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The authors are available for advance interviews. The full study, to be published by Health Affairs Nov. 3, is available for media preview on request (contact: Sue Ducat, +1-301-841-9962, sducat@projecthope.org).

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Study Shows Developing Country Firms are Major New Pipeline of Products to Fight “Neglected” Diseases of the Poor

*Experts propose “Global Health Accelerator”
to help new drugs, diagnostics, vaccines reach the poor*

Research firms in developing countries have a medicine cabinet full of affordable and innovative drugs, diagnostics and vaccines on shelves or in development to address “neglected tropical diseases” but need help to get such products to more potential users.

Canadian research, published today by the journal *Health Affairs* (“*A Business Plan To Help The ‘Global South’ In Its Fight Against Neglected Diseases*”), says roughly 1 billion people worldwide are killed or sickened by “neglected tropical diseases” (NTDs). More than 30 such diseases, caused by worms, protozoa, bacteria, fungi or viruses, afflict the poorest people in the poorest countries, and collectively cause a health burden comparable to malaria, tuberculosis or AIDS (known as the “Big 3” tropical diseases).

The McLaughlin Rotman Centre for Global Health study notes earlier research that, of 1,556 new drugs approved between 1975-2004, only 21 (1.3%) targeted NTDs. That represents “a public health failure,” authors say, given that NTDs affect roughly 15% of humanity.

The authors go on to profile for the first time the products and capabilities of 78 homegrown, small to medium-sized health biotechnology companies in Brazil, China, India and South Africa.

They found such firms collectively produced 123 products (such as vaccines, drugs, and diagnostic tests) for all “neglected” diseases, including the "Big 3" (malaria, tuberculosis or AIDS). Of these 123 products:

- * 69 were already on the market with 54 more in development; and
- * Roughly half (62) specifically target NTDs (the term NTD excludes the "Big 3"), with 28 products on the market and 34 in development.

“The NTD-related product pipeline in developing countries is like a rich new deposit of gold that needs to be fully mined,” says MRC Director and co-author Peter A. Singer, MD. “Companies in emerging economies are filling a void by creating innovative products to address NTDs. Many such firms are successful at reaching local and regional markets. What they urgently require is help getting these products and their benefits to distant places.”

The study is the first ever to detail the developing country pipeline of new products against neglected tropical diseases based on a survey of firms in emerging economies.

Drug donations by multinational firms, as generous as they are, just don’t go far enough and “we need to build upon them,” says Dr. Singer.

“We are not calling for replacement of the charity of multinationals. Rather, we are pointing out that there is a well of affordable innovation in developing countries themselves that has not been fully tapped. Governments and foundations can help by making sure home-grown biotechnology products developed by firms in emerging economy countries reach additional markets where they are needed.”

NTDs include trachoma, the leading cause of preventable blindness worldwide, elephantiasis, leprosy, dengue fever, hookworm infection and schistosomiasis. World spending to battle such illnesses, however, amounts to a relative drop in the bucket -- just \$500 million in 2007 – or about 5% of the total invested in new drugs, vaccines and diagnostics worldwide.

According to MRC researcher and co-author Sarah Frew, firms in emerging economies see neglected diseases as significant business opportunities but typically lack expertise in

such areas as international regulatory environments, market assessments, positioning products including pricing, accessing financing, and identifying international commercialization partners.

Says Dr. Frew: "The R&D potential of the South is far greater than the 78 firms documented in the study. There are more than 500 health biotechnology companies, in addition to many more academic institutes and universities in other countries like Malaysia, Indonesia and Mexico. The creative talent is there but obstacles, of which financing is just one, impede progress and hamstring current efforts."

"Neglected tropical illnesses rarely make headlines but they cripple the economic productivity of affected communities and stunt national development."

"Without proper drugs, vaccines and diagnostics for sleeping sickness, intestinal parasites, elephantiasis and other tropical diseases, an enormous percentage of the world's people will remain trapped in poverty."

Innovative NTDs-related products in the South:

* Shanghai United Cell Biotechnology Co. Ltd. (Shanghai, China) manufactures a novel oral cholera vaccine, as does Shantha Biotechnics (Hyderabad, India), whose product provides longer, broader protection at a third of the local price of Dukoral, the only other vaccine on the Indian market;

* Indian Immunologicals created the Abhay Clinic model to deliver affordable and safe vaccines for rabies to patients in semi-urban and rural areas India. A network of local general practitioners and pediatricians provide affordable initial and follow-up vaccination and wound care at a price determined by the company. In turn, Indian Immunologicals equips the clinics with refrigerators and ensures delivery of the rabies vaccine from its manufacturing depots;

*FK Biotecnologia (Porto Alegre, Brazil) is developing point of care diagnostic testing platforms for Chagas' disease, dengue fever, leptospirosis, and syphilis, and is developing tests for schistosomiasis and treponematoses;

* Vision Biotech (Cape Town, South Africa) is developing rapid diagnostic test platforms for African trypanosomiasis, schistosomiasis, and dengue fever;

* Bhat Biotech (Bangalore, India), sells an immunoassay-based rapid test for leishmaniasis and is developing a diagnostic kit for leprosy;

*Hebron Farmacêutica Ltd. (Recife, Brazil) is selling Giamebil®, an extract from the plant *Mentha crispa* (small leaf mint) that has anti-giardia and amoebicidal properties;

* Silvestre Labs (Rio de Janeiro, Brazil) offers Dermacerium (a formulation of cerium nitrate and silver sulfadiazine), a topical anti-microbial agent to prevent and treat skin wound infections, including those from leprosy;

* Lifecare Innovations (Gurgaon, India) offers two treatments for leishmaniasis.

“Global Health Accelerator”

The authors propose a not-for-profit service to provide much-needed expertise to help Southern firms get their products from the lab to additional villages worldwide.

The “Global Health Accelerator” (GHA), would help get innovative NTD-related health products to distant markets by connecting a diverse international community of biotech innovators, facilitate public-private partnerships, provide business support services, and operate as an independent hub linking companies, investors, and interested parties.

The proposal also includes an annual prize, the ‘Global Health EnterPrize,’ to encourage and recognize new diagnostics, drugs, vaccines, or devices with global health impact developed by Southern companies.

“We think of the Global Health Accelerator as a FedEx for new drugs, vaccines and diagnostics to combat neglected tropical diseases. It will use the power of networking to link to funding agencies, foundations, development finance institutions, private individuals, and venture capitalists interested in financing innovative Southern companies,” says Dr. Singer.

“Currently there is no efficient global showcase of potential Southern R&D investments for venture capitalists to consider. The GHA could easily fill that role, a vehicle to harness the skills and talents of small and medium sized companies in the South.”

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The **McLaughlin-Rotman Centre for Global Health**, is based at the University Health Network and the University of Toronto. Working at the nexus of science, entrepreneurship, and the developing world, the Centre conducts translational research on malaria, on ethics and on commercialization in global health to help researchers and companies get life sciences technologies (such as diagnostics, drugs, and vaccines) to those who need them in developing countries. For more information: www.mrcglobal.org.