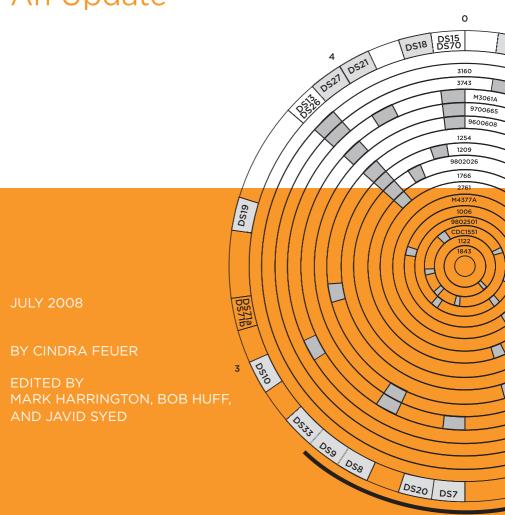


TUBERCULOSIS RESEARCH AND DEVELOPMENT:

## A Critical Analysis of Funding Trends, 2005–2006: An Update



"AS TB CASES CONTINUE TO INCREASE, WE PEOPLE LIVING WITH HIV AND AIDS ARE DYING AT ALARMING RATES. THE NEED FOR RAPID DIAGNOSTIC TOOLS AND NEW TB DRUGS HAS NEVER BEEN HIGHER. TO THE PEOPLE THAT HOLD THE POWER IN YOUR HANDS TO MAKE THIS HAPPEN, I WOULD LIKE TO SAY THAT YOU CANNOT BEGIN TO IMAGINE THE TRAUMA, THE DESPAIR, AND THE ANGUISH WE FEEL AFTER FIGHTING TO PROLONG OUR LIVES WITH ARVS AND NOW WE SIT, WAIT, AND WATCH AS TB KILLS OUR COLLEAGUES AND GETS CLOSER TO US DAY BY DAY..."

-CAROL MAIMBOLWA, TREATMENT ADVOCACY & LITERACY CAMPAIGN, ZAMBIA

"THE PRESENT FAILURE TO ADEQUATELY CONTROL TB IS THE RESULT OF LOST OPPORTUNITIES IN FUNDING OVER THE LAST FEW DECADES."

-STEFAN H E KAUFMANN & SHREEMANTA K PARIDA, MAX PLANCK INSTITUTE

"THERE ARE MANY COUNTRIES SUCH AS BOTSWANA,
SOUTH AFRICA, AND THAILAND THAT ARE EQUIPPED WITH
INTERESTED INVESTIGATORS, LOTS OF PATIENTS, GOOD LABS,
AND EXPERIENCE IN CLINICAL TRIALS. WHAT WE DON'T
HAVE IS THE MONEY TO CONDUCT THE NEEDED TRIALS."
—BILL BURMAN, TB TRIALS CONSORTIUM

"AS INSUFFICIENT RESEARCH AND DEVELOPMENT ON NEW DRUGS AND DIAGNOSTICS HAS LEFT HEALTH STAFF WITHOUT THE RIGHT TOOLS TO TREAT THE DISEASE, SOME PATIENTS WILL GO ON TO DEVELOP EXTENSIVELY DRUGRESISTANT (XDR) TB REGARDLESS OF THE QUALITY OF CARE THEY ARE OFFERED."

-MÉDECINS SANS FRONTIÈRES

## TUBERCULOSIS RESEARCH AND DEVELOPMENT:

# A Critical Analysis of Funding Trends, 2005–2006 An Update

**JULY 2008** 

BY CINDRA FEUER

EDITED BY MARK HARRINGTON, BOB HUFF, AND JAVID SYED

#### **ABOUT TAG**

The Treatment Action Group (TAG) is an independent AIDS research and policy think tank fighting for better treatment, a vaccine, and a cure for AIDS. TAG works to ensure that all people with HIV receive lifesaving treatment, care, and information.

TAG's TB/HIV Project strengthens community-driven advocacy for better TB/HIV research, programs, and policy in order to secure more effective services worldwide.

You can reach TAG by phone at +1.212.253.7922. To find out more about TAG's projects go to www. treatmentactiongroup.org.

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THIS REPORT IS DEDICATED TO

# Ronald Louw 1957-2005

Human rights activist and university professor, South Africa

Died from undiagnosed tuberculosis due to unreliable tests developed more than a hundred years ago

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### Foreword

#### BY MARK HARRINGTON

The Treatment Action Group (TAG) report on tuberculosis (TB) research and development (R&D) in 2006 finds that while funding for TB research increased from 2005 it fell far short of the need. The report also finds that although funding from philanthropic sources rapidly increased from 2005 to 2006, public sector spending did not keep up; the proportion of total investment derived from public sources actually declined in 2006. The increased investment in new diagnostics, drugs, and vaccines is welcomed but nowhere near levels needed according to the *Global Plan to Stop TB: 2006–2015*, which estimated that \$900 million per year would be required to advance this research. TAG's report shows that in 2006, only \$429 million was spent on all TB R&D (including basic science and operational research, two categories not addressed by the *Global Plan*), leaving almost a \$500 million gap. Indeed, TAG has estimated that \$2 billion per year may be actually required to support the full gamut of needed TB R&D. This \$2 billion figure includes TAG's estimates for basic science and operational research in addition to the amount needed for diagnostics, drugs, and vaccines according to the *Global Plan*.

That the world is falling short of the *Global Plan's* targets is depressing but not surprising news. After being unveiled with great fanfare in January 2006, the *Global Plan* has received only nominal support from many key countries, despite being endorsed by the UN General Assembly at the UNGASS review in June 2006 and by the World Health Assembly in May 2007. Many governments, in fact, are failing to adhere to their promises on TB, on universal access to HIV prevention, care, and treatment by 2010, and on many other aspects of global public health.

For TB research and development, comprehensive tracking of investments will continue to be vital to assess the gaps and measure our success in meeting the challenge of mobilizing the \$2 billion a year needed for the research to assure that the necessary tools are developed and made accessible.

### **Executive Summary**

Treatment Action Group's reports on global tuberculosis (TB) research and development (R&D) investments in 2005 and 2006 documented the real world baseline TB research spending at the start of the Global Plan to Stop TB 2006–2015. The plan estimated that \$9 billion in R&D is needed over the ten years from 2006 to 2015 just for new diagnostics, drugs, and vaccines (Stop TB Partnership/WHO 2006). Because the plan did not include basic science and operational research, TAG's reports documenting 2005 and 2006 spending—provide estimated needs for these areas. Both reports concluded that TB R&D investments needed to increase fivefold to \$2 billion per year in order to achieve the plan's goals.

TAG documented that in 2005 the top global investors spent \$393 million (in U.S. dollars) on TB R&D and \$414 million in 2006. But after publishing the 2006 analysis in November 2007, additional and in some cases corrected investment data were received for 2005 and 2006. This second edition of the report on 2006 TB R&D reflects revisions for both years. In sum, our new data show that 2005's total investment in TB R&D was \$368 million, down from the originally reported amount of \$393 million. Our new data for 2006 show investments of \$429 million, an increase from the originally reported \$414 million. These updated figures indicate a 16% increase in investment from 2005 to 2006. Our original estimates showed only a 5% increase. Nonetheless, even with the more accurate revised estimated investments between 2005 and 2006, expenditures are still woefully inadequate by almost fivefold when measured against the Global Plan and TAG's estimates of annual need in TB R&D.

