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Fighting the World's Most Devastating Diseases: A Plan for Action

Tuberculosis (TB), malaria, and HIV/AIDS have much in common with neglected tropical diseases—infectious diseases found mainly in low-income tropical and subtropical regions, such as African sleeping sickness, Chagas disease, and leishmaniasis: They all cause millions of deaths worldwide every year. They make millions more seriously ill. They significantly reduce economic growth. They fracture political stability. And they disproportionately affect people in developing countries.

New medical interventions are desperately needed for each of these diseases, from diagnostics and treatments to vaccines and other preventive measures. Yet research on these diseases is severely underfunded.[1] (See "Researching Infectious Diseases That Disproportionately Affect Low-Income Nations" on page 7.)

To make progress in, and ultimately win, the fight against these deadly diseases, we must dramatically expand our research investment.

The Fight against the World's Most Devastating Diseases Is Grossly Underfunded

A few facts vividly tell the story of how research spending has overlooked some of the world's most devastating diseases, which are far more common in developing countries:

- Between 1975 and 2004, 1,556 new drugs were introduced to the market. Of those, 179 were for cardiovascular disease, and only 21 were for TB and neglected tropical diseases, which affect roughly the same number of people as cardiovascular disease.[2]
- This stark difference can be attributed to the fact that innovation follows "market potential"—potential profits. Cardiovascular disease is common in developed countries—it is a "First World" disease with a global drug market of $70 billion.[3] TB, in contrast, is a disease largely of the developing world. The global market for first-line TB drugs is a comparatively small $315 million.[4] The funding situation is even more dire for neglected tropical diseases, which primarily affect regions where there is virtually no commercial market.[5]

- The current vaccine to prevent TB was introduced in 1923—84 years ago. Over time, its effectiveness has greatly diminished, especially in adults. Research on new vaccines is underway, but more funding is needed to continue this work.
- Malaria, TB, diarrheal diseases, and pneumonia account for 21 percent of all human illness worldwide, yet they receive just 0.31 percent of all public and private funds devoted to health research.[6]
- Collectively, neglected tropical diseases affect one in six people worldwide and kill more than 500,000 people every year.[7] These diseases receive only $1 out of every $100,000 spent worldwide on biomedical research and product development (R&D).[8]

Spending on research for diseases that primarily affect developing countries is meager compared to their impact. Increased medical research and the resulting improvements can dramatically reduce the toll these diseases take.[9]

Why the Lack of Funding?

Governments fund much of the early-stage research that is the foundation of scientific discoveries. Industry finances much of the later-stage research, such as clinical trials, that is necessary to translate discoveries into medical interventions (such as vaccines) that can be used. However, when it comes to diseases of the developing world, industry invests comparatively little.

Pharmaceutical companies focus their research and development (R&D) spending on the most profitable markets: chronic diseases that are prevalent in developed countries.[10] This isn't surprising, given that the financial return from products that target those diseases can be substantial: Revenue from each of the top-selling prescription drugs exceeded $2.5 billion in 2001.[11] Each of these top-selling drugs targeted a chronic disease, such as heart disease, that is common in developed, wealthy countries.

The global market for all drugs used to treat TB was estimated at between $412.5 and $470.5 million in 2000.[12] In contrast, global sales for Lipitor, a cholesterol-lowering drug with a large, wealthy market, totaled $7 billion in 2001.[13] And Prilosec, an acid reflux medicine, had sales of $6.1 billion—15 times greater than sales of the entire line of anti-TB drugs.[14]

Unfortunately, the commercial market structure that has driven the development of medical advances for diseases that are more common in developed countries—cancer, heart disease, and diabetes—has failed when it comes to diseases of the developing world.

Fixing the Problem

When commercial markets fail to address a need, governments often step in. There are many examples of this in the U.S., such as government subsidies for the construction of public housing and government assistance with developing rural power sources.

Because pharmaceutical company research on diseases of the developing world has lagged far behind what is needed, wealthy nations' governments need to step in. Unfortunately, these governments have not yet provided adequate funding to fill the gap left by industry's minimal interest in developing new products.[15] Wealthy, developed countries have failed in large part because these diseases are easy to ignore unless they become a stark, personal reality for policymakers' constituents. Thus, the approach of many policymakers in developed countries has been to wait and see if a disease that is a problem "over there" becomes a problem here.

