
OPINION PIECE

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Biotechnology: The underutilised tool in the fight for global health and security

Abstract

Biotechnology companies can contribute to developing new treatments for diseases of the developing world without losing money or converting to charity.

A small but growing number of biotechnology companies are taking on the infectious disease epidemics of the developing world (commonly referred to as *neglected diseases*). They are doing it without losing money or converting to charity. Along with international health and aid initiatives, they are tackling some of the most urgent global health problems of our time. More help is needed and more can be done.

The statistics are staggering. The 10–14 million people who die each year of infectious diseases reside in the developing world. This year there will be 300–500 million clinical cases of malaria, which will result in 1–2 million deaths (90 per cent of victims will be children in sub-Saharan Africa). An additional 2 million people will fall victim to tuberculosis. About 40 million people are currently infected with HIV. Diseases such as leishmaniasis, Chagas disease and African sleeping sickness threaten millions of additional lives.

Biotechnology offers one of the best hopes for developing desperately needed vaccines and drugs. However, it has been estimated that only 1 per cent of new drugs launched between 1975 and 1997 was approved specifically for neglected diseases. Critical brainpower and technology reside in the companies of the developed world, where market-driven economies make the following scenarios all too common:

- A malaria vaccine candidate sits on a shelf because a company cannot afford

to invest in what is perceived as a relatively unprofitable disease. Instead, funds are directed towards cancer and diabetes.

- A molecular biologist at a university discovers a drug target for leishmaniasis but she abandons the project when she cannot get funding or the necessary support to do product development work. A biotechnology or pharmaceutical company's compound library would yield hits if she had access to it.

Given that a vaccine or drug for a neglected disease will never be as profitable as the next blockbuster for depression or Alzheimer's, how can companies be enticed to get to work?

In the late 1990s a number of public private partnerships (PPPs) were established to test one possible model. Examples such as the International AIDS Vaccine Initiative (IAVI), Medicines for Malaria Venture (MMV), Malaria Vaccine Initiative (MVI) and Global Alliance for TB Drug Development (GATB) were founded and continue to be supported by groups such as the World Health Organization, the Rockefeller Foundation and a new champion of international health, Bill Gates. The common mandate of each PPP is to tackle a specific neglected disease through the development of new and improved treatments or vaccines. This is to be achieved by funding and managing R&D projects that involve companies with cutting edge biomedical technology

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and know-how. In return for their investment, PPPs retain the right to distribute any resulting product at an affordable price in the developing world. Partners retain sales and marketing rights for developed world markets as well as full rights to any other disease applications of their technology.

To date the PPPs have partnered with numerous biotechnology companies in addition to academics and pharmaceutical companies. Some projects involve licensing unwanted compounds to PPPs. Others involve PPPs funding companies to apply their technologies to a neglected disease. Table 1 provides a summary of some prominent deals.

Meanwhile, other models for product development initiatives are under consideration. The Biotechnology Foundation (BTF) at the Institute for Global Health is developing a full range of services to provide to companies seeking to participate in neglected diseases. In March 2002 Médecins sans Frontières (MSF; Doctors without Borders), the humanitarian medical relief organisation that was awarded the Nobel Peace Prize in 1999, announced the formation of the Drugs for Neglected Diseases Initiative

(DNDi). The initiative will lay the groundwork for MSF establishing a public pharmaceutical company to develop drugs for leishmaniasis, tripanosomiasis, schistosomiasis and Chagas disease.

However, *product development* – while critical – is only *one part* of the solution. As new drugs and vaccines are approved for human use, endemic countries must develop the infrastructure and trained personnel to use them effectively. A recent evaluation of the Global Alliance for Vaccines and Immunization (GAVI) reveals that immunisation programmes in certain African countries for diseases such as hepatitis B (for which a vaccine exists) are still hampered by lack of proper refrigerators, insufficient fuel and transport, low staffing levels and infrequent supervision. This has led to a call for increased accountability from local governments that are not properly funding and maintaining national health systems. (In April, Nelson Mandela, speaking at a conference on childhood immunisations, told a gathering of health and finance ministers from developing nations, 'If we do not make saving children's lives a priority in our own countries, it will be more difficult to ask

Table 1

PPP	Partner	Project
Global Alliance for TB Drug Development	Chiron	Chiron licensed out PA824. GATB will proceed with pre-clinical and clinical development.
Institute for One World Health	Celera	Celera licensed out CRA-3316 for Chagas disease. IOWH will leverage a network of non-profit and government resources to get the drug to market.
International AIDS Vaccine Initiative	AlphaVax	IAVI funds AlphaVax to apply its ArV™ delivery technology to an antigen identified at the University of Capetown.
International AIDS Vaccine Initiative	Maxygen	Design a vaccine antigen using Maxygen's MolecularBreeding™ technology to protect against all strains and mutations of the HIV virus.
International AIDS Vaccine Initiative	Targeted Genetics	Apply Targeted Genetic's AAV gene therapy technology to a vaccine based on the HIV subtypes most prevalent in Eastern and Southern Africa.
Medicines for Malaria Venture	Dr Phil Rosenthal at University of California, San Francisco & GlaxoSmithKline	GSK will structurally modify a class of compounds called falcipain inhibitors and apply them to the drug target identified by Rosenthal.

the industrialised world to take on that responsibility.’)

International health and aid organisations recognise that capacity building must be made a priority along with the procurement of products and technologies. Last year UN Secretary-General Kofi Annan and Gro Harlem Brundtland, Director-General of the WHO, established the Global Fund to Fight AIDS, Tuberculosis and Malaria (Global ATM fund). One of its main objectives is to ‘support the substantial scaling up and increased coverage of proven and effective interventions, which strengthen systems for working within the health sector and across government departments.’

While these are critical steps, much work remains to be done. No PPP deal has proceeded past Phase II clinical trials. Given that only 10–15 per cent of drug and vaccine candidates succeed (in any disease), many more R&D projects for

neglected diseases will be needed to achieve the goal of effective and affordable new products. The UN and WHO requested US\$10bn dollars from the international community to support the Global ATM fund. So far only US\$2bn has been committed.

The bio-terrorism threat of 2001 showed that in domestic emergencies private industry will put other considerations aside to focus on public security. With emergency public funds coming in, pharmaceutical and biotechnology companies were able to supply government laboratories with bio-defence agents (that many had not even realised they owned) along with personnel and expertise. Speaking shortly after 11th September, Peter Piot, executive director of UNAIDS, stressed that ‘AIDS is a massive attack on global human security’. Biotechnology may be our greatest defence. The question is, who is willing to go to war?