Product Development Public-Private Partnerships (PDPs):

A Driving Force for New Vaccines and Drugs

Background

While the average life expectancy in high-income countries is nearly 80 years, a child born in one of the world's least-developed countries can barely expect to reach age 50. A handful of communicable diseases, most of which are either non-existent or minimally present in the developed world, are responsible for much of the health gap between rich and poor.

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Existing private sector-driven research has not proven to work well in stimulating the discovery of the vaccines, microbicides, drugs, and diagnostics needed to fight neglected global infectious diseases. Thus, the international community has launched an innovative mechanism, product development public-private partnerships (PDPs), to develop urgently needed new health products.

The Problem

The crucial need for new health tools is plainly apparent for the world's three leading infectious killers, which together account for more than five million deaths annually:

- *HIV:* While a range of prevention tools currently exist—such as male and female condoms, harm reduction for injecting drug users, and antiretroviral prophylaxis for mother-to-child transmission—none is 100% effective or reaches more than a small fraction of those needing protection. Women lack a prevention method designed for their use and control.
- *Tuberculosis (TB):* The screening technology used to diagnose TB remains unchanged since its development more than a century ago, no new class of TB drugs has emerged since the 1960s, and the existing vaccine for TB has limited efficacy.
- *Malaria:* No vaccine exists for malaria, which kills a child every three minutes. Throughout much of Africa, resistance to the least expensive malaria medications has become widespread, while bed nets are insufficiently used and pose the challenge of requiring periodic re-treatment with insecticide to remain effective.

The well-established relationship between public and private sectors to promote the development of vaccines and drugs for affluent markets has yielded many new products in recent decades. Public sector agencies such as the US National Institutes of Health, the Medical Research Council in Britain, and the Agence Nationale de Recherche sur le Sida in France finance basic research and early discoveries that private phar-

maceutical and biotechnology companies then translate into new vaccines or drugs, through testing, manufacturing, and marketing.

This relationship has not worked well for the diseases of the poor. It has been difficult to convince the private sector to invest in medicines for neglected illnesses—traditionally high-volume products that provide relatively low returns on investment. Of the 1,123 drugs that reached the global market between 1975 and 1997, only 13 were developed to combat tropical diseases that primarily affect poor countries. In the area of AIDS vaccine research and development (R&D), pharmaceutical and biotechnology companies contribute less than 10% of current investment.[1]

A New Approach

PDPs have formed over the past decade to unite the public sector's commitment to international public goods for health with private industry's business discipline and expertise in product development and marketing. These not-for-profit organizations bridge public- and private-sector interests, with a view toward resolving the specific incentive and financial barriers to increased industry investment in the development of safe and effective products.

Within its own specific product niche—i.e., AIDS vaccine, malaria vaccine, TB diagnostics, etc.—each PDP manages a portfolio of product candidates. By rapidly advancing promising approaches, the PDPs help to expand the product pipeline. Through advocacy, they also strive to attract substantial new funding for research on diseases primarily affecting poor countries.

In a short period of time, PDPs have dramatically strengthened global efforts to create critical new health tools. A recent study of a group of PDPs dedicated to new drugs found that "they now manage three-quarters (47) of all identified neglected disease drug development projects. Nearly one-third of these projects (13) are at the clinical trial stage, including six drugs now in Phase III trials. Another two products are in the registration stage. Based on standard attrition rates, this combined portfolio would be expected to yield six to seven new neglected disease drugs within five years."[2]

By modeling new ways of working, the PDPs are helping to drive change in both public and private sectors. Governments are contributing more funds for neglected disease R&D and industry is also becoming more active. Over the past five years, for example, four of the 12 largest multinational pharmaceutical companies have established infectious disease divisions.

The International AIDS Vaccine Initiative (IAVI) has been at the forefront of the PDP movement, driving positive change in the search for a vaccine to stop the AIDS pandemic and overall efforts to find solutions to the world's most pressing health challenges (see box below).

IAVI: the First Product Development Public-Private Partnership

With the global AIDS epidemic growing more severe and little progress apparent in the search for an AIDS vaccine, the Rockefeller Foundation convened an international meeting in Bellagio, Italy in 1994 to discuss strategies to invigorate AIDS vaccine research and development. The leading scientists, public health officials, industry representatives, and non-governmental organizations in attendance agreed that an innovative new mechanism was needed to catalyze the vaccine field. The result was the launch in 1996 of the International AIDS Vaccine Initiative, the world's first biomedical product development public-private partnership.

In its first 10 years, IAVI developed six new vaccine products, established major new clinical trial capacity in Africa and Asia, mobilized more than $460 million in new funding for vaccine research, significantly increased awareness of and commitment to vaccines through its advocacy and communications initiatives, and established itself as a leading center for the global AIDS vaccine effort. Since its creation, IAVI has been used as a model for the creation of numerous other PDPs focusing on other needed health tools, such as malaria and TB vaccines and drugs, and microbicides for the prevention of HIV and other sexually-transmitted infections.

The International AIDS Vaccine Initiative (IAVI) is a global not-for-profit organization whose mission is to ensure the development of safe, effective, accessible, preventive HIV vaccines for use throughout the world. Founded in 1996 and operational in 23 countries, IAVI and its network of collaborators research and develop vaccine candidates. IAVI's financial and in-kind supporters include the Alfred P. Sloan Foundation, the Bill & Melinda Gates Foundation, The New York Community Trust, The Rockefeller Foundation, and The Starr Foundation; the Governments of the Basque Country, Canada, Denmark, European Union, Ireland, The Netherlands, Norway, Sweden, United Kingdom, and the United States; multilateral organizations such as The World Bank; corporate donors including BD (Becton, Dickinson & Co.), Continental Airlines, DHL, Merck & Co. Inc., and Pfizer Inc.; leading AIDS charities such as Broadway Cares/Equity Fights AIDS, Crusaid, Deutsche AIDS-Stiftung, and Until There's A Cure Foundation; other private donors such as the Haas Charitable Trusts; and many generous individuals from around the world. For more information, see www.iavi.org.

[1]HIV Vaccines and Microbicides Resource Tracking Working Group, Adding It All Up: Funding for HIV Vaccine and Microbicide Development, 2000-2006 (New York: IAVI, August 2006).

[2]Moran M., Ropars A., Guzman J., Diaz J., and Garrison C., *The New Landscape of Neglected Disease Drug Development* (London: Pharmaceutical R&D Policy Project, September 2005).

Imagine a world without AIDS

IAVI–Headquarters
110 William Street
New York, NY 10038
United States

IAVI–East Africa
Floor 16, Rahmutulla Tower, Upperhill Road
PO Box 340 KNH 00202, Nairobi
Kenya

IAVI–Southern Africa
6 Albury Park, Unit 006
Magalieszicht Ave, Dunkeld West 2196
South Africa

IAVI–Europe
Herengracht 206-216
1016 BS Amsterdam
The Netherlands

IAVI–India
193 Floor 1, Jor Bagh
New Delhi, 110003
India

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