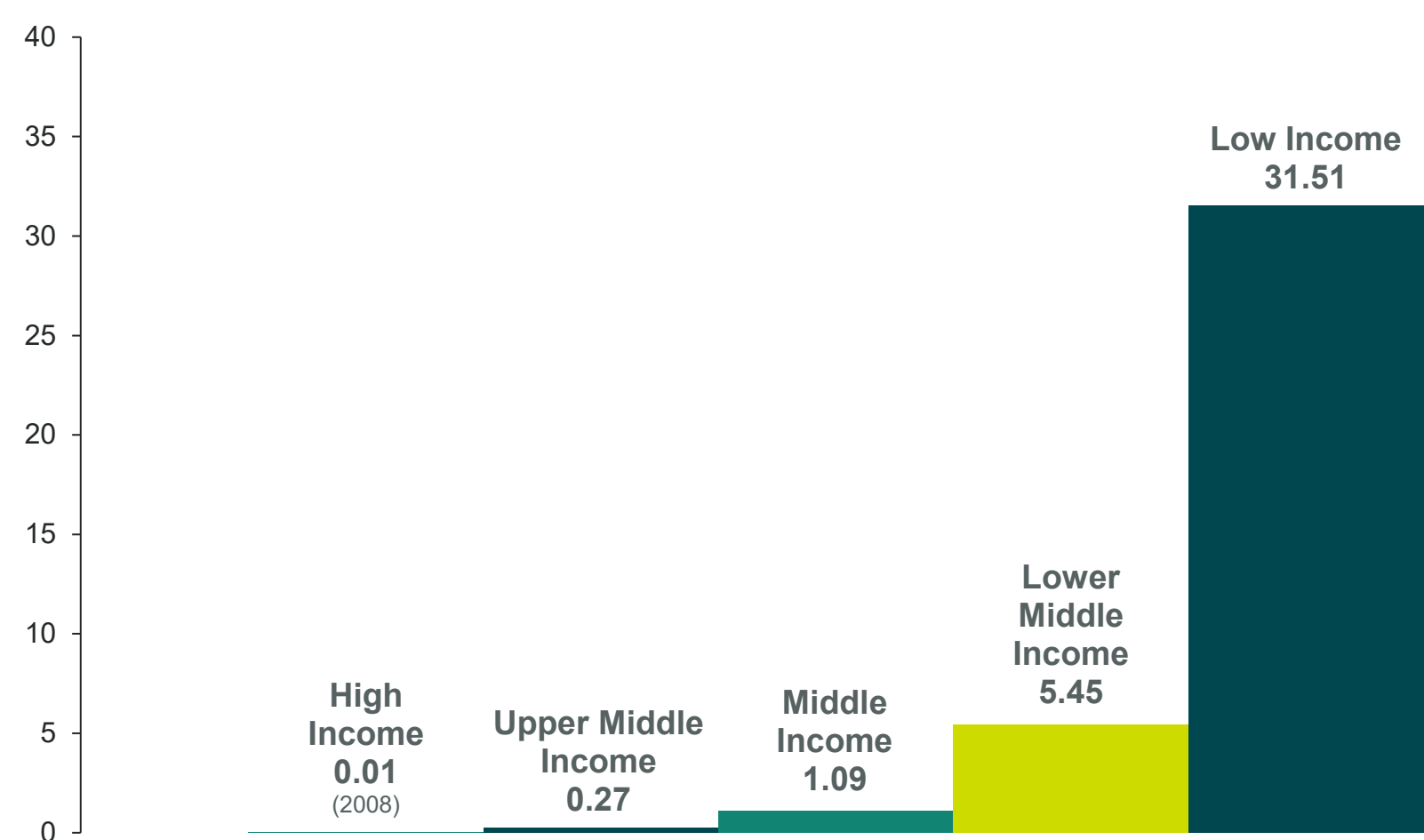
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Introduction

Many low- and middle-income countries (LMICs) rely partially on donor funding from wealthier countries and multilateral organizations to fund health systems, including paying for health technologies such as vaccines and medicines. On average, in 2022, 31% of health funding in low-income countries came from external sources (Figure 1).¹






Figure 1. External health expenditure as % of current health expenditure – 2022 ¹



The United States (U.S.) is historically one of the largest donors for global health – both through bilateral and multilateral funding mechanisms – and has played a key role in guiding the implementation of health funding in various ways.

Since taking office in January 2025, the Trump administration has significantly decreased the amount of funding the US contributes to global health, the ways in which funding is delivered, and policies that enable access to vaccines and medicines in LMICs.

These actions have included:²

-  Dissolving the US Agency for International Development (USAID) and cancelling 83% of USAID programs
-  Putting forth a budget request for FY 2026 that proposed significant decreases, and in some cases eliminations, of funding for global health activities
-  Withdrawing the US from the World Health Organization (WHO)
-  Halting foreign aid or assistance delivered or provided to South Africa unless under certain circumstances
-  Removing all 17 members of the Advisory Committee for Immunization Practices (ACIP), which makes recommendations about vaccines – these in turn largely determine coverage in the US³

Objectives

- Explore the impact of recent policy changes in the U.S. enacted by the Trump administration on health funding in LMICs.
- Explore the implications of these policies on enabling access to vaccines and medicines in LMICs.