The main impression is one of inadequacy and failure of political will for TB R&D funding from 2005 to 2006. Despite the release of the *Global Plan* at the World Economic Forum in January 2006 with much fanfare, and despite the emerging worldwide threat of extensively drug-resistant TB (XDR-TB), identified in 2006 and now present in over forty countries, governments have not responded with the urgency or ambition to step up their investments in TB R&D.

In the first year covered by the *Global Plan*, increases in public sector spending were scant and, despite a 42% surge in philanthropic spending, increases in research investment fell short of the need, especially with respect to operational research. TAG's analysis of TB R&D disbursements from 2005 to 2006 identified the following trends:

• TB R&D investments were insufficient in 2006, rising just \$60 million to \$429 million, 16% above the 2005 \$368 million tally. This means that given inflation and reporting changes (China and South Africa reported this year, but France's INSERM did not) there was little growth overall.

- With only an overall 6% increase in disbursements from 2005 to 2006, the proportion of public sector investment retreated from 63.6% of the total in 2005 to 57.5% in 2006. The National Institutes of Health (NIH), the world's largest health research investor, posted an \$8 million decline in TB R&D funding from 2005 to 2006. This reduction reflects the impact of the NIH's overall flat funding since 2004, which, when considering inflation, amounts to an effective 12.4% decrease in NIH research purchasing power.
- Philanthropies, principally the Bill and Melinda Gates Foundation, substantially boosted their contributions, increasing this sector's proportion of total investment from 24.2% to 29.7%.
- Reported industry investment grew by 23% but continues to lag behind other funding sources by a wide margin and shows no signs of closing the gap. The proportion of industry funding remained relatively flat, rising from 11.7% to 12.4%.
- Investment in research on diagnostics, drugs, vaccines, and basic science increased, while operational research funding was nearly unchanged.
- Measured against the Global Plan's 2006 targets for new tools research funding, TAG's report reveals that actual investments fell short by over half a billion dollars. The 2006 funding gap for TB diagnostics research was \$28 million, for drugs \$274 million, and for vaccines \$213 million.

### Recommendations

- 1. To meet the ambitious R&D goals set by the Global Plan—and to address the need for basic and operational research—TB R&D investment must increase fivefold, from approximately \$430 million to over \$2 billion per year, for basic science, applied research, and operational research.
- 2. A comprehensive, global TB R&D agenda that includes basic and operational research must be developed.
- 3. TB R&D requires better coordination globally and nationally.
- 4. Governments, of both donor and high-TB-burden countries, the private sector, and foundations all need to increase their investment and more accurately track and transparently report on TB R&D investments.

### 1 Introduction

### 1.1 The Importance of TB R&D

To meet the Stop TB Partnership and World Health Organization (WHO) goals to reduce TB incidence and death by 50% in 2015 relative to 1990 levels, and to eliminate TB as a public health threat by 2050, massive scale-up is needed in basic, applied, and operational research and in development of better tools to prevent, diagnose, and cure TB.

In the spring of 2006, TAG began a resource-mapping exercise to establish a baseline for TB R&D funding disbursed in 2005 against which future funding trends could be analyzed. The findings were published in "Tuberculosis R&D Investments: A Preliminary Assessment" in August 2006. The final edition of the report, *Tuberculosis Research & Development: A Critical Analysis*, published in October 2006, presented a more comprehensive set of 2005 TB R&D data. In the following report, published in November 2007, TAG provided data on reported TB R&D funding in 2006, and compared 2006 with 2005 spending levels. In this second edition report charting spending trends from 2005 to 2006, TAG revises its original 2005 and 2006 investment figures to more accurately reflect data provided by donors after publication of *A Critical Analysis of Funding Trends*, 2005–2006.

The 2006 Tuberculosis Research & Development: A Critical Analysis identified \$393 million invested by forty donors in TB R&D in 2005. Though we now know that this number was inflated, due to a discrepancy in reporting, and should have been \$363 million, this report did have a significant impact on raising awareness of the dismal state of investment in TB research (Feuer 2006). The report's findings were used widely by researchers and policy makers, and the results were presented as a late-breaker at the 37th IUATLD World Conference on Lung Health in Paris in November 2006. Stefan Kaufmann and Shreemanta Parida cited the report in the special TB issue of Nature Medicine in March 2007. Neil Schluger of Columbia University cited it as the most important TB paper of 2006 at the March 2007 Keystone TB pathogenesis meeting in Vancouver.

TAG presented its results at the Stop TB Partnership Coordinating Board meeting in Jakarta and at the NIH National Institute of Allergy and Infectious Diseases (NIAID) Advisory Council special meeting on MDR- and XDR-TB

in May 2007. The Foundation for Innovative New Diagnostics (FIND), Médecins Sans Frontières, the WHO, and other organizations have cited TAG's data.

One goal of TAG's R&D funding reports is to lay the groundwork for global agencies to undertake R&D resource tracking. In 2008 the Stop TB Partnership was to begin tracking national investments in TB R&D and report on investments for 2007, though these plans are currently on hold. Another Gates Foundation—funded—initiative is planning to track resources for TB R&D along with 16 other neglected diseases, though this effort will not track operational research and will therefore not provide a full understanding of what was spent on TB research in 2007.

### 1.2 Objectives

By tracking spending trends and highlighting underfunded areas of research, this publication aims to drive advocacy for new TB diagnostics, treatment, and prevention tools, and for expanded basic and operational research.

This 2006 mapping of TB research provides a revealing survey—if not a comprehensive global tally—of the year's research investments. It primarily documents contributions from G8 member nations' public research agencies, international development agencies, major nonprofit charitable foundations and trusts, pharmaceutical and biotechnology companies, and a few reporting countries with endemic TB.

The figures presented in this report should not be interpreted as absolute findings, because some public funding institutions and most industry funders did not provide complete data. Nevertheless, most of the major sponsors of TB R&D are likely included here.

### 1.3 Methodology

A list of 128 potential TB research funders was generated using information from the Stop TB Partnership website, reports by Aeras, FIND, and the TB Alliance, and from Internet research, as well as from contacts garnered through last year's TB R&D survey respondents. Key informants in the TB research community were consulted to assist in confirming a core list of significant donors.

TAG used an e-mail survey to solicit information from funders and recipients about actual annual disbursements (not commitments or awards) for TB research for 2006. The survey also collected information about future commitments; the amount of funding an institution disbursed or received; grant portfolios describing the research; and qualitative responses about priorities and obstacles in TB research.

### 1.4 Limitations of the Data

Of 128 potential research donors or recipients queried, 42 respondents provided 2006 investment data. Five respondents stated that they are not primary funders of TB and three respondents declined to provide data; two from industry provided qualitative but not quantitative data (see appendix B).

Eight of thirty-one surveyed pharmaceutical and biotechnology companies disclosed financial information. Because the commercial sector is often unwilling to reveal investments or returns to the public, TAG is not able to quantify industry support for TB research in total. Responses are presented without identification if requested.

### 1.5 Correction

In 2005 the MRC was incorrectly ranked number three with a total donation of \$31 million. The corrected amount invested by the MRC in 2005 was \$6.2 million, which knocks its ranking down to number 14. The revised 2005 spending breaks down in to \$1.8 million for basic science research, \$2.8 million for diagnostics, \$352 thousand for drugs, \$934 thousand for vaccines, and \$317 thousand for operational research. The MRC's investments in basic and operational research were erroneously reported at \$9 million and \$18 million, respectively. The corrected MRC contribution of \$6.2 million in 2005, compared with 2006's contribution of \$8.1 million, shows *upward investment* of 31% between 2005 and 2006, not the previously reported 74% drop.

