

Global Health Advocates Support Accelerating New Technologies

The imperative to address global health problems

- Seven million people die each year worldwide of HIV/AIDS, tuberculosis, and malaria. Millions more lives – especially in developing countries – are profoundly affected by the impact of these and other neglected diseases.
- To slow these epidemics, the world desperately needs new vaccines, drugs, microbicides and diagnostics. However, the global community continues to face significant barriers in developing safe and effective technologies for these diseases.

The obstacles

- Private sector investment in research and development for these technologies has been limited, in large part due to the fact that such products are unlikely to be commercially profitable.
- This is particularly troubling given that the needed expertise for product development largely resides within industry.

Required solutions

As advocates for accelerated development of these urgently needed products, we believe that bold new steps are required to make a difference in saving lives around the world. We believe that the following measures/principles are essential to any long-term solution.

- Comprehensive menu: While we applaud past legislative efforts to tackle this problem, none have provided a comprehensive menu of choices to stimulate action by the full range of potential players, ranging from small biotech companies to large, fully integrated pharmaceutical firms.

Different measures will be needed to attract the involvement of different players. All can play an important role.

- “Push” mechanisms that will reduce the costs of R&D and encourage companies to do more in the field of neglected infectious diseases. Such mechanisms would include measures such as tax credits and provisions to foster creation of capital for companies that are focusing on the target diseases (to take effect upon initiation of relevant R&D work) and support for product development public-private partnerships.
- “Pull” mechanisms that will reward success by improving or creating positive market conditions. For example, an advance purchase commitment would encourage investment in R&D by guaranteeing a market for the urgently needed but commercially unattractive products.

An advance purchase commitment focused on technologies for use primarily outside of the United States must incorporate flexible measures recognizing that the U.S. government will not be the sole, or even primary purchaser. Steps should be taken to ensure that such commitments are in cooperation, not in conflict with those undertaken by other national governments and international bodies, to promote a global response to a global problem.

- Measures that will significantly stimulate private sector interest in R&D for these diseases by focusing on successful market principles: competition, risk and the potential for reward. This might include offering to the developer of a successful preventive technology a carefully calibrated patent bonus that would extend the effective patent life of a more profitable product. We note that similar measures

successfully stimulated research into “orphan” drugs and for pediatric formulations of existing medicines. The impact of the global epidemics of HIV/AIDS, TB and malaria necessitates similarly bold initiatives now.

- Measures to provide reasonable protections for both consumers and suppliers of preventive health technologies. Liability protection will be needed to protect health care workers and manufacturers from frivolous litigation, while also providing compensation for injury. This would include appropriate protection during the research process.
- Support for the objective of ensuring that at-risk populations in developing countries will have access to health technologies developed for HIV/AIDS, TB, malaria, and other neglected diseases. Measures that accelerate such technologies should be structured so as to support future access by these populations, including through their impact on pricing, intellectual property, and other facets of product distribution.
- Provisions to ensure needed accountability. Any measures enacted should provide for accountability in the use of financial resources (including the establishment of appropriate benchmarks and guidelines in a monitoring system), but should avoid unnecessary bureaucratic hurdles that might

interfere with needed progress on the development of health technologies.

- Increasing scientific collaboration and innovation. Measures to accelerate technologies focused on HIV/AIDS, TB and malaria and other neglected diseases should enhance opportunities for scientific collaboration and innovation. Such measures should seek creative means to resolve any financial, legal or regulatory barriers to collaborative and innovative efforts.
- Recognition of vital role and contributions of all R&D entities. While we believe that encouraging greater private sector investment is of paramount importance, this in no way diminishes the important role of universities and public sector research institutions. We also support significant resources and increased flexibility for public research institutions involved in R&D for prevention technologies, including the NIH, CDC, and FDA. At the same time, we note that public-private partnerships, especially those focused on product development, can play a critical part in both building bridges between public and private sectors, and demonstrating how innovative approaches in both financing and organizational paradigms can support the accelerated development of new preventive technologies and global health solutions.

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BIO Ventures for Global Health
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