'Benchmarking AIDS: Evaluating Pharmaceutical Company Responses to the Public Health Crisis in Emerging Markets'
Pfizer Analysis and Comments (September 12, 2006)

General Discussion

Before sharing specific observations on the report, we would like to identify two issues of process. First, we note that the title has changed from "Benchmarking AIDS: Evaluating Pharmaceutical Company Responses to the HIV-TB-Malaria Pandemics" to "Benchmarking AIDS: Evaluating Pharmaceutical Company Responses to the Public Health Crisis in Emerging Markets." This considerably expands the objective of the report in covering: (1) the entire range of neglected disease; (2) all issues that account for the public health crisis (e.g. infrastructure, human resources, R&D etc) and (3) geographic regions including "emerging markets." This represents highly differentiated areas of inquiry, requiring the adoption of alternative approaches among a complex array of stakeholders and institutional factors. Generalizations from the initial report to the latter are misleading and bundling these issues together muddles the objective and overall value of the report.

Second, it is unclear how the author decided to integrate the information that Pfizer provided in its response to the draft in April. Some corrections we made were not addressed. For example, despite a detailed Pfizer response to the philanthropy critique, the report still suggests that the Diflucan Partnership Program is available in only 21 countries, whereas it is now available in 47 countries. It also omits our profiles of the International Trachoma Initiative, the Infectious Diseases Institute and the Global Health Fellows, and the principles we developed in outlining our approach to philanthropic initiatives.

Limited assessments of best practices are not a useful method to benchmark pharmaceutical companies. We believe the process followed by ICCR could be improved by incorporating the approach used by the UNAIDS Programme AIDS in Africa Scenario project, which brought together 60 participants from diverse backgrounds to discuss the issue of HIV/AIDS in the context of developing countries, in a consultative framework that built consensus and developed solutions[1]. The project identified the following issues as most critical in addressing the AIDS pandemic:

- infrastructure (lack of trained healthcare professionals, poorly equipped clinics)
- governance (corruption, political will and high taxation of medicines)
- culture (stigma of the disease, gender inequities)
- economics (debt and trade barriers)
- demographics (poorly controlled immigration).

Our comments below are organized according to the four segments of the 8/1/2006 report – Introduction & Context, Methodology, Best Practices and Company Profile for Pfizer.

[1] http://www.unaids.org/en/AIDS+in+Africa_Three+scenarios+to+2025.asp

Some of this reiterates our previous response in April, which we submit because it was not incorporated into the report.

Introduction & Context (pages 13-16)

There is no acknowledgement of the R&D-based sector's contributions to HIV/AIDS and neglected diseases in the introduction and context section. A more robust and compelling perspective would recognize the R&D sector's accomplishments, contributing to the fight against HIV/AIDS and other diseases endemic in resource limited settings. For example, the industry has produced some 80 approved therapies for HIV/AIDS-related illnesses, including 24 anti-retrovirals with improvements in dosage and combinations decreasing the pill burden per day from 20 pills per day to one in just ten years. Additionally, the industry has approximately 79 potential therapies under development including several new drugs that attack unique mechanisms of action[2].

Meeting "global expectations on access to medicines" (page 14)

It is unclear what "global expectations" refers to as stakeholders diverge on (1) what the barriers to access are; (2) how to address them; and (3) where to prioritize activities that best take account of limited resources. Further, for those activities that have been prioritized, it is doubtful that governments most affected by the epidemics have allocated appropriate funding. At the African Summit on HIV/AIDS, Tuberculosis, and Other Related Infectious Diseases in Abuja, Nigeria in 2001, the region's political leaders pledged to allocate 15% of their annual budgets to strengthening health systems.[3] However, most countries remain well short of the target.[4]

There is a continuing need to bring all relevant stakeholders to the table to discuss openly what the real issues are that impede access to enhance healthcare in resource limited settings. Pfizer supports a broader approach to understanding this set of problems and has participated in numerous partnerships to address the real issues comprehensively. Without this dialogue, individual stakeholders will tend to proceed based on their own experiences and likely arrive at different conclusions, thwarting efforts to build consensus around solutions.

Finally, for many diseases that are often referred to as neglected (i.e., endemic in tropical zones), successful control and elimination programs have been established. Examples of such successful programs are briefly described in the table below.

[2] "79 New Medicines In Development For HIV/AIDS." PhRMA Press Release, November 2004.
[3] Abuja Declaration on HIV/AIDS, Tuberculosis and Other Related Infectious Diseases. African Summit on HIV/AIDS, Tuberculosis and Other Related Infectious Diseases. Abuja, Nigeria, 24-27 April, 2001.
[4] Martin, G. A comparative analysis of the financing of HIV/AIDS programmes in Botswana, South Africa, Swaziland and Zimbabwe, October 2003. (Research Monograph, Research Programme on the Social Aspects of HIV/AIDS and Health). Cape Town: HSRC Publishers.