The inaccurate account of the MRC's contribution of \$31 million in 2005 was due to the bundling of a five-year award that should have been annualized to represent spending in 2005. This inaccuracy affected TAG's 2005 reporting totals. When adjusted to represent the accurate MRC numbers, the total of 2005 spending dips to \$368 million from \$398 million. This new total—along with other adjustments—also affects the 2005–2006 trend, bringing the increase in spending trend to 16%, up from the previously reported 5%.

The MRC error is a good illustration of the perils and pitfalls of R&D tracking. It is also an apt example of the need for explicit and standardized annual accounting on the part of R&D donors of all neglected diseases.

### 2 Results

### TABLE 1

### 41 Funders of TB R&D in 2006 Reported to TAG by February 2008

(see appendix A for investments by research category)

	Rank Institute	Total
1	U.S. NIAID, NIH	119,771,818
2	Bill & Melinda Gates Foundation (BMGF)	96,466,861
3	Otsuka Pharmaceutical Company	22,900,000
4	The Wellcome Trust	18,380,741
5	Other NIH institutes & centers	17,579,000
6	U.S. Centers for Disease Control & Prevention (CDC)	17,057,774
7	U.S. NHLBI, NIH	13,139,592
8	European Commission Sixth Framework Programme	12,844,807
9	UK Department for International Development (DFID)	12,576,339
10	Institut Pasteur	8,785,490
11	Novartis Institute for Tropical Diseases	8,700,000
12	Company X	8,700,000
13	UK Medical Research Council (MRC)	8,111,736
14	USAID	7,700,000
15	AstraZeneca	7,200,000
16	India ICMR/TB Research Center (TRC)	6,347,873
17	Netherlands Minisitry of Foreign Affairs (DGIS)	5,864,942
18	Brazil (amalgamated)	4,031,671
19	Irish Aid	3,765,210
20	Sequella, Inc.	3,743,000
21	UK Health Protection Agency (HPA)*	3,689,954
22	Canadian Institute of Health Research	3,257,764
23	Russian TB institutes	2,772,000
24	Germany, Max Planck Institute for Infectious Biology	1,910,000
25	Ellison Medical Foundation	1,850,000
26	Global Fund to Fight AIDS, Tuberculosis and Malaria	1,534,259
27	Company Y	1,500,000
28	Swedish International Development Cooperation (Sida)	1,415,691
29	Research Institute of Tuberculosis, Japan Anti-TB Association (JATA)	1,358,568
30	All India Institute of Medical Sciences (AIIMS)	1,299,004
31	South Africa Medical Research Council (SA MRC)*	1,240,620
32	U.S. FDA	651,224
33	China CDC National Tuberculosis Reference Laboratory*	626,059
34	Rockefeller Foundation	450,000
35	Denmark Ministry of Foreign Affairs (Danida)	415,627
36	Anda Biologicals*	395,347
37	Ireland Health Research Board*	385,705
38	Thailand Ministry of Public Health	226,463
39	KNCV Tuberculosis Foundation	199,556
40	Eli Lilly Foundation	140,000
41	France Ministry of Foreign Affairs Coöperation Française	131,782
42	Swiss Agency for Development and Cooperation	50,203
	Total	429,166,680

<sup>\*</sup>Newly reporting for 2006

### 2.1 Research Investment Categories

Scientific grants and research programs focusing on *Mycobacterium tuberculosis* (MTB) and tuberculosis (TB) disease are categorized according to the descriptions below.

- basic research: undirected, investigator-initiated research that aims to uncover fundamental knowledge about Mycobacterium tuberculosis and other, closely related organisms
- applied, preclinical, infrastructure, or otherwise unspecified: research that the donor or funder was unable to further categorize
- diagnostics: preclinical or clinical trials of diagnostic technologies and algorithms
- drugs: preclinical or clinical research on treatments and treatment strategies for tuberculosis disease (including prophylaxis, latent, and active TB)
- vaccines: preclinical or clinical research on TB vaccines
- operational research: includes randomized controlled studies
  of existing interventions within routine program settings, as well as
  epidemiology, surveillance, or targeted evaluation of new or existing
  interventions to improve TB program performance and reduce TB rates

### 2.2 Donor Categories

In this revised report on 2006 TB research investment, five new funding sources responded, while one source from 2005 did not report. The 42 investing institutions reported spending \$429 million on TB R&D in 2006, up from the \$368 million reported by 40 institutions in 2005's report. This increase of \$60.7 million, or about 16%, suggests sluggish momentum in TB research despite the release of the Global Plan and the emergence of XDR-TB as a global threat.

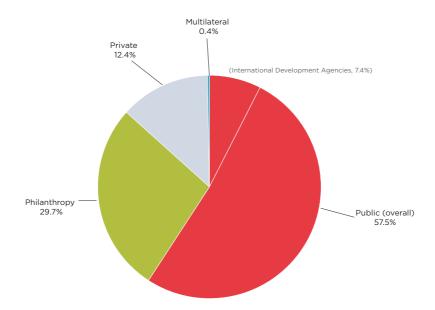
Of \$429 million reported to TAG by the 42 investors in TB R&D in 2006, \$247million (57.5%) came from the public sector, \$128 million (29.74%) from philanthropic foundations, \$53 million (12.4%) from industry, and \$1.5 million (0.4%) from the Global Fund.

The primarily foundation-funded product development public-private partnerships (PDPs), such as Aeras, FIND, the TB Alliance, and other research consortia, passed along \$70 million for TB R&D in 2006; however, this was not included in the global total in order to avoid double counting.

Public sector investment decreased from 63.6% of total investment in 2005 to 57.5% in 2006. Philanthropies substantially increased the amount disbursed, and the proportion of their investment grew from 24% to 30% of the total. The proportion of industry investment hovered around 12% in both 2005 and 2006.

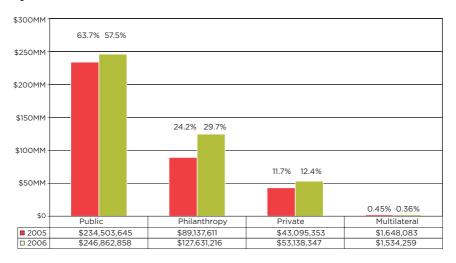
### FIGURE 1

### TB R&D Funding by Donor Category, 2006



### FIGURE 2

## Amounts and Proportion of Total Investment by Donor Sector: 2005 vs. 2006



#### **TABLE 2**

### **Public Donors by Country**

	2005	2006	Trend a	nd % change
USA	184,972,531	175,899,408	▼	-4.9%
UK	8,187,290	24,378,029	<b>A</b>	197.8%
EU	13,332,711	12,844,807	▼	-3.6%
India	9,217,954	7,646,877	▼	-17.0%
Netherlands	3,368,204	5,864,942	<b>A</b>	74.1%
Ireland	360,000	4,150,915	<b>A</b>	1053.0%
Brazil	755,587	4,031,671	<b>A</b>	433.6%
Canada	2,376,098	3,257,764	<b>A</b>	37.1%
Russia	1,930,343	2,772,000	<b>A</b>	43.6%
Germany	2,500,000	1,910,000	▼	-23.6%
Sweden	486,599	1,415,691	<b>A</b>	190.9%
South Africa**		1,240,620	<b>A</b>	
China**		626,059	<b>A</b>	
Denmark	170,344	415,627	<b>A</b>	144.0%
Thailand	430,957	226,463	▼	-47.5%
France*	6,229,928	131,782	▼	
Switzerland	195,099	50,203	▼	-74.3%
Total (public)	\$234,503,645	\$246,862,858	<b>A</b>	5.3%

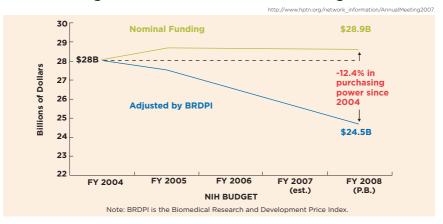
<sup>\*</sup>INSERM France did not report for 2006.

