



## Fighting the World's Most Devastating Diseases: A Plan for Closing the Research Gap

Tuberculosis (TB), malaria, HIV/AIDS, and neglected tropical diseases (NTDs) – infectious diseases found mainly in low-income tropical and subtropical regions, such as African sleeping sickness, Chagas disease, and leishmaniasis – have much in common: 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.<sup>1</sup>

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.<sup>2</sup>

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.<sup>3</sup> 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.<sup>4</sup> The funding situation is even more dire for neglected tropical diseases, which primarily affect regions where there is virtually no commercial market.<sup>5</sup>

- The current vaccine to prevent TB was introduced in 1923 – 85 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.<sup>6</sup>
- Collectively, neglected tropical diseases affect one in six people worldwide and kill more than 500,000 people every year.<sup>7</sup> Yet these diseases receive only \$1 out of every \$100,000 spent worldwide on biomedical research and product development (R&D).<sup>8</sup>

Spending on research for diseases that primarily affect developing countries is meager compared to the impact of these diseases. Increased medical research and the resulting improvements can dramatically reduce the toll these diseases take.<sup>9</sup>

## 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. 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.<sup>10</sup> 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 was at least \$4 billion in 2006.<sup>11</sup> Each of these top-selling drugs targeted a chronic disease, such as heart disease, that is common in developed, wealthy countries.

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.

A recent study estimated the global market for *all* drugs used to treat tuberculosis (TB) at \$369 million.<sup>12</sup> In contrast, in 2006 alone, global sales for Lipitor, a cholesterol lowering drug with a large, wealthy market, totaled \$13.6 *billion*.<sup>13</sup> And 2006 sales for Nexium, an acid reflux medicine, totaled \$6.7 *billion* – 18 times greater than sales estimates for the entire line of anti-TB drugs.<sup>14</sup>

## 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.<sup>15</sup> 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 last year's trans-Atlantic flights of a man with drug-resistant TB underscores the flaw in this reactionary approach: The public needs 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.

## Bolstering Research through the National Institutes of Health

Closing the research gap will require all countries that fund research on global infectious diseases to do more. The U.S. can show leadership by funding its share of research. A big step in that direction would be to provide more funding to the institutes and centers within the National Institutes of Health (NIH) that contribute the most to R&D on these diseases.

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 most devastating 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 1 percent of its research budget – only \$98 million – to funding malaria research.<sup>16</sup>
- Funding for TB research was similarly meager, at \$150 million, or one-half of 1 percent of NIH's budget.<sup>17</sup>

- NIH devoted only 2.5 percent of its 2006 budget to research on an AIDS vaccine and microbicides to prevent HIV transmission.<sup>18</sup> 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.<sup>19</sup> NIAID takes the lead in researching infectious diseases that are relevant to global health. Fogarty takes the lead in building domestic and international capacity to conduct global health research, including research that moves discoveries into practice in developing nations.

Adequately funding NIH's research on infectious diseases of global importance – including research to move discoveries into practice – is important to making advances against these diseases.

### **Other U.S. Government Agencies and Global Health Research**

While NIH is the largest U.S. government agency that conducts health research and is a major force in global infectious disease research worldwide, other U.S. government agencies play an important role as well.

The Centers for Disease Control and Prevention (CDC), the U.S. Agency for International Development (USAID), and the Department of Defense (DOD) all make important contributions to global health research. USAID and CDC have field offices around the world that conduct clinical research. CDC also plays a critical role in protecting people worldwide from disease outbreaks. DOD researches treatments and vaccines for the many infectious diseases that threaten our troops, such as malaria and dengue fever. These agencies also work collaboratively with NIH on many research projects.

Although the focus of this piece is the research funding needs of NIH, the work of these other agencies is also critical. Providing adequate funding for their research efforts would advance global health generally and, because there are many collaborative efforts across these agencies, it would also strengthen NIH.

## 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 preventative 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 in the next section.

Our analysis shows that NIAID's research in these areas is significantly underfunded. The institute's investment in TB, malaria, neglected tropical diseases, and HIV/AIDS vaccine and microbicide research falls more than \$580 million short of what's needed for NIAID to meet its share of global research spending. To address that shortfall, NIAID would need a 12.5 percent increase above its fiscal year (FY) 2008 budget. That would bring NIAID's 2009 budget to \$5.223 billion, excluding any adjustments for inflation.<sup>20</sup>

The Fogarty Center is also 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. Its work is essential to furthering the creation and use of new interventions in developing countries. By working directly with scientists in developing countries, Fogarty also fosters a positive image of the U.S. abroad. Yet it is the smallest of NIH's 27 institutes and centers.<sup>21</sup> This testifies to the fact that global health has been undervalued. Increasing funding for Fogarty by 25 percent would bring its budget up to \$84.7 million, giving it some of the added funds it needs to support its important work. Even at that funding level, it would still remain NIH's smallest center, but the added funds would go a long way toward supporting Fogarty's important mission.