Methods

The authors conducted a landscape review of published peer-reviewed articles (Pubmed, Embase, etc.), news articles, and grey literature. We conducted targeted searches using key words to identify information published in English in the last five years, focusing on information published since January 2025 by nonprofit, nonpolitical organizations in the global health field.

Results

Funding

The United States is historically one of the largest donors to global health

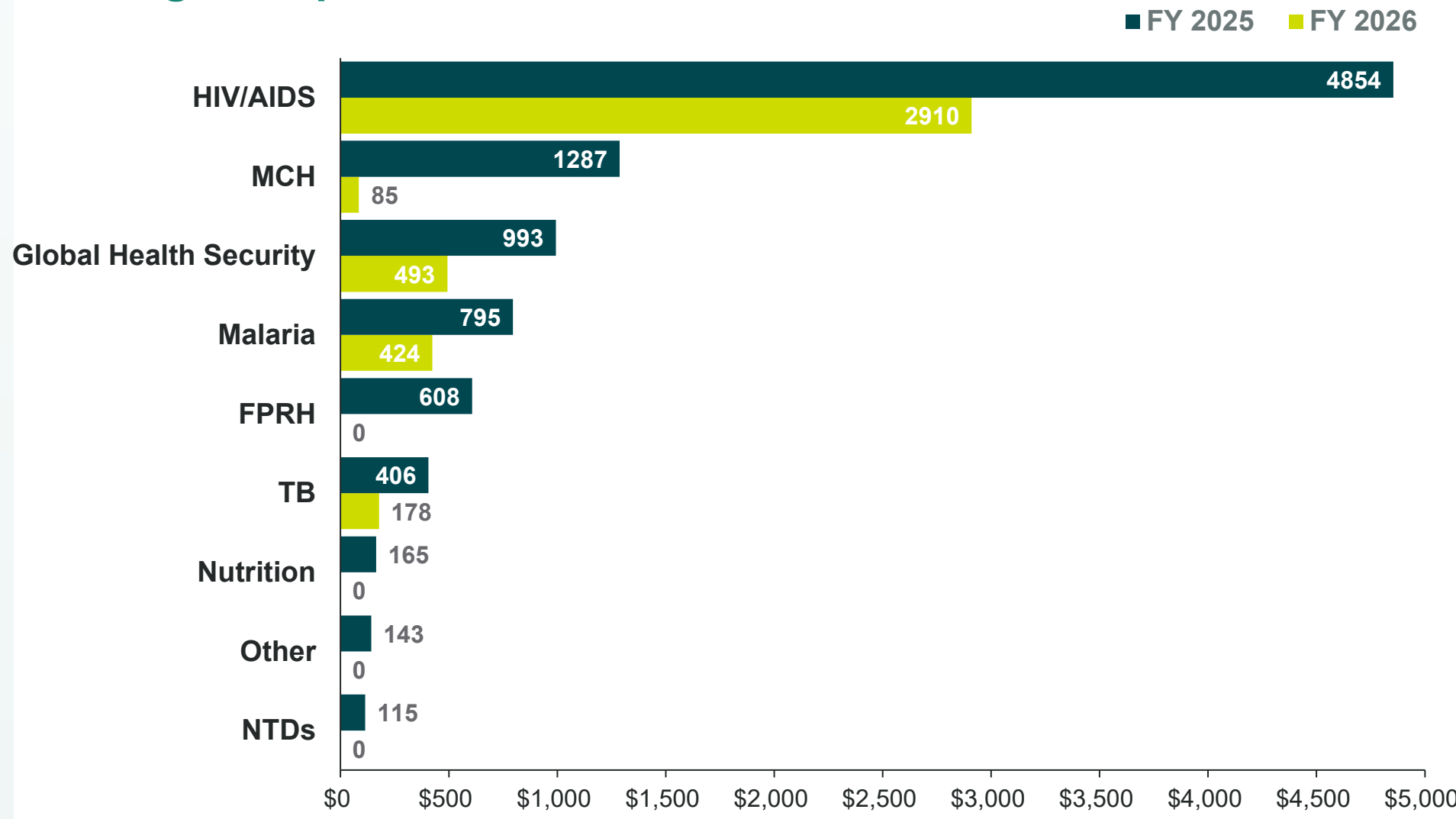
-  In 2024, the U.S. provided nearly \$10 billion in bilateral funding for global health.⁴
-  The U.S. government currently accounts for 13% of Gavi's funding, which in 2024 was \$300 million.⁵
-  The U.S. government is the Global Fund's largest donor - in FY 2024, the U.S. provided \$1.65 billion.⁶

Results (con't)