<sup>&</sup>quot;China and South Africa first reported for 2006. In 2006, the NIH budget appropriated by Congress for all health research

totaled \$28.8 billion, up only slightly from \$28.6 billion in 2005. The 0.5% increase is a reduction in real terms as the budget fails to keep pace with inflation for the first time in 24 years (AAAS 2006), resulting in a 12.4% loss in purchasing power (Fauci 2007). The flat NIH budget since 2004 inhibits progress in all emerging research priorities, including tuberculosis.

#### FIGURE 3

### A Flat NIH Budget: The Effect of Inflation on Purchasing Power



Within the NIH, NIAID awarded \$120 million to TB R&D. This is 80% of all NIH TB funding and 28% of all TB research reported to TAG for 2006. Of NIAID's \$120 million, \$51 million went to basic research and \$7.6 million, \$42 million, and \$20 million went to TB diagnostics, drug, and vaccine research, respectively.

### TABLE 3

### TB Research Investors: 2006 vs. 2005

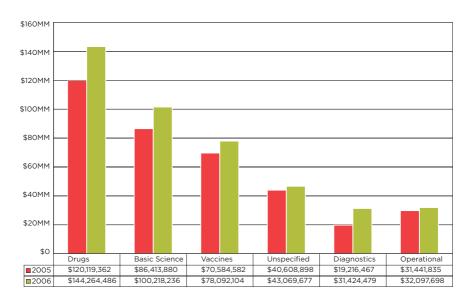
(change in rank; change in amount invested; % change)

	Rank 2006 <sup>1</sup>	2006	Am 06 <sup>2</sup>
US NIAID, NIH	1	119,771,818	•
Bill & Melinda Gates Foundation (BMGF)	2	96,466,861	_
Otsuka Pharmaceutical Company	3	22,900,000	_
Wellcome Trust	4	18,380,741	_
US other institutes & centers, NIH	5	17,579,000	•
US Centers for Disease Control & Prevention (CDC)	6	17,057,774	•
US NHLBI, NIH	7	13,139,592	•
European Commission Framework 6	8	12,844,807	$\blacksquare$
UK Department for International Development (DFID)	9	12,576,339	
Institut Pasteur	10	8,785,490	
Novartis Institute for Tropical Diseases	11	8,700,000	
Company X	12	8,700,000	$\blacksquare$
UK Medical Research Council (MRC)	13	8,111,736	
USAID	14	7,700,000	
AstraZeneca	15	7,200,000	•
India ICMR/TB Research Center (TRC)	16	6,347,873	
Netherlands Ministry of Foreign Affairs (DGIS)	17	5,864,942	
Brazil (aggregated)	18	4,031,671	
Irish Aid	19	3,765,210	
Sequella, Inc	20	3,743,000	_
UK Health Protection Agency (HPA)*	21	3,689,954	_
Canadian Institute of Health Research	22	3,257,764	_
Russian TB Institutes	23	2,772,000	_
Germany, Max Planck Institute for Infectious Biology	24	1,910,000	•
Ellison Medical Foundation	25	1,850,000	
Global Fund to fight AIDS, Tuberculosis and Malaria	26	1,534,259	•
Company Y	27	1,500,000	
Swedish International Development Cooperation (Sida)	28	1,415,691	
Research Institute of Tuberculosis, Japan Anti-TB Association	29	1,358,568	•
All India Institute of Medical Sciences (AIIMS)	30	1,299,004	•
South Africa Medical Research Council (SA MRC)*	31	1,240,620	_
US FDA	32	651,224	•
China CDC National Tuberculosis Reference Laboratory*	33	626,059	•
Rockefeller Foundation	34	450,000	•
Denmark Ministry of Foreign Affairs (Danida)	35	415,627	_
Anda Biologicals*	36	395,347	_
Ireland Health Research Board*	37	385,705	_
Thailand Ministry of Public Health	38	226,463	•
KNCV Tuberculosis Foundation	39	199,556	_
Eli Lilly Foundation	40	140,000	_
France Ministry of Foreign Affairs Coöperation Française	41	131,782	•

<sup>\*</sup> Newly reporting for 2006

### FIGURE 4

## TB Research Investment in 2005 and 2006 by Research Category



### 2 The Bill & Melinda Gates Foundation (BMGF)

The Bill & Melinda Gates Foundation is the world's largest private philanthropic organization, with an endowment at the end of 2005 of \$29.2 billion and growing. The Gates Foundation disbursed \$96 million for TB R&D in 2006, up 68% from 2005. It invested \$15.6 million in basic science, up from only \$2.6 million in 2005. With \$15 million and \$20 million going to diagnostics and drugs in 2006, respectively, the Gates Foundation more than doubled its disbursements for research in these areas since 2005. The \$36 million for vaccine research was a 25% increase over 2005.

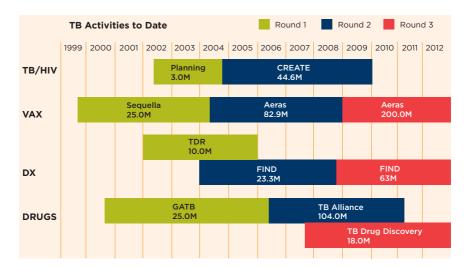
The Gates Foundation is the major supporter for six major initiatives in TB R&D:

• The **Aeras Global TB Vaccine Foundation** received \$32 million from the Gates Foundation in 2006, up from \$24 million in 2005. Aeras seeks to develop and license an improved TB vaccine for use in high-burden countries.

- The **Foundation for Innovative New Diagnostics (FIND)** received \$15 million in 2006, almost quadruple the \$4.3 million from 2005. Its mission is to accelerate late stage development of diagnostic tests for neglected infectious diseases including TB.
- The Global Alliance for TB Drug Development (TB Alliance)
  received \$15 million in 2006, triple the amount from 2005. Its mission
  is to develop new and effective anti-TB drugs and regimens that are
  affordable worldwide.
- The Consortium to Respond Effectively to the TB/HIV Epidemic (CREATE) received \$9.5 million in 2006, a slight decrease from 2005's \$10.2 million. Its mission is to develop and validate novel, community-level intervention strategies to reduce rates of TB in populations with epidemic rates of HIV infection and escalating TB incidence.
- The **Grand Challenges in Global Health (GCGH)** is a set of large grants to "transform health in the world's poorest countries and bring state-of-the-art solutions to people who need them most." The Grand Challenges initiative is supported by \$450 million from the Gates Foundation, \$27.1 million from the Wellcome Trust, and \$4.5 million from the Canadian Institutes of Health Research (CIHR). In 2006, the Gates Foundation spent \$11 million on four GCGH grants that address TB diagnosis, treatment, and vaccines.
- **Preclinical drug discovery grants** will provide up to \$18 million over two years to accelerate the discovery of new TB drugs. Awards were announced in September 2007.