## Methodology for 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.

## Sources for Recommendations on Research Spending

Disease	Sources for Spending Recommendation
<b>HIV/AIDS</b> 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)
<b>Malaria</b> 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
<b>TB</b> 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
<b>Neglected Tropical Diseases</b> 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 percentage of global spending to estimated worldwide research funding needs, as indicated in the figure below. (Please contact Families USA for details on sources, calculations, and assumptions used to determine NIAID's global health R&D funding shortfall.)



### Is NIH's Share of Worldwide Global Health Research Appropriate?

NIH accounts for between 46 and 77 percent of all public sector spending on medical research related to malaria, HIV/AIDS vaccine and microbicide development, TB, and neglected tropical diseases.<sup>22</sup> 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. In an analysis of biomedical research spending across countries with significant research capacity, Families USA found that NIH funds approximately 80 percent of government-sponsored cancer research. For Alzheimer's disease research, NIH's share is 88 percent. For diabetes research, NIH's share is about 93 percent.<sup>23</sup> For neglected diseases, where government's role is particularly critical because private industry isn't stepping in, NIH's 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.

For these reasons, in our analysis, we kept NIH's—and NIAID's—share of global spending at their current levels. As a world leader in medical research, it's appropriate that NIH lead in research on global infectious diseases.

### Next Steps:

#### How to Get There from Here—A Strategy for Correcting the Shortfall

Considering federal budget constraints, it is unlikely that government funding for NIAID or Fogarty will be increased to the needed levels in one fell swoop. However, small and consistent increases, with the goal of expanding funding for research on neglected infectious diseases that have a high global burden, would make significant progress in addressing the longstanding shortfalls.

If the budget for NIAID were increased by just 1.8 percent over its 2008 budget level for each of the next seven years, in addition to annual adjustments for inflation, the agency could reach its funding target.<sup>24</sup> Similarly, we could reach the funding target for Fogarty with an additional 3.6 percent increase over its 2008 budget for each of the next seven years, in addition to adjustments for inflation. Over seven years, that amounts to an additional \$83.1 million for NIAID and \$2.4 million for Fogarty annually, on top of inflation adjustments.<sup>25</sup>

In 2009, the research community is calling for a budget increase of 6.7 percent for NIH overall. That includes an increase to keep pace with inflation plus an additional 3 percent to make up for recent years in which funding has failed to keep up with inflation. With that 6.7 percent adjustment, plus additional funding for global health research, for 2009, NIAID funding would be \$5 billion, and Fogarty funding would be \$74.6 million.<sup>26</sup> (See “NIH and the Budget Process: A Thumbnail Sketch.”)

### **NIH and the Budget Process: A Thumbnail Sketch**

Every year, each of the 27 NIH institutes and centers develops a budget. Budgets are also drawn up for the NIH Office of the Director, for special research offices, and for items such as facilities management.

NIH submits its budget to the department it is part of—Health and Human Services (HHS). HHS and, eventually, the Office of Management and Budget (OMB), analyze the NIH budget and, as necessary, revise it for consistency with the Administration’s priorities. It then becomes part of the President’s proposed budget.

Throughout the budget and appropriations process, there is an overall NIH budget number, as well as specific amounts for each institute and center within NIH. Generally, when the overall budget for NIH is raised, the institutes and centers see roughly comparable increases. So, if the budget for NIH increases by 10 percent, the institutes and centers could expect to see increases of about 10 percent. Exceptions include “bump-ups” for pressing public health needs—such as added funding for AIDS or obesity research. Then, the specific institutes or centers that research these problems will get larger increases. Global health research is just such a pressing public health need that merits increased funding.

Over the past few years, the NIH budget has not kept up with biomedical research inflation, which has effectively cut its real purchasing power. This hurts research, stymies innovation, and delays advances in health here and globally. Medical research institutes, health advocacy organizations, universities, and scientists have come together to evaluate NIH budget needs. For 2009, many of these groups are recommending that the NIH budget be increased by 6.7 percent, which includes projected biomedical research inflation plus an additional 3 percent to counter the inadequate funding of recent years. (For a description of the annual budget timeline, see the NIH Office of the Budget, “Budget Process Calendar,” available online at <http://officeofbudget.od.nih.gov/GenBudgetInfo/Budget%20Process%20Chart.pdf>.)



While seven years may seem like a long time, spending on research for global health has been neglected for much longer. Annual increases of 1.8 percent for NIAID and 3.6 percent for Fogarty, spread out over several years, are small amounts to spend to address 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;
- new ways to prevent HIV/AIDS; and
- an AIDS vaccine.

Increasing our investment in global health research would also substantially improve the lives of billions of people worldwide.

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## Endnotes

<sup>1</sup> 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/>.