The public outcry created by the recent trans-Atlantic flights of a man with drug-resistant TB underscores the flaw in this reactionary approach: The public wants action, not just reaction, when it comes to protecting their health. With greater global mobility, diseases that we thought were gone can suddenly become very real problems here. We cannot wait for these problems to arise—more needs to be done right now.

The National Institutes of Health: The Foundation for Government Action

The U.S. National Institutes of Health (NIH) is one of the world's leading biomedical research agencies. Through NIH, America has the capacity to advance research and move forward medical discoveries that target the world's neglected infectious diseases.

NIH already funds research on TB, malaria, HIV/AIDS, and neglected tropical diseases, but the level of funding does not begin to match the massive impact of these diseases:

- In 2006, NIH devoted less than one-half of one percent of its research budget—only $98 million—to funding malaria research.[16]
- Funding for TB research was similarly meager, at $150 million, or one half of one percent of NIH's budget.[17]
- NIH devoted only 2.5 percent of its 2006 budget to research on an AIDS vaccine and microbicides to prevent HIV transmission.[18] Development of those types of interventions is essential to curtailing the spread of HIV in Africa and Asia.
- The agency does not even list the amount spent on African sleeping sickness, Chagas disease, leishmaniasis, and numerous other neglected tropical diseases.

One way to bolster research efforts is to increase funding for NIH's National Institute of Allergy and Infectious Diseases (NIAID) and the Fogarty International Center (FIC).[19] NIAID takes the lead in researching infectious diseases that are relevant to global health. The Fogarty International Center takes the lead in building domestic and international capacity to conduct global health research, including research that moves discoveries into practice in developing nations.

Adequate funding for NIH's research on infectious diseases of global importance—including research to move discoveries into practice—is essential if we are to make advances against these diseases.

How Much More Is Needed?

The leading global health agencies, research organizations, and advocacy groups have estimated the total amount needed to adequately fund research on infectious diseases that have been neglected by industry and government. There are estimates of the need for research on treatments, diagnostics, and vaccines for malaria and TB; research on HIV/AIDS vaccines and preventive microbicides; and research on neglected tropical diseases.

Working from those estimates, Families USA determined the additional amount of research spending needed by NIAID to effectively combat the devastating diseases that disproportionately affect developing nations. We provide an explanation of our methodology on page 5. Our analysis shows that NIAID's research in these areas is significantly underfunded. The institute's investment in TB, malaria, neglected tropical diseases, and AIDS vaccine and microbicide research falls $5.214 billion short of what's needed for NIAID to meet its share of global research spending. What NIAID needs is a 20.4 percent increase above its fiscal year (FY) 2007 budget.

The Fogarty International Center is similarly underfunded. Fogarty provides critical support to build research capacity in developing countries and to make sure that new interventions will be adopted once they are available. Fogarty's work is essential to furthering the creation and use of new interventions in developing countries, yet it is the smallest of NIH's 27 institutes and centers. This testifies to the fact that global health has been undervalued. Funding for Fogarty should be increased by about the same as funding for NIAID: A 20.4 percent increase above its FY 2007 funding level would bring Fogarty's budget up to $80.0 million.

Methodology: Estimating the Funding Shortfall

To determine what NIH and, particularly, what NIAID should be spending on research on TB, malaria, HIV/AIDS, and neglected tropical diseases, Families USA first looked at what leading groups consider the amount that should be spent on research for specific diseases and interventions worldwide. The sources we used included the following:

