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A Review of Pharmaceutical Company Contributions:

HIV/AIDS, Tuberculosis, Malaria and Other Infectious Diseases

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I. Annual Contributions to HIV/AIDS, Tuberculosis, and Malaria

The contributions of pharmaceutical companies for global HIV/AIDS, tuberculosis, malaria, and other infectious diseases are substantial. The estimate for pharmaceutical companies' total foreign assistance for 2003 is just over \$2 billion. This estimate is based on the dollar value of their product donations and cash contributions for global health programs. It remains a conservative figure since it does not include cause-related marketing or philanthropic contributions by overseas affiliates.

Thus pharmaceutical research and development industries play a far larger role in the advancement of global health than is generally realized. When compared with the annual budgets of governments and international health organizations, the combined aid of pharmaceutical corporations rivals and even exceeds those of public sources. Consider the budgets of the largest international organizations and governmental contributors for 2003:

- The World Health Organization's annual budget was \$1.37 billion
- UNICEF annual budget was \$1.3 billion
- Total bilateral disbursements from European Union countries for HIV/AIDS were \$849.8 million
- The USAID Global Health Budget was \$1.374 billion
- Disbursements from the Global Fund for HIV/AIDS, TB and Malaria were \$150 million
- The World Bank's Multi-Country HIV-AIDS Program for Africa approved \$1.03 billion, of which less than \$400 million was disbursed
- The European Commission disbursements for HIV/AIDS, TB and Malaria were \$451 million

The dollar value of pharmaceutical industries' foreign assistance, however, does not provide the full measure of their philanthropic contributions abroad. Highlighted below are the global activities of several drug companies. Included in the following descriptions are some of the key

collaborative efforts among pharmaceutical corporations, humanitarian agencies, foundations, and international organizations.

Merck & Co.

The Merck Foundation provides \$50 million to the African Comprehensive HIV/AIDS Partnership in Botswana. At this time, over 26,000 AIDS patients are enrolled. Of those, 24,000 receive antiretroviral treatment with drugs donated by Merck. The partnership supports the construction of 32 regional treatment centers, and has reached educators in 70 percent of the nation's primary and secondary schools. The partnership has also supported the development of laboratory capacity to test and monitor patient response to treatment.

Merck supports a HIV/AIDS clinical training program for African physicians to help strengthen local health care capacity. Since 1997, more than 2,200 African physicians from 24 countries have participated in clinical HIV training in local workshops.

Merck and DHL announced an agreement on May 5, 2004 to team up to expand access to critically needed HIV medicines in two dozen countries throughout sub-Saharan Africa. DHL will deliver Merck's HIV/AIDS medicines at cost by air express to designated treatment centers in these countries. The partnership combines the core capabilities of the two companies to ensure rapid, secure and flexible supply for the benefit of patients in Africa.

Eli Lilly and Company

The Lilly MDR-TB partnership supports treatment, prevention and surveillance of this deadly form of drug resistant TB, now prevalent in virtually all of the countries with primary TB. This \$70 million global partnership through 2006 involves Lilly, the World Health Organization, Harvard/Brigham and Women's Hospital, Partners in International Health, the Centers for Disease Control and Prevention (CDC), Purdue University, the International Red Cross, the International Council of Nurses, the International Hospital Federation and the World Medical Association.

Lilly is transferring technology and technical assistance to three manufacturing plants in India, South Africa and China, so that they can increase the supply of critical drugs to treat MDR-TB. The company is also supporting training courses in the treatment of MDR-TB through a multimillion dollar grant to Harvard/Brigham and Women's Hospital, which, in turn, has developed a training center in Tomsk, Russia. Training and treatment activities are underway in South Africa and China as well.

The project also supports CDC and the WHO in the monitoring and surveillance of MDR-TB. To meet the growing crisis in drug-resistant TB, Lilly has doubled production of one of its own critical drugs for MDR-TB and is providing two other drugs at a fraction of their cost to WHO-approved "DOTS-Plus" treatment programs.

Pfizer, Inc.

Pfizer and the Pfizer Foundation have contributed over \$48 million to HIV/AIDS programs around the world, with grants totaling more than \$8 million and products totaling more than \$39 million. The foundation has awarded \$5 million in grants to improve HIV/AIDS prevention, care and treatment in Africa, Asia, the Caribbean and Latin America since 2002.