### FIGURE 5

#### **Evolution of Gates Foundation TB Funding**



In September 2007 the Gates Foundation announced \$280 million in grants to build and coordinate an effort to develop new vaccines, drugs, and diagnostic tests to support the Global Plan to Stop TB 2006–2015. Aeras will receive \$200 million over five years to conduct clinical trials of up to six TB vaccine candidates. FIND will receive \$63 million over five years to develop more accurate and easier-to-use TB tests. The foundation will disburse nine grants totaling \$18 million to address key questions in preclinical TB drug development. TAG's reporting on TB investment has been supported by a Gates grant.

### 3 Otsuka Pharmaceutical Company

Otsuka Pharmaceutical Company in Japan supports discovery work on new TB drug classes. Otsuka jumped from tenth ranked in 2005 to the third-largest investor in TB research in 2006 as its funding rose from \$12 million to \$23 million, which was invested in developing the nitroimidazo-oxazole compound OPC-67683. Otsuka expects to launch a global phase II study to evaluate the safety and efficacy of OPC-67683.

#### 4 The Wellcome Trust

The Wellcome Trust is a UK-based private philanthropy that runs a diverse range of grant programs supporting biomedical research, as well as activities in medical humanities, technology transfer, and public engagement with science. The Wellcome Trust was the second-largest philanthropic investor and the fourth-largest overall in TB R&D in 2006, contributing \$18 million. Its 2006 investment in basic science increased by \$4.4 million while drug development dropped by \$5 million. Although the trust's funding remained flat, in 2006 it climbed to fourth from its 2005 ranking as the sixth largest TB R&D contributor, due to drops in rank by other institutes and centers of the U.S. NIH and CDC.

#### 5 Other NIH Institutes & Centers

Fourteen of the NIH's twenty-seven institutes and centers contributed \$17.6 million in 2006 in addition to the larger and more focused NIAID and National Heart, Lung and Blood Institute (NHLBI) efforts, which are listed separately. This is a decline from \$20 million in 2005.

#### 6 U.S. Centers for Disease Control & Prevention (CDC)

CDC funding for TB, like the CDC budget as a whole, is declining. In 2005, the CDC spent \$20 million on TB research, falling to \$17 million in 2006. While spending for diagnostic research increased to \$1.6 million from a meager \$25 thousand, drug and operational research monies plummeted from \$11 million to \$8 million and from \$8 million to \$3.6 million, respectively. The Tuberculosis Trials Consortium (TBTC) received \$8 million, the TB Epidemiologic Studies Consortium (TBESC) \$3.6 million, and \$800,000 went to TB vaccine research.

### 7 National Heart, Lung and Blood Institute (NHLBI), NIH

The NHLBI funds basic research relative to cardiac, lung, and circulatory health. Many of its TB projects investigate host immune responses in the lungs during TB infection. In 2006, NHLBI disbursed \$13 million in TB research grants (\$10 million for basic science), which was a 23% drop from 2005 when it provided \$17 million.

### **8 European Commission Sixth Framework Programme**

The European Commission's Sixth Framework Programme (FP6) aimed to integrate European efforts toward small-scale, phase I clinical trials for new TB vaccines and to establish production technologies for lead compounds for new anti-TB drugs. The Sixth Framework contributed \$13 million to TB R&D in 2006. Of this, \$7 million went to preclinical vaccine studies, \$2.7 million to basic science, and \$2.7 million to preclinical drug studies. The Sixth Framework ended in 2006 and was replaced by the Seventh Framework Programme, which runs from 2007 to 2013.

### 9 UK Department for International Development (DFID)

The TB priorities of the UK Department for International Development are disease control and access to effective, affordable interventions for vulnerable people. In 2006, DFID contributed \$12.6 million to TB research; \$7 million went to the TB Alliance, and \$5.7 million for operational research. DFID's 2006 investment in TB R&D spiked 84% from 2005 when it spent just \$2 million and ranked twenty-first.

#### 10 Institut Pasteur

The Paris-based Institut Pasteur is a private foundation dedicated to biological research for the prevention and treatment of diseases. It supports a mycobacterial genetics unit and TB vaccine discovery. Pasteur's investments remained steady, from \$8.5 million in 2005 to \$8.8 million in 2006.

### 2.4 Other Funders

The middle rank of the list of investors in TB R&D in 2006 includes 21 entities that spent over \$1 million. Together with the top 10, these 31 TB R&D funders sponsored 99% of the reported research. They include:

• Nine public research agencies, including the UK Medical Research Council (no. 13); India's TB Research Centre, Chennai (no. 16); Brazil (aggregated public sector; no. 18); the UK Health Protection Agency (no. 21); the Canadian Institute of Health Research (no. 22); four Russian TB institutes (no. 23); Germany's Max Planck Institute for Infection Biology (no. 24); the All India Institute of Medical Sciences, including the Ministry of Science and Technology (no. 30); and the South African Medical Research Council (SA MRC; no. 31)

- Five drug and biotechnology companies, including the Novartis Institute of Tropical Diseases (no. 11); Company X (no. 12); AstraZeneca (no. 15); Sequella (no. 20); and Company Y (no. 27)
- Four development agencies, including USAID (no. 14); the Netherlands Ministry of Foreign Affairs (no. 17); Irish Aid (no. 19); and the Swedish International Development Cooperation (Sida; no. 28)
- **Two foundations**, the Ellison Medical Foundation (no. 25); which is leaving the TB field, and the Japanese Anti-TB Association (JATA) Research Institute of Tuberculosis (no. 29)
- One multilateral funding mechanism, the Global Fund to Fight AIDS, Tuberculosis and Malaria (no. 26); which supports only operational research relevant to program implementation

Eleven additional funders who reported to TAG each spent less than \$1 million on TB research in 2006 (see appendix A).

### 2.5 Challenges to Estimating Industry Investment

Eight of thirty-one companies surveyed agreed to provide TB investment figures for 2006, two declined to disclose, three are not involved in TB research, and eighteen did not respond to TAG's survey. Two companies—Company X and Company Y—accepted TAG's offer of anonymity in exchange for data. The eight responders reported investing \$53 million in 2006—12% of the reported total. Combined, these companies allocated 92% of the \$53 million to drug development, 6% to diagnostics, and no reported amounts to vaccines. TAG's 2005 survey reported that industry provided \$43 million, which was 11.6% of reported TB R&D—mostly on drugs. The \$10 million spike from 2005 to 2006 is largely due to Otsuka's increase in spending, from \$12.3 million to \$23 million.

# 2.6 Product Development Public-Private Partnerships and Research Consortia

Product development public-private partnerships (PDPs) are funding managers that provide collaborative mechanisms enabling industry, governments, private philanthropic organizations, academic institutions, and public health programs to collaborate on specialized research agendas. Along with research consortia and clinical trial networks, PDPs are not original funding sources. They both receive and disburse grants and therefore do not appear in this review's list of top TB R&D donors. PDPs and other funding consortia disbursed \$70 million in TB R&D funds during 2006, a 20% increase from \$58 million in 2005. The greatest increase is due to the TB Alliance's doubling of expenditures from \$5.5 million to \$11.7 million.