Sources for Recommendations on Research Spending

Disease	Sources for Spending Recommendation
HIV/AIDS Vaccine and Microbicides	The AIDS Vaccine Advocacy Coalition, the Alliance for Microbicide Development, the International AIDS Vaccine Initiative, Joint United Nations Programme on HIV/AIDS (UNAIDS)
Malaria Diagnostics, Treatments, and Vaccines	The Roll Back Malaria Partnership, an organization made up of international partners including the UN, the World Bank, the World Health Organization, governments, corporations, NGOs, foundations, and universities
TB Diagnostics, Treatments, and Vaccines	The Stop TB Partnership, an organization made up of nearly 600 partners worldwide, including NGOs, professional associations, foundations, corporations, governments, and universities
Neglected Tropical Diseases Diagnostics, Treatments, and Vaccines	Global Network for Neglected Tropical Disease Control, a partnership of NGOs and research institutes working in collaboration with international aid organizations and industry

From these sources, Families USA determined the current percentage of global spending in each research area that is supported by NIH and NIAID. In estimating funding needs for NIH/NIAID, we assumed that the percentage of global spending that is supported by NIH and NIAID is appropriate and would remain unchanged. To determine what would be an appropriate spending level for NIAID, we applied NIAID's current percent of global spending to estimated worldwide research funding needs, as indicated below.

Estimating NIAID Funding Needs

Amount needed, worldwide, to adequately fund TB, malaria, HIV/AIDS, and neglected infectious disease research **X** **NIAID's current percent** of worldwide research spending **=** **Funding needed by NIAID** to make significant medical progress

NIH's Share of Global Health Research Spending

For these diseases, the estimate of the share of total global research spending that is supported by the NIH ranged from 35 percent to 64 percent. NIAID alone accounts for between 25 and 51 percent of total global research spending. These are high percentages, but they are not high compared to NIH's share of global research spending in other areas.

As the world's leading biomedical research institute, NIH funds a large share of world research in many clinical areas. For cancer research, studies show that NIH's National Cancer Institute funds approximately 80 percent of worldwide government-sponsored research. For Alzheimer's disease research, NIH's share is 88 percent. For diabetes research, NIH's share is about 93 percent.[20] For neglected tropical diseases, where governments are covering the bulk of research costs, our suggested NIH spending as a percent of the worldwide total is consistent with, if not lower than, the percent of government funding it comprises in other areas.

Next Step: Getting Policymakers to Correct the Shortfall

Considering federal budget constraints, it is unlikely that government funding for NIAID or the Fogarty International Center will be increased by 20 percent. However, small and consistent increases, with the goal of expanding funding for research on neglected infectious diseases that have a high global burden, could make significant progress in addressing the longstanding shortfalls. If the budgets for NIAID and the Fogarty International Center were increased by just 2.9 percent, plus inflation, each year for the next seven years, funding would reach the target level.

While seven years may seem like a long time, spending on research for global health has been neglected for much longer. An additional 2.9 percent increase for NIAID and the Fogarty International Center is a small amount to spend to begin addressing massive global health problems. With this investment, we will make progress toward

- the development of new TB drugs;
- a new, effective TB vaccine;
- powerful new malaria medicines;
- a malaria vaccine;
- treatments, preventives, and diagnostics for neglected tropical diseases that affect millions; and
- an AIDS vaccine.

We would also substantially improve the lives of billions of people worldwide.

Researching Infectious Diseases That Disproportionately Affect Low-Income Nations

Infectious disease research includes a wide spectrum of activities that are needed to discover a potential drug compound, known as a "lead," and develop it into a product that is safe, effective, and approved for use. This process begins with what's called "basic research," which provides insight into the disease, its causes, and ways to affect disease progression. It continues to the discovery of a product lead, then to testing on animals and in people to make sure that the product is safe and effective. Research continues even after a product is approved and in use, to evaluate how it works in the "real world" and in the general population (as opposed to carefully controlled clinical studies), and to confirm its long-term safety and effectiveness.

In addition, research on infectious diseases that affect low-income nations must ensure that medical interventions are appropriate for use in particular settings where transportation and storage are often issues. Research must also be performed to ensure that the product will be accepted and actually used by the intended populations.

Infectious disease research can be successful only if the capacity exists to conduct it in countries where diseases have a high burden. Laboratories and necessary equipment must be available; scientists and other experts must be appropriately educated, trained, and available in the geographic areas where the research will be performed; and potential study subjects must be educated about how the research will affect them.