<sup>2</sup> Jeffery Sachs and Pia Malaney, "The Economic and Social Burden of Malaria," *Nature* 415 (February 7, 2002), available online at <http://www.cid.harvard.edu/cidinthenews/articles/sachsmalariafeb02.pdf>; 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>.

<sup>3</sup> 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=](http://www.researchandmarkets.com/reportinfo.asp?report_id=227903&t=d&cat_id=).

<sup>4</sup> 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](http://www.tballiance.org/downloads/publications/Pathway_to_Patients_Overview_FINAL.pdf).

<sup>5</sup> 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>.

<sup>6</sup> 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>.

<sup>7</sup> Families USA, *Investing in Global Health Research: Neglected Tropical Diseases*, op. cit.

<sup>8</sup> Ibid.

<sup>9</sup> 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%20reports.php](http://www.globalforumhealth.org/Site/002__What%20we%20do/005__Publications/001__10%2090%20reports.php).

<sup>10</sup> M. Kremer and R. Glennerster, *Strong Medicine: Creating Incentives for Pharmaceutical Research on Neglected Diseases* (Princeton, NJ: Princeton University Press, 2004).

<sup>11</sup> For the 10 top-selling drugs, 2006 global sales ranged from \$4 billion to \$13.6 billion. IMS Health, *Leading Products by Global Pharmaceutical Sales, 2006*, current as of March 20, 2007, available online at [http://www.imshealth.com/ims/portal/front/articleC/0,2777,6599\\_80528184\\_80528228,00.html](http://www.imshealth.com/ims/portal/front/articleC/0,2777,6599_80528184_80528228,00.html).

<sup>12</sup> This is the sum of the market estimates for first- and second-line TB drugs. The TB Alliance, op. cit.

<sup>13</sup> IMS Health, op. cit.

<sup>14</sup> Ibid.

<sup>15</sup> "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>.

<sup>16</sup> Families USA, *Investing in Global Health Research: Malaria*, op. cit.

<sup>17</sup> 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.

<sup>18</sup> 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.

<sup>19</sup> Ibid.

<sup>20</sup> This calculation is based on NIAID's 2008 budget of \$4.642 billion, which included a \$300 million pass-through to the Global Fund to Fight AIDS, TB, and Malaria. The Global Fund is a critically important multilateral organization that provides funds to developing countries, allowing them to develop the capacity to fight these devastating diseases. However, these funds are not available to NIAID and are not necessarily used for research.

<sup>21</sup> Information on comparative NIH funding by institute and center from *The NIH Almanac: Appropriations* (Bethesda, MD: National Institutes of Health, Office of Communications and Public Liaison, Online Information Branch, updated September 19, 2007), available online at <http://www.nih.gov/about/almanac/appropriations/index.htm>, accessed on January 9, 2008.

<sup>22</sup> Malaria Research and Development Alliance, *Malaria Research and Development: An Assessment of Global Investment* (Seattle: Program for Appropriate Technology in Health (PATH), November 2005), available online at [http://www.malariaalliance.org/PDFs/RD\\_Report\\_complete.pdf](http://www.malariaalliance.org/PDFs/RD_Report_complete.pdf); Cindra Feuer, *Tuberculosis Research and Development: A Critical Analysis of Funding Trends, 2005-2006* (New York: Treatment Action Group, November 2007), available online at <http://www.aidsinfonyc.org/tag/tbhiv/tbrandd/2007tbranddreport.pdf>; HIV Vaccine and Microbicide Resource Tracking Working Group, *Building a Comprehensive Response, Funding for HIV Vaccines, Microbicides, and Other New Prevention Options: 2000-2006* (HIV Vaccines and Microbicides Resource Tracking Working Group, November, 2007), available online at [http://www.hivresourcetracking.org/content/RT\\_Report\\_Nov2007.pdf](http://www.hivresourcetracking.org/content/RT_Report_Nov2007.pdf).

<sup>23</sup> Families USA developed estimates of NIH's share of government spending for cancer, Alzheimer's disease, and diabetes research using government research spending reported by the U.S. (NIH), Canadian, Australian, French, British, and Japanese governments, plus data from the European Union reporting on behalf of its member states. This was supplemented with data reported in S. Eckhouse and R. Sullivan, "A Survey of Public Funding of Cancer Research in the European Union," *PLoS Medicine* 3, no. 7 (July 18, 2006): e267.

<sup>24</sup> A 1.8 percent increase based on NIAID's 2008 budget translates into \$83.1 million.

<sup>25</sup> These numbers are in 2008 dollars. Over the seven years for which we have proposed additional catch-up funding for global health research, these numbers (the \$83.1 million for NIAID and \$2.4 million for Fogarty) should be adjusted for inflation in the cost of biomedical research.

<sup>26</sup> This includes a \$300 million pass-through to the Global Fund (see endnote 20).

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