PDP and funding consortia monies were not included in the global total in order to avoid double counting.

### TABLE 4

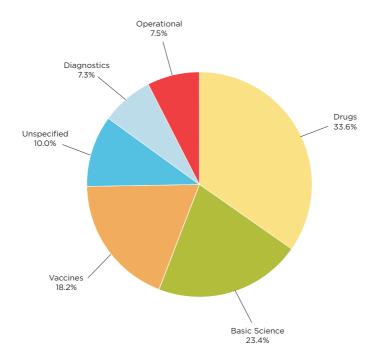
### Significant TB R&D PDPs and Research Consortia

PDP	Total
Aeras	29,740,656
CREATE	8,298,826
EDCTP	6,878,975
FIND	5,492,942
TB ALLIANCE	11,743,498
TBVAC	4,497,321
TDR	2,995,748
	\$69,747,966

# 3 Trends in TB Research by Category

#### FIGURE 5

### 2006 TB Research: Investment by Category (Total = \$429,166,680)



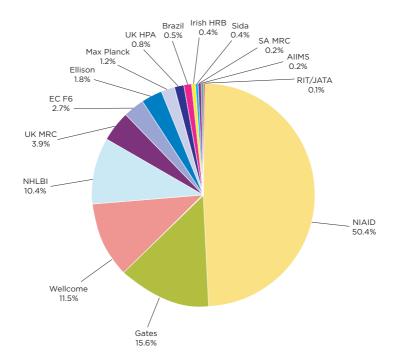
### 3.1 Basic Science

Total reported funding for basic science on TB was \$100 million in 2006, 23% of reported research. Of this, \$62 million came from the NIH's NIAID, \$15.6 million from the Gates Foundation, and \$11.5 million from the Wellcome Trust; together they supported 89% of all reported TB basic science. Basic science saw a 16% increase from the \$86 million spent in 2005.

The Global Plan to Stop TB did not make a specific recommendation for increasing basic science funding. However, TB basic science is essential to ensure that the new tools pipelines become more robust than they are today. The example of HIV/AIDS research, where basic science received a substantial boost in the early 1990s with continuing benefit to this day, demonstrates that basic science investment must be increased early and substantially to support a healthy research field.

### FIGURE 6

## **TB Basic Science** (Total = \$100,218,236)



### 3.2 TB Diagnostics

Diagnostics research remains the lowest-funded research category. The \$31.4 million invested in 2006 is just 7.3% of all 2006 TB R&D.

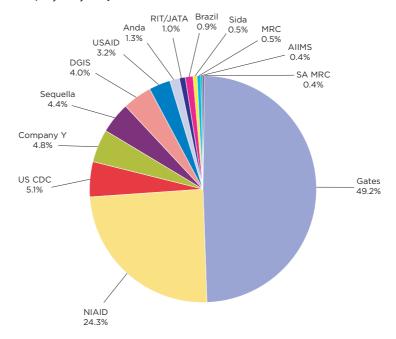
In 2006, TB diagnostics research spending increased from survey year 2005's paltry \$19.2 million—thanks to large increases by the Gates Foundation, the CDC, and Company Y.

The largest single contributor to this category was the Gates Foundation, with \$15.5 million to FIND. This puts the Gates Foundation contribution at 50% of the total diagnostic research funding committed in 2006. NIAID provided another 24% (\$7.6 million) in funding for diagnostics.

Diagnostic investments remain wholly inadequate compared with the need. In order to fulfill *The Global Plan's* 2006 projected R&D needs, diagnostic spending needs to double again to at least \$59 million.

### FIGURE 7

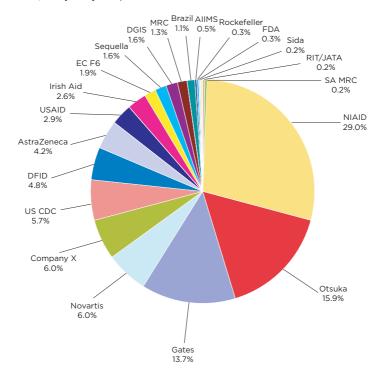
### TB Diagnostics Research (Total = \$31,424,479)



### 3.3 TB Drugs

#### FIGURE 8

### **TB Drug Research** (Total = \$144,264,486)



TAG's 42 respondents reported investing \$144 million in new TB drugs for 2006. This amounts to 34% of all TB R&D funding reported, rendering drug development the highest-funded category of investment.

NIH's NIAID was the leading donor, allocating \$42 million. Otsuka spent \$23 million, and the Gates Foundation contributed \$20 million to TB treatment research, with \$15 million of that supporting the Global Alliance for TB Drug Development. The Imperial College of London received \$4 million in Grand Challenge money to improve treatment for latent tuberculosis.

In 2005, reported TB drug development investments totaled \$120 million. The 20% increase for 2006 is largely due to the Gates Foundation and Otsuka each approximately doubling their funding in this area. Company X's expenditures dropped temporarily in 2006.

The Global Plan's proposed 2006 budget for drug research was \$418 million, almost three times more than actual 2006 spending. The Global Plan estimated that developing new, affordable TB drugs over the next ten years would cost \$4.8 billion. TAG's survey reveals a \$275 million shortfall in the investment toward new TB drugs in the first year of the Global Plan. If funding remains flat over the next decade, the investment gap for new TB drugs will reach \$2 billion.

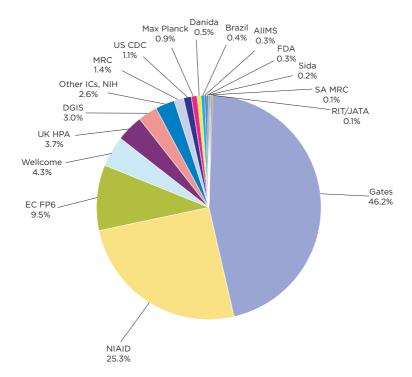
Increased disclosure by industry would be welcome. TAG salutes AstraZeneca, Company X, Novartis, Otsuka, Sequella, and Anda Biologicals for reporting investments of \$23 million, \$8.7 million, \$8.4 million, \$6 million, \$2.4 million, and \$395 thousand, respectively, in new TB drugs in 2006.

In June 2007, Eli Lilly and Co. announced the formation of a nonprofit research organization with a focus on early-phase drug discovery for TB, including emerging resistant strains. The Eli Lilly Foundation committed \$15 million over the next five years, with partners, including Merck, contributing funding, expertise, laboratories, and compound libraries. (If Lilly's annual investment of \$3 million had been available in 2006, Lilly would have been the 22nd-largest research donor.)

### 3.4 TB Vaccines

#### FIGURE 9

### TB Vaccine Research (Total = \$78,092,104)



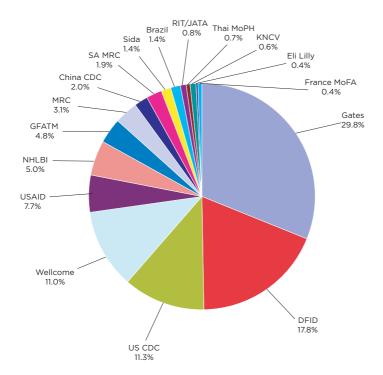
In 2006, TB vaccine R&D spending was \$78 million; 18% of all reported research, and \$8 million more than 2005's total investment of \$70 million. The Gates Foundation was the leading benefactor, providing \$36 million, mostly to the Aeras Global TB Vaccine Foundation. NIAID supported \$20 million in TB vaccine research. The EC spent \$7.4 million; the Wellcome Trust, \$3.4 million; and the UK Health Protection Agency (HPA), \$3 million.