Endnotes

[1] Families USA, *Investing in Global Health Research: Malaria* (Washington: Families USA, April 2007); Families USA, *Investing in Global Health Research: Tuberculosis* (Washington, Families USA, February 2007); Families USA, *Investing in Global Health Research: Neglected Tropical Diseases* (Washington: Families USA, January 2007); Families USA, *Investing in Global Health Research: HIV/AIDS* (Washington: Families USA, January 2007), all available online at http://www.familiesusa.org/issues/global-health/publications/.

[2] Families USA, *Investing in Global Health Research: The Government Should Play a Larger Role* (Washington: Families USA, February 2007), available online at http://www.familiesusa.org/issues/global-health/government-funding.PDF.

[3] Research and Markets, *Cardiovascular Disease: Current Research, Devices and Drugs* (Dublin, Ireland: Drug and Market Development Publishing, 2004), available online at http://www.researchandmarkets.com/reportinfo.asp?report_id=227903&t=d&cat_id=.

[4] The TB Alliance, *Pathways to Patients: Charting the Dynamics of the Global TB Drug Market* (New York: The TB Alliance, 2007), available online at http://www.tballiance.org/downloads/publications/Pathway_to_Patients_Overview_FINAL.pdf.

[5] Hotez et al, "Control of Neglected Tropical Diseases," *New England Journal of Medicine* 357, no. 10 (2007): 1,018-1,027, available online at http://content.nejm.org/cgi/reprint/357/10/1018.pdf.

[6] Thomas W. Pogge, "Human Rights and Global Health: A Research Program," *Metaphysiology* 36, no. 1/2 (January 2005), available online at http://www.cptech.org/ip/health/prizefund/files/pogge-rights-and-health.pdf.

[7] Families USA, *Investing in Global Health Research: Neglected Tropical Diseases* , op. cit.

[8] Ibid.

[9] Secretariat of the Global Forum for Health Research, *10/90 Report on Health Research, 2003-2004* (Geneva: Global Forum for Health Research, May 10, 2004), available online at http://www.globalforumhealth.org/Site/002__What%20we%20do/005__Publications/001__10%2090%20 reports.php.

[10] M. Kremerm and R. Glennerster, *Strong Medicine: Creating Incentives for Pharmaceutical Research on Neglected Diseases* (Princeton, NJ: Princeton University Press, 2004).

[11] IMS Health, *World Pharma Sales 2001: US Still Driving Growth*, available online at http://www.imshealth.com/web/content/0,3148,64576068_63872702_70260998_70328515,00.html.

[12] The Global Alliance for TB Drug Development, *The Economics of TB Drug Development* (New York: The Global Alliance for TB Drug Development, October 2001), available online at http://www.tballiance.org/downloads/publications/TBA_Economics_Report.pdf

[13] IMS Health, op. cit.

[14] Ibid.

[15] "Global Spending on Health Research Still Skewed towards Wealthy Nations," *British Medical Journal* 329, no. 1,064 (November 6, 2004), available online at http://www.bmj.com/cgi/content/full/329/7474/1064-e.

[16] Families USA, *Investing in Global Health Research: Malaria,* op. cit.

[17] NIH provides data on the research it funds by diseases, conditions, and research areas. This information, which is available online at http://www.nih.gov/news/fundingresearchareas.htm, is updated periodically. Families USA estimates for TB research funded through NIH are based on NIH's 2006 estimates as of February 2007. NIH reports both TB vaccine research spending and total TB research spending, which includes vaccine research.

[18] Families USA, *Investing in Global Health Research: HIV/AIDS* , op. cit. Microbicides are compounds that are being developed that are designed to block or kill the HIV virus to reduce transmission during intercourse.

[19] Ibid.

[20] NIH's share of cancer research spending was derived by Families USA based on data reported in S. Eckhouse and R. Sullivan, "A Survey of Public Funded Cancer Research in the European Union," *PLoS Med* 3, no. 7 (July 18, 2006): e267. Families USA developed estimates of NIH's share of government spending for Alzheimer's disease and diabetes research using government research spending reported by the U.S. (NIH), Canadian, Australian, and Japanese governments and the European Union reporting on behalf of its member states.