In Uganda, Pfizer initiated a partnership between its leading medical school and the University of Utah to establish peer-to-peer relationships among their respective medical faculties. For each Ugandan physician trained in HIV care and treatment, he or she is then responsible for training 10 more of his countrymen. Those 10, in turn, will continue the upward cycle of physician training in clinical AIDS care.

Based on this experience, Pfizer then built Uganda's first Infectious Disease Institute in Kampala which opened on October 21, 2004. It provides both a training site for physicians and technicians, and a first-rate laboratory for monitoring and testing patients undergoing AIDS treatment and care. Taken together, Pfizer has spent over \$60 million in these two endeavors.

Bristol Myers Squibb

In 1999, BMS initiated a five year \$115 million HIV/AIDS program in five Southern African countries. Called, "Secure the Future," the program provides ARV medicines, as well as inputs to health management, medical research and education, community education and outreach, and capacity-building programs for women and children infected or affected by HIV/AIDS. The partnership involves local governments, UNAIDS, medical and religious institutions, and communities.

The UN/Industry Accelerating Access Initiative (AAI)

UN/AAI is a cooperative endeavor of six research-based pharmaceutical companies, UN/AIDS, WHO, UNICEF, the UN Population Fund, and the World Bank. Participants are committed to working with governments, international organizations, and other stakeholders to find ways to broaden access while ensuring rational, affordable, safe and effective use of drugs for HIV/AIDS-related illness. Since May 2000, 89 countries have indicated their desire to heighten efforts to deal with the HIV epidemic. Of these, 59 countries have developed comprehensive national programs—and 49 of these have reached agreement with the individual manufacturers involved in AAI to implement increased access to antiretroviral treatments at significantly reduced drug prices in the context of their national plans.

In July 2004, WHO estimated that 440,000 AIDS victims were receiving antiretroviral treatment in the developing world, including 136,000 in Brazil alone. Of the total, more than 350,000 are provided with discount medications through AAI in Africa. Outside of Brazil, which began its national program in 1998, almost 50% of the remaining patients are obtaining their AIDS drugs through the AAI program.

The AAI program has attached no monetary value to its discount drugs. Given, however, that its products of proven FDA quality, safety and efficacy are priced lower then untested copy products from India, and sold at no profit, that value has to be considerable.

GlaxoSmithKline

As a partner in the UN/AAI Program, GSK distributed daily at discounted rates, 27,000 ARV treatments of its fixed dose combination drug in 56 countries.

In 2003, GSK extended a voluntary license to the generics manufacturer Aspen Pharmacare, in South Africa. Under this agreement Aspen can now manufacture and sell key GSK ARV's across sub-Saharan Africa, in both the public and private sectors. These will be true generic products rather than copy products of uncertain quality and safety.

GSK's preferential pricing for ARV products in the UN/AAI Program extends also to vaccines. This applies to the UNICEF/WHO Expanded Programme for Immunization, but it now includes combination vaccines when purchased for use in other public immunization programmes in the developing world.

The Partnership for Quality Medicines Donations

In 2003, a survey was conducted by the Center for Pharmaceutical Health Services Research at the Temple University School of Pharmacy, sponsored by the Partnership for Quality Medical Donations (PQMD), an alliance of nine drug companies and a dozen humanitarian agencies. The survey found that:

- Medical product donations distributed overseas by PQMD nongovernmental (NGO) members funded 4,147 long-term development projects and 189 disaster-relief missions in 89 countries in Africa, Asia, the Caribbean, Latin America, and Eastern Europe
- The dollar value of these donations topped \$1.4 billion, up from \$812 million in 2002 and \$546 million in 2001

The annual figure is undervalued because it does not include drug donations made by the other 24 non-PQMD pharmaceutical firms. Nor does it take into account that PQMD members, as well as other pharmaceutical companies and humanitarian agencies, administer healthcare free of charge to uncounted millions of patients who otherwise are unlikely to receive care. Doctors, nurses, pharmacists, and technicians donate their time as well to these programs. They teach and provide logistical services, manage the programs, and arrange transportation and warehouse storage for medicine and equipment.

The following table provides a break down of the \$2 billion estimate. The table includes the donated medical products of nine pharmaceutical companies to the Partnership for Quality Medicines Donations program as well as the total value of cash contributions by pharmaceutical companies to global AIDS, TB and malaria programs.