The Global Plan estimated that \$291 million was needed to support TB vaccine R&D in 2006. Meeting this target would require a nearly fourfold increase from the \$78 million reported in 2006.

### 3.5 Operational Research

#### FIGURE 10

### TB Operational Research (Total = \$32,097,698)



Operational research saw the smallest increase of all TB R&D categories, from \$31 million in 2005 to \$32 million in 2006. The Gates Foundation was the largest investor in this area, with \$9.5 million directed to the Consortium to Respond Effectively to the AIDS/TB Epidemic (CREATE).

DFID was the second largest investor in operational research, with \$5.7 million supporting the Knowledge Program at the London School of Hygiene & Tropical Medicine and Tropical Disease Research, among other programs.

The US CDC, the third largest contributor, spent \$3.7 million on TB operational research in 2006. Botswana and the CDC are jointly implementing isoniazid preventive therapy. The CDC supports a variety of intensified TB case-finding activities in HIV programs in Africa, as well as HIV testing within TB programs.

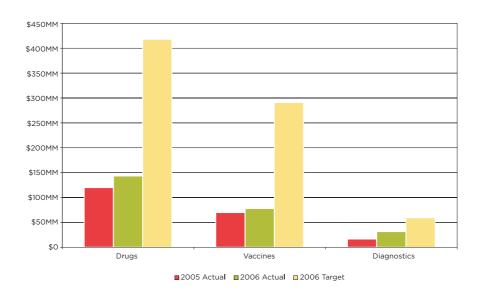
### 4 Funding for TB R&D in Context

### 4.1 TB R&D Relative to the Global Plan

Although investments in applied science increased from 2005 to 2006, when measured against the Global Plan's projection of \$768 million needed in 2006, funding fell short by over \$300 million. Diagnostics funding lagged by \$28 million, drug development by \$274 million, and vaccines by \$213 million during this period. However, this shortfall does not reflect the true need for TB R&D as it did not include resource estimations for basic and operation research.

#### FIGURE 11

### **Global Plan Investment Targets 2006**



### 4.2 TB R&D Funding Relative to Other Diseases

HIV/AIDS received the most funding of any specific infectious disease at the NIH in 2006 at \$2.9 billion. By contrast, and despite the rising worldwide death toll and increasing drug resistance, TB research receives far less than its due.

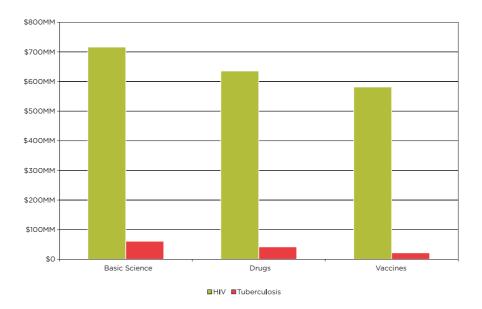
### TABLE 5

### NIH Spending on Selected Infectious Diseases in 2005 and 2006 (millions of US dollars)

Infectious disease	FY05 actual	FY06 actual	FY07 actual	FY08 est.	
HIV/AIDS	2,921	2,902	2,906	2,913	
STDs/herpes	252	264	288	287	
Smallpox	187	149	122	123	
Anthrax	183	150	105	105	
Influenza	164	207	271	271	
Tuberculosis	158	150	166	165	
Pneumonia	154	145	132	132	
Hepatitis C	179	177	174	173	
Malaria	104	98	104	106	
http://www.nih.gov/news/fundingresearchareas.htm					

### FIGURE 12

### NIH Investment in HIV and TB Research (2006)



### 5 Conclusion

From 2005 to 2006, global spending on TB research and development increased by 16% from the shameful \$368 million to the still embarrassingly inadequate \$429 million, compared to the \$2 billion annual investment that TAG estimates is needed.

TAG's report on 2006 TB R&D spending reveals a grave picture of inadequate growth. Public-sector investment is falling as a proportion of the total. Philanthropic investment is rising, but not fast enough to meet the needs laid out in the *Global Plan*. The funding gap for new tools research in 2006 reached half a billion dollars. The world is not coming close to meeting obligations outlined in the *Global Plan*, committed to by countries at the World Health Assembly, and at the UNGASS review. TAG stands by its recommendation that TB R&D investments must increase fivefold to \$2 billion per year in order to support the basic, applied, and operational research necessary to develop new tools to ultimately eliminate TB.

The U.S. National Institutes of Health (NIH), by far the world's largest funder of TB research as well as biomedical research as a whole, has suffered from flat funding since 2004. With inflation factored in, NIH-supported research is actually shrinking. Until this trend is reversed, it is unlikely that new NIH investments for TB or for many other urgent health research needs will be forthcoming.

Europe's research funding situation is a jigsaw puzzle of complexity, lack of transparency, lack of coordination, and lack of clear priorities. With few exceptions, most of the wealthier European Union (EU) countries were not in a position to either report on or increase their investments in TB research. A few exceptions were the UK's DFID, Irish Aid, and the Netherlands Foreign Ministry.

In spite of the disappointing overall results, TAG would like to salute the individual donors whose increased investments are on track to meet the global R&D goals: Irish Aid, which increased its investment 946% in one year; DFID (526%), Brazil (434%), Novartis (286%), Company Y (200%), Sida (191%), Sequella (167%), Danida (144%), Otsuka (86%), DGIS (85%), and the Gates Foundation (68%). These 11 donors get gold stars for their commitment to increased TB research funding in 2006.

# Appendix A: 42 Reporting TB R&D Funders in 2006

1	U.S. NIAID, NIH	119,771,818
2	Bill & Melinda Gates Foundation (BMGF)	96,466,861
	Otsuka Pharmaceutical Company	22,900,000
	The Wellcome Trust	18,380,741
5	Other NIH institutes & centers	17,579,000
6	U.S. Centers for Disease Control & Prevention (CDC)	17,057,774
7	U.S. NHLBI, NIH	13,139,592
8	European Commission Sixth Framework Programme	12,844,807
9	UK Department for International Development (DFID)	12,576,339
_	Institut Pasteur	8,785,490
11	Novartis Institute for Tropical Diseases	8,700,000
12	Company X	8,700,000
13	UK Medical Research Council (MRC)	8,111,736
14	USAID	7,700,000
15	AstraZeneca	7,200,000
16	India ICMR/TB Research Center (TRC)	6,347,873
17	Netherlands Minisitry of Foreign Affairs (DGIS)	5,864,942
18	Brazil (amalgamated)	4,031,671
19	Irish Aid	3,765,210
20	Sequella, Inc.	3,743,000
21	UK Health Protection Agency (HPA)*	3,689,954
22	Canadian Institute of Health Research	3,257,764
23	Russian TB institutes	2,772,000
24	Germany, Max Planck Institute for Infectious Biology	1,910,000
25	Ellison Medical Foundation	1,850,000
26	Global Fund to Fight AIDS, Tuberculosis and Malaria	1,534,259
27	Company Y	1,500,000
28	Swedish International Development Cooperation (Sida)	1,415,691
29	Research Institute of Tuberculosis and Malaria	1,358,568
3C	All India Institute of Medial Science (AIIMS)	1,299,004
31	South Africa Medical Research Council (SA MRC)*	1,240,620
32	U.S. FDA	651,224
33	China CDC National Tuberculosis Reference Laboratory*	626,059
34	Rockefeller Foundation	450,000
35	Denmark Ministry of Foreign Affairs (Danida)	415,627
36	Anda Biologicals*	395,347
37	Ireland Health Research Board*	385,705
38	Thailand Ministry of Public Health	226,463
39	KNCV Tuberculosis Foundation	199,556
40	Eli Lilly Foundation	140,000
41	France Ministry of Foreign Affairs Coöperation Française	131,782
42	Swiss Agency for Development and Cooperation	50,203
	Total	429,166,680
	*Newly Reporting for 2006	