Funding Gaps

Decisions about funding global health are made primarily by the US Congress. At the time of development of this posted, a budget for FY 2026 has not been passed, so much remains uncertain; however, *the Trump administration's proposed FY 2026 budget includes a reduction from \$10.0 billion to \$3.8 billion for the Global Health Programs (GHP) Account.*⁷

Figure 2: Analysis of Global Health Funding in the FY 2026 Budget Request⁷



The budget request includes significant cuts in funding for HIV/AIDS (PEPFAR), tuberculosis (TB), malaria, maternal and child health (MCH), and global health security – cuts range from 40% to 93%.⁷ Funding for family planning and reproductive health (FPRH), neglected tropical diseases (NTDs), and nutrition has been cut entirely.²

The Trump administration has also:

- Eliminated the Centers for Disease Control and Prevention (CDC) Global Health Center and funding for most of its bilateral programs.⁷
- Eliminated funding for the Global Vaccine Alliance (Gavi), the Pan American Health Organization (PAHO), the United Nations Children's Fund (UNICEF), the United Nations Population Fund (UNFPA), and the WHO.² Gavi estimates that this loss of funding alone could result in more than 1.2 million children dying as a result.⁵
- Proposed to limit support for the Global Fund to \$2.4 billion over the 2026-2028 period⁷ during the next replenishment which will be held in November 2025.⁶

The impact will not only be to direct funding, as Gavi and the Global Fund also play important market shaping roles through pooled procurement.⁶ Lack of funding for these two organizations could limit their ability to do this and further drive prices for health commodities up.

Though the exact figures are not yet known, LMICs are likely to face significant funding gaps for health over the next several years as a result of U.S. funding and support being withdrawn. Most countries will not be able to replace this funding and will have to make tradeoffs and significant cuts to expenditures.

Technical and Implementation Gaps

The policy changes made by the Trump administration may also create technical gaps that limit access to medicines and vaccines. The US plays a key role not only in funding for global health but also in providing leadership, governance, and technical assistance.

Changes to U.S. domestic policies, particularly those made to ACIP may also affect access to vaccines in LMICs through spillover effects.

WHO draws on ACIP's models and processes when setting global immunization norms, and many National Immunization Technical Advisory Groups (NITAGs) adapt ACIP frameworks to guide their own national recommendations.⁸ ACIP's recommendations also strongly influence vaccine coverage in the United States, shaping global market demand, manufacturing priorities, and pricing.⁹ An ACIP endorsement can boost manufacturer confidence, encouraging production and helping to stabilize or lower prices, which in turn may improve vaccine availability in LMICs.

As a result, changes to ACIP's decision-making processes or uncertainty in U.S. vaccine procurement could have downstream impacts on vaccine access and affordability worldwide.

Evidentiary Requirements

Like high-income countries, LMICs determine which medicines and vaccines to fund based on how they prioritize and assign value to each one within the funding they have available. With some notable exceptions (namely the U.S. and Germany), many high-income countries make these decisions through HTA processes that assess cost-effectiveness, i.e. how well a new drug performs and how affordable it is relative to existing therapies.^{10, 11}

Results (con't)

Evidentiary Requirements (con't)

The decision-making processes in LMICs are variable and are often less standardized and more flexible. For example:

- The top prioritized factors for the choice of new vaccines in Nigeria over the past several years were cost, valency, cold chain capacity and scheduling methods.¹²
- The South African NAGI considers disease burden, cost effectiveness, and the impact on the Expanded Programme on Immunisation but also involves provinces in decision making and ultimately requires funding from the Ministry of Finance.¹³

The variance is at least partially due to the fact that *LMICs have to consider factors that are less important or non-existent in high-income countries, namely donor perspectives* and whether donors will provide earmarked funding for a health technology, or whether implementation of a new technology may help achieve targets that lead to funding in other areas, such as achieving the Sustainable Development Goals. Operational considerations¹⁴ to roll-out a medicine, e.g. cold chains and health workers to implement a vaccine campaign, are also important in LMICs.

Conclusion

As donor funding and influence becomes increasingly limited, and as global recommendations become less definitive and enforced, manufacturers of vaccines and medicines should anticipate that many LMICs may struggle to introduce new health technologies or even sustain existing programs.

Evidentiary needs are likely to become more variable across LMICs. In some countries, national priorities may take precedence over donor priorities since fewer funding incentives will be available. These countries are likely to prioritize interventions that deliver the greatest public health impact for the lowest cost, address the highest disease burdens, and are feasible to implement within existing systems. Other countries may continue to try to attract U.S. funding by aligning their strategies with the Trump administration's policies, such as those that emphasize alternative approaches to vaccination, limited support for gender and sexual diversity programs, and restrict certain family planning services.

To support continued access and uptake, manufacturers will need to engage early with LMIC governments to understand their specific priorities, needs, and constraints, generate evidence that their products help meet these priorities, and work with LMICs to co-develop innovative financing models, pricing strategies, and delivery solutions that make new technologies both affordable and practical to deploy.

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