Table 1. Estimated International Contributions byPharmaceutical Companies, 2003*

The Partnership for Quality Medicines Donations**	\$ billions
Value of Donated Products	\$1.400
Transport, Insurance and Handling (10%)	.140
Taxes, Custom Duties (15% of original value)	.210
In-country transport, storage, distribution, logistical services, volunteer time of doctors, nurses, pharmacists, and program management (15% of original value)	.210
Subtotal	\$1.960
Cash Value of Company Projects Annualized for 2003 (separate from PQMD)***	\$.175

Total	\$2.135

*This table does not include the estimated \$9 million in donated transportation and insurance costs by the six companies selling drugs at cost to the UN/AAI program. **Abbott, Becton Dickinson, Boehringer Ingelheim, Bristol-Myers Squibb, GlaxoSmithKline, Johnson and Johnson, Merck, Pfizer, and Wyeth

*** Merck, Pfizer, Bristol-Myers Squibb, Eli Lilly and Company, GSK, Abbott, Astra-Zeneca, Aventis, and Roche

II. Additional Ways that Pharmaceutical Companies Contribute to Global Public Health

Beyond the scope of direct donations and cash contributions, pharmaceutical companies continue to contribute to global public health in three significant ways. First, many have agreed to share medical and technological expertise, a step that will allow countries afflicted with HIV/AIDS, tuberculosis, malaria and other infectious diseases to develop their own pharmaceutical industries. Since 2003, Eli Lilly and Company has transferred technologies for tuberculosis drugs and has mentored three countries (India, Russia, South Africa) on how to produce these drugs in their own production plants. In July of 2004, Merck agreed to license one of its ARV products to the South African pharmaceutical company, Aspen. This will allow Aspen to use Merck's patent and produce a true generic ARV, in accordance with FDA standards, for the African market.

Second, several drug companies continue to invest in the development of new medicines for HIV/AIDS, malaria, and tuberculosis, even though these drugs yield low returns when compared with drugs for cancer, hypertension, heart disease or even erectile dysfunction. Drugs for tropical diseases, and many infectious diseases, have minimal markets in developed countries compared to markets in developing countries where people generally cannot afford them, even at a zero price, because the medical infrastructure to support therapies is largely absent.

Pharmaceutical R&D industries have chosen to invest capital for AIDS, tuberculosis, malaria and infectious diseases -- in spite of severe financial set backs. Losing 27 percent of its stock value after pulling Vioxx from the market in October 2004, Merck continues to fund a massive R&D effort of several hundreds of millions of dollars on a vaccine for AIDS. It also continues to

donate all the products necessary to combat river blindness in Africa and South America, as well as to provide program support activities. In 2003, 40 million patients were treated for river blindness.

Other examples of current research and development efforts include (companies are unable to provide exact values as this is proprietary information):

- Novartis has invested several hundred of millions of dollars to develop an Infectious Disease Research Center in Singapore, focusing initially on tuberculosis and malaria. When drugs are finally produced, they will be sold at no profit.
- Pfizer has an extensive R&D effort for a malaria therapy, which is now in clinical trials. It is also developing drugs to control opportunistic AIDS infections.
- GSK has an extensive R&D effort underway on WHO's priority diseases: HIV/AIDS, tuberculosis and malaria. It currently has 15 clinical development programmes for products of relevance to the developing world. Several of these are aimed specifically at diseases that disproportionately affect developing countries, such as vaccines for HIV, dengue fever, hepatitis E, pediatric pneumonia, and N. meningitides. It is currently investing more than \$200 million in a new R&D facility in Spain dedicated to Diseases of the Developing World (DDW), such as tuberculosis and malaria.
- Merck, Bristol-Myers-Squibb and Gilead announced in May 2004 plans to develop a onceday, fixed dose combination of three anti-HIV drugs in response to simplified treatment regimens in developing countries. This multi-company effort to create a fixed-dose product with three patented HIV/AIDS medicines is the first of its kind in the field of HIV.

Third, the largest contribution of pharmaceutical companies by far, has been their unprecedented response in developing the initial drugs to treat HIV/AIDS.

Up until 1988, there were no medicines to combat global AIDS. After Dr. Robert Gallo and Dr. Luc Montagnier discovered the virus in 1981, there was an explosion of new drug discoveries. Since 1988, twenty-five separate HIV-related medicines were developed by research based industries. According to the Tufts University Center for the Study of Drug Development, it costs a company \$802 million to get one new medicine from the laboratory to patients, placing the total value of these discoveries to the benefit of humankind at \$17.6 billion.

