Multilateral Leadership

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In the last four years, the Trump administration withdrew US leadership from the global stage, initiating a withdrawal from the World Health Organization (WHO) and generally abdicating the US role as a global leader. The Biden-Harris administration, however, has taken early steps to resume the mantle of global leadership. In its first week in office, the administration ended US withdrawal from WHO and publicly committed the United States to join ACT-A, the Access to COVID-19 Tools Accelerator—a multilateral research and development (R&D) partnership for developing and equitably delivering COVID-19 therapeutics, diagnostics, and vaccines—and COVAX, its COVID-19 Vaccine Global Access Facility—focused on vaccine distribution. Despite these promising movements, gaps remain for the US Congress and administration to address.

Policy recommendations

Authorize and support US participation in the Coalition for Epidemic Preparedness Innovations with annual appropriations of at least $200 million, and facilitate ongoing scientific collaboration with key US agencies.

The Coalition for Epidemic Preparedness Innovations (CEPI) is an international organization created to co-finance and coordinate the development of vaccines against emerging infectious disease threats. US government scientists at the National Institutes of Health and the Biomedical Advanced Research and Development Authority have collaborated with CEPI to align vaccine research and reduce duplication, but to date the US government's only commitment to CEPI is $20 million, spread over five years, delivered through the US Agency for International Development—subject to annual appropriation. Congress should permanently authorize US participation in CEPI and commit to providing it with at least $200 million annually. By investing in CEPI, the US government can leverage funding from other global funders to support promising vaccine candidates, while not bearing the full cost of development. It would also significantly accelerate global access, by funding the development of vaccines that are being designed with global access in mind—a modest investment in preparedness that pales in comparison to the cost of responding to a pandemic.

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Push for the inclusion of R&D capacity strengthening in multilateral health preparedness frameworks.

No global framework currently exists for assessing and strengthening the capacity of every country to develop, approve, manufacture, and deploy vaccines, treatments, diagnostics, and other medical countermeasures—despite the importance of these tools in preparing for and responding to global health challenges. In the absence of an agreed-upon global framework for R&D capacity strengthening, donors and implementing countries have been slow to prioritize, finance, and mobilize this work. The Biden-Harris administration should leverage US global leadership to push for the inclusion of R&D capacity strengthening in multilateral frameworks, including the implementation of WHO's International Health Regulations, which govern the obligations of countries to international public health preparedness, and the Global Health Security Agenda, an international partnership to strengthen the capacity of participating countries to detect, prevent, and respond to infectious disease threats in compliance with the International Health Regulations.

Advance commitment to innovative financing models and unlock investment from international financial institutions to strengthen R&D capacity in low- and middle-income countries.

A largely untapped source of new sustainable financing for global health R&D is international financial institutions, including the World Bank. Health R&D has the potential to both multiply the outcomes of development investments and foster new hubs of health innovation. The Biden-Harris administration should push the World Bank and other regional development banks to support mechanisms to provide financing for global R&D capacity-building, particularly in low- and middle-income countries. Building this capacity could improve both global and local resilience to persistent and emerging global health challenges.

Promote collaboration between the Food and Drug Administration, the World Health Organization, and other international partners to improve regulatory coordination and harmonization to facilitate product approvals.

Strong regulatory systems play a critical role in global health R&D. As new global health innovations move further through the pipeline, regulatory bodies are required to ensure they are safe and effective and ultimately approve them for use in a timely manner to ensure populations have access to new tools as soon as possible. The Food and Drug Administration (FDA) is a global leader in the safety, efficacy, and security review of biomedical products and regulates products marketed in the United States—and it could play a stronger role in providing more technical support to under-capacitated national and regional regulatory authorities.

The Global Health Technologies Coalition encourages legislative provisions or administrative actions that support FDA in deploying its expertise to strengthen global regulatory pathways in low- and middle-income countries, such as by providing technical support and work product sharing with international partners through improved global clinical data interoperability, evidence sharing, mutual recognition agreements, and increased coordination and harmonization, especially with WHO.