Global health needs to fill the innovation gap

Trevor Mundel

In recent years, the pharmaceutical industry has struggled to deliver new therapies, especially for diseases that affect the most vulnerable in developing countries. The global health community can fill this vacuum by catalyzing innovative partnerships across academia, government and the private sector, fostering a more rigorous environment for scientific decision making and creating the tools and infrastructure to conduct effective translational research.

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Within the next generation, we may see the unholy trinity of global disease neutralized. In this future scenario, all people have access to safe vaccines for HIV and malaria and easy-to-use point-of-care diagnostics coupled with effective short-duration therapies for tuberculosis. Biomedicine has the potential to deliver a portfolio of innovative interventions of this ilk. The catalyst, however, is likely to come from the global health community, given that pharmaceutical companies are largely focused on developing lucrative therapies for diseases affecting people in developed nations.

Global health organizations, including the Bill & Melinda Gates Foundation, are uniquely positioned to move beyond the traditional research and development (R&D) model. As one example, in January the foundation helped facilitate an unusual alliance among 13 pharmaceutical companies, several governments and other organizations to accelerate research, development and delivery of drugs for ten neglected tropical diseases. More than a billion people worldwide suffer from at least one of these score of ailments, which include river blindness (onchocerciasis) and sleeping sickness (trypanosomiasis).

One aspect of the coalition centers on innovative licensing or collaboration agreements with 11 of the 13 pharmaceutical companies—enabling the sharing of compounds and knowledge that will lead to new drugs. Within this framework, the Geneva-based Drugs for Neglected Diseases initiative is coordinating one product development partnership—with Abbott, Johnson & Johnson and Pfizer—to develop flubendazole, a new drug to treat river blindness and lymphatic filariasis. Abbott conducted the initial drug reformulation studies and provided scientific expertise for early-stage preclinical development. Johnson & Johnson has agreed to provide drug supply as well funding and scientific expertise for the final reformulation and preclinical work. If preclinical development is successful, Johnson & Johnson will co-fund the clinical trials and collaborate with other partners; for example, Pfizer's staff scientists will provide technical support. This partnership is unlike any that has been created in the drug development space before.

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More recently, in June, we joined with seven pharmaceutical companies and four US research institutions in another groundbreaking partnership—the TB Drug Accelerator (TBDA). The aim of the TBDA is to speed up early-stage research leading to a new tuberculosis drug regimen that radically shortens the current course of treatment. This is urgently needed and long overdue. Tuberculosis is the second leading infectious cause of death. In 2011, it killed 1.4 million people; virtually all of these victims were in low- and middle-income countries.

Existing tuberculosis drugs are decades old, and the current drug regimen requires a six-month course of treatment. As a result, the patient dropout rate is high, leading to increased mortality, TB drug resistance and spread of infection. The TBDA aims to develop five new preclinical drug candidates within five years and proof of concept for a one-month, three-drug regimen within a decade.

Even the best scientists, however, would be hampered by the conventional requirements that new tuberculosis drugs be evaluated separately in clinical trials and tested in combination only after they individually receive market approval. To address this obstacle, the Critical Path to TB Drug Regimens (CPTR) Initiative was created several years ago. This consortium brings together US and other regulatory authorities, pharmaceutical companies, public health experts and others.

The goal is to reduce the time it takes to introduce new combination tuberculosis treatments from as long as a quarter-century to as few as six years. The CPTR encourages innovative matchups of pharmaceutical companies, including testing promising combinations of individual tuberculosis drug candidates from different companies early in the development pipeline.

The approval process for MenAfriVac, a vaccine developed to protect against meningococcal meningitis, is a model of such efficiency. Repeated epidemics across Africa's 'meningitis belt' created an urgency for large-scale introduction of the vaccine. In early 2010, following a review supported by Health Canada, the Drugs Controller General of India authorized the vaccine for export and use. Just three months later, the World Health Organization gave its stamp of approval—something that often takes a year or longer.

Equity investments in biopharmaceutical startups are another way global health is seeking to move beyond the traditional model of drug development. In September, the Gates Foundation announced an investment in Atreca, a California-based startup with a technology that may form a broad platform for the discovery and development of antibody-based vaccines, therapeutics and diagnostics. Initially, Atreca will focus initially on three diseases—tuberculosis, HIV and malaria—that disproportionately affect people in the developing world. We also recently announced an equity investment in Genocea Biosciences, a Massachusetts-based biotech that is working on technology to quickly identify T cell antigens that induce broader and more powerful immune responses than existing vaccine antigens. Particularly promising is an early-stage candidate for an affordable pneumococcal vaccine that provides broad coverage against bacterial strains.

Creating and delivering vaccines and drugs for the developing world demands new approaches to discovery, development and the regulatory infrastructure. No single organization alone can accomplish this. Indeed, the Gates Foundation's investment in global health is a small fraction of what pharmaceutical companies invest in R&D. But what we lack in financial resources, we hope to make up for with curiosity unburdened by financial motive, a willingness to take risks, and the capacity to catalyze, convene and advocate on behalf of those who cannot yet do so for themselves on a scale that has never been tested before.

Trevor Mundel is president of the Global Health Program at the Bill & Melinda Gates Foundation in Seattle, Washington. Previously, he was global head of development for Novartis in Basel, Switzerland.