New research and development continues. In 2003, pharmaceutical companies had the following HIV-related medicines in Phase 1, 2 and 3 clinical trials: 4 for antifugals; 7 for anti-infectives; 33 for antivirals; 9 for immunomodulators; 15 for an AIDS vaccine; and 13 for other types of opportunistic infections.

The number of AIDS cases continues to rise unchecked. Patients the world over are depending on this engine of innovation to continue its all-out efforts to develop novel and more effective therapies and vaccines to contain this disease.

III. Private vs. Official Development Assistance Resource Flows

While the pharmaceutical industry is the largest international philanthropic donor, international assistance from the entire range of U.S. private organizations is amazingly high. Compared to \$9.9 billion USG official development assistance (ODA) in 2000, U.S. international private philanthropy was \$35.1 billion. Even though U.S. ODA ranked last among other developed countries as a percentage of GNP, adding international private assistance shows the full and true measure of U.S. generosity. As president Bush has said, "Compassion is the work of a nation, not just a government."

Better understanding of private giving is needed to accurately assess American generosity toward poor people overseas. Indeed, this "silent" private financing has become the dominant expression of U. S. concern for poor people abroad

	\$US billions	Percent of Total
U.S. Official Development Assistance	9.9	17%
All Other Government Assistance	12.7	22%
Total U.S. Private Assistance	35.1	61%
Foundations	3.0	
Corporations	2.8	
PVOs (including volunteer time)	6.6	
Universities & Colleges	1.3	
Religious Congregations	3.4	
Individual Remittances	18.0	
Total U.S. International Assistance	57.7	100%

Table 2. More Assistance Than Meets the Eye

Estimated U.S. International Assistance to Developing

Countries, 2000

Notes to table 2:

- 1. Only the \$9.9 billion is counted toward ODA, and considered as part of a 0.7% donor performance measure originated by the World Council of Churches in 1958. While the Development Assistance Committee (DAC) of Organization for Economic Co-operation and Development (OECD) has since abandoned this percentage, it lingers as a sole expression of a government's largesse by the World Bank.
- 2. The OECD does not allow the \$12.7 billion for all other U. S. government assistance to be counted as ODA even though it represents significant foreign assistance. It consists of contributions to the IMF, Export-Import Bank, OPIC, State Department operations, Department of Defense international security assistance, and Part 2 countries. These include

all of Central and Eastern Europe, Belarus, Israel, Russia, Ukraine, and a variety of island states, such as Cyprus.

- 3. Private assistance at \$35.1 billion is easily an undercounted figure. For instance, there is no complete accounting of international giving by religious organizations. Also, many corporations have decentralized their charitable giving to overseas operations where they are aggregated in either marketing or advertising budgets. As such, they are not reflected in the Conference Board report used as the source for corporate international giving here.
- 4. Nor does the corporate total include "cause-related marketing." This is a new form of giving, mainly by corporations. For instance, when a consumer purchases a cup of coffee from Starbucks, there will be a notation on the cup: you have just contributed 5 cents to Global AIDS. As in item (3) above, these are considered marketing/advertising expenses and are not included in standard surveys or reported to the IRS. Experts believe that "cause related marketing" accounts for tens of billions of dollars in contributions.
- 5. Remittances are a newly recorded form of development assistance. In 2000, they accounted for 10% of GNP in six Latin American countries, exceeding the amounts sent by USAID and all multilateral funding agencies. The U. S. Department of Commerce's Bureau of Economic Analysis began collecting data on remittances in 1998, and the Inter-American Development Bank is helping to create a new remittance transfer system that generates development capital from transfer fees. Private giving by immigrants fills basic needs for poor people in developing countries. President Vicente Fox of Mexico has proposed matching remittances if they are used for social projects, such as schools and health clinics. A World Bank conference on this subject reported, "poverty is much lower among households that have been left by emigrants."
- 6. Whether church/corporate/cause related giving is accurately counted or reported to the IRS is immaterial to the measurement of American generosity. In one way or the other, it represents 'the commons' of giving for international assistance, setting the U. S. apart from almost every other country in the world.
- 7. The year 2000 was the last year for which comparable public/private data were available. In 2004 ODA has increased because of increased contributions to AIDS and the beginning of the Millennium Challenge Corporation (MCA). We have not yet updated the private international aid numbers to correspond to higher ODA numbers in 2004.