Basic Science	Diagnostics	Drugs	Vaccines	Operational	Unspecified/ Infrastructure
50,550,368	7,633,583	41,850,752	19,737,115		
15,620,000	15,457,000	19,782,659	36,084,667	9,522,535	
		22,900,000			
11,495,530			3,378,897	3,506,314	
			2,055,000		15,524,000
	1,607,973	8,182,615	873,500	3,620,934	2,772,752
 10,429,308				1,585,284	1,125,000
 2,673,440		2,728,522	7,442,845		
		6,901,864		5,674,475	0.705.400
		0.700.000			8,785,490
		8,700,000			
 0.000.000	100 510	8,700,000		4 000 707	
 3,936,082	160,510	1,910,305	1,101,112	1,003,727	
	1,008,333	4,244,583		2,447,084	1 000 000
		6,000,000			1,200,000
	1.055.070	0.050.100	0.050.740		6,347,873
 E00.170	1,255,070	2,259,126	2,350,746	422.002	907.964
 509,179	296,732	1,589,191	305,622	433,083	897,864
	1 205 000	3,765,210			
 764,654	1,385,000	2,358,000	0.005.300		
 704,054			2,925,300		3,257,764
					2,772,000
 1,200,000			710,000		2,112,000
 1,850,000			7 10,000		
1,000,000				1,534,259	
	1,500,000			1,004,200	
381,148	163,349	272,248	163,349	435,597	
85,985	300,949	257,956	68,788	257,956	386,934
150,744	136,571	710,107	219,505	82,077	
186,093	124,062	248,124	62,031	620,310	
		453,224	198,000		
		·		626,059	
		450,000			
			415,627		
	395,347				
385,705					
				226,463	
				199,556	
				140,000	
				131,782	
				50,203	
100,218,236	31,424,479	144,264,486	78,092,104	32,097,698	43,069,677

# Appendix B: Actual or Potential TB R&D Funders Not Reported On

### Respondents not disclosing (3)

GlaxoSmithKline
Sanofi Aventis
Howard Hughes Medical Institute\*
\* HHMI does not track data by specific funding areas.

### Respondents stating they are not original sources of TB research funding (5)

Boehringer Ingelheim Gilead Sanofi Pasteur Swedish Institute for Infectious Disease Control International Centre for Diarrhoeal Disease Research, Bangladesh

# Appendix C: Methodology in Detail, and Data Limitations

Funding data were collected largely from original-source donors. In some cases TAG relied on data from funding recipients. TAG also tracked product development public-private partnerships. When possible data were cross-referenced in order to avoid double counting.

In our 2005 report, we received a low response rate from the private sector. For 2006's report, TAG emphasized the option of anonymous disclosure, which failed to boost industry response. Two companies provided information on a confidential basis in both reports. They are designated Company X and Company Y.

TAG asked respondents to classify TB R&D investments into five major research categories:

- Basic Science
- Diagnostics
- Drugs
- Vaccines
- Operational Research

In 2005, we found that most respondents had difficulty categorizing their investments as preclinical or clinical. Thus, in neither report could we distinguish between preclinical and clinical research. However, we strongly recommend that future R&D mapping efforts gather and present data on the magnitude of investments in preclinical and clinical research.

On the recommendation of the WHO's Global TB Surveillance, Planning and Financing Project (Floyd 2006), TAG sought to ensure exchange-rate consistency by using the Oanda currency site (www.oanda.com/convert/classic) and selecting 30 June 2006 as the date to convert foreign expenditures into U.S. dollars at interbank conversion rates. Among funders there are different fiscal years, and domestic investments are not converted, so purchasing power parity (PPP) conversion rates may be more appropriate in some cases (e.g., Brazil, India, Russia, Thailand).

#### **Data Limitations**

Five respondents stated that they are not primary funders of TB and three respondents declined to provide data; two from industry provided qualitative but not quantitative data (see appendix B).

Some of the surveyed investors did not have data on their TB R&D investment readily available. In some cases, respondents appeared to select information from disparate lines of funding, producing data that were difficult to categorize. These findings were placed in the catchall "unspecified" category. In addition to some investors' poor internal tracking, another challenge was the lack of universal standards defining categories of TB R&D.

Attempts to gather data for TB research conducted within other research programs such as those for HIV proved difficult. For example, researchers investigating TB and HIV together may only code their studies as HIV research; TAG's survey could not identify that research.

Some donors reported money awarded to research institutions that focus on infectious diseases but did not specify the amount apportioned to TB. In these cases, TAG relied on the recipient to report on spending activity; there may be discrepancies between stated donor funding and reports from the recipient agency. TAG deferred to donors' statements whenever possible. Funders and research organizations employ various means of recording grants—for example, commitments or awards made one year may be disbursed the following year. TAG tried to adhere as strictly as possible to counting actual money disbursed in calendar year 2006.

Eight of thirty-one surveyed pharmaceutical and biotechnology companies disclosed financial information. Two declined, despite being given the option to have their totals presented anonymously or only as an aggregate. Three companies replied that they do not participate in TB research and another eighteen did not respond at all. Because the commercial sector is often unwilling to reveal investments or returns to the public, TAG is not able to quantify industry support for TB research in total. The eight responding companies include the two that preferred to remain anonymous, as well as Anda Biologicals, AstraZeneca, Eli Lilly, Novartis, Otsuka, and Sequella, whose commitments to TB R&D and to transparency are commended.

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Newland, UK Medical Research Council (MRC); Matti Ojanen, AstraZeneca; Ikushi Onozaki, Research Institute of Tuberculosis, Japan Anti-TB Association; Hannah Peavy, NHLBI, National Institutes of Health (NIH); Viveka Persson, Swedish International Development Cooperation (Sida): Carol Rocha, Ellison Medical Foundation: SK Sharma. All India Institute of Medical Sciences; Christine Sizemore, National Institute of Allergies and Infectious Diseases (NIAID), NIH; National Institutes of Health (NIH); Martin Smith, **UK** Department for International Development (DFID); Marge Tenério, Brazil, MOH Department of Science & Technology (DECIT); Jelle Thole, TB-VAC; Marieke van der Werf, KNCV Tuberculosis Foundation; Harry van Schooten, Netherlands Ministry of Foreign Affairs (DGIS); Caroline Shewchuk, Canadian Institute of Health Research; Andrew Vernon, Centers for Disease Control and Prevention (CDC); Amy Welton, Bill & Melinda Gates Foundation: Karin Weyer, South Africa Medical Research Council (SAMRC); Jennifer Woolley, Aeras Global TB Vaccine Foundation; Zhao Yanlin, China CDC National Tuberculosis Reference Laboratory; and Marty Zug, Sequella, Inc.

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