Successful Diseases Control Programs[5]

Disease/Program	Pharmaceutical Industry's Contributions[33]	Achievements
Onchocerciasis *Mectizan Donation Program*	Merck donates Mectizan® (ivermectin) to all who need it and as long as necessary. To date, the company has donated over one billion tablets, with more than 300 million cumulative treatments distributed.	Over 25 years, the Onchocerciasis Control Program has protected approximately 11 million children against onchocerciasis – and around 1 million people have been saved from blindness. Some 250,000 km2 of previously infested areas has been resettled and is now being cultivated. [34]
Leprosy *Global Alliance to Eliminate Leprosy*	Novartis donates $35 million in multi-drug treatment for leprosy, and works with WHO and other partners to improve delivery and care.	Over 13 million people have been cured of leprosy and the prevalence rate has dropped by over 90 percent since 1985, and the number of countries considered endemic has been reduced from 122 to 15.[22]
Lymphatic Filariasis *Global Alliance to Eliminate Lymphatic Filariasis*	GlaxoSmithKline donates albendazole, and Merck donates ivermectin (Mectizan®). To date 250 million treatments of albendazole and 20 million treatments of Mectizan® have been donated.	By the end of 2003 almost 80 million people in 37 countries had received treatment for lymphatic filariasis. This is a marked increase compared to the year 2000 when only 3 million people at risk were covered.[35]
Guinea Worm *Guinea Worm Eradication Program*	Johnson&Johnson has donated enough medical supplies such as Tylenol®, forceps and gauze, to treat more than 3,000 villages in the endemic countries.	The number of people suffering from guinea worm has dropped from 10-15 million at the start of the 1980s to 32,000 in 2003. Globally, over 150 countries and territories have been certified free of parasite transmission.[22]
Blinding Trachoma *International Trachoma Initiative*	Pfizer has donated more than $130 million in product donations (Zithromax®) and health educational grants.	Over 5 million people have been rid of active trachoma infection through antibiotic treatment and more than 70,000 cases of blindness have been prevented through surgeries.[36]
African trypanosomiasis *WHO Program to Eliminate Sleeping Sickness*	Aventis has supplied some 1.2 million drug ampoules of three medicines used in treatment, as well as financially supported the work of mobile medical teams and research activities of WHO on a new formulation of a drug for African trypanosomiasis.	During the past three years, more than 60,000 people have benefited from this initiative, receiving medical counsel, screening and treatment.

[5] IFPMA. Research and Development of Neglected Diseases: Lessons Learned and Remaining Challenges. October 2004.

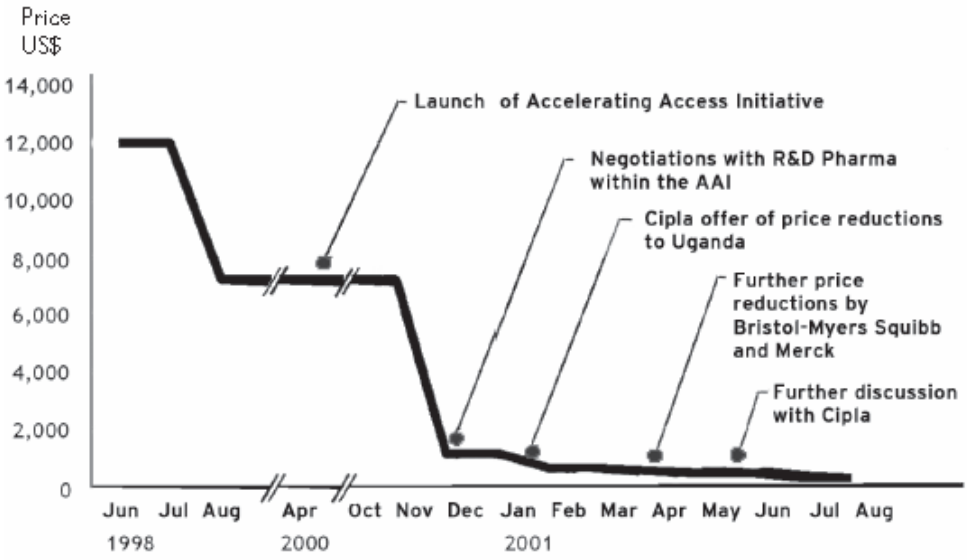
"The Medicines and Related Substance Control Act" (page 14)

Pfizer was not party to the lawsuit -- filed in 1998 -- seeking to challenge South Africa's amended Medicines and Related Substance Control Act (Act 90 of 1997).

"Generic production of AIDS drugs has led to a remarkable drop in the cost of treatment from 2000 to 2006." (page 15)

As illustrated by the chart below, R&D-based companies have contributed to the effort to reduce the cost of medicines in developing countries.

Figure 6.1: Prices (US$/year) of a first-line anti-retroviral regimen in Uganda, 1998–2001



Source: UNAIDS (2002b), p. 146, Figure 34. Reproduced with permission.

As of December 2005, the Accelerated Access Initiative (AAI) reported that more than 716,000 people living with HIV/AIDS in developing countries were receiving treatment with at least one ARV medicine provided by the AAI companies -- over half of the estimated 1.3 million under treatment in LDCs[6,7].

The members of the AAI, in collaboration with UNAIDS and WHO, have agreed on a common approach to identify patients treated. The information is collected and calculated by an independent party, Axios International. Few other organizations have

[6] The Accelerating Access Initiative (AAI) is a partnership of five United Nations organizations (UNAIDS Secretariat, WHO, UNICEF, UN Population Fund, and the World Bank) and seven research-based pharmaceutical companies (Abbott, Boehringer-Ingelheim, Bristol-Myers Squibb, Gilead Sciences, GlaxoSmithKline, Roche, and Merck & Co., Inc.), designed to improve access to more affordable HIV-related medicines and diagnostics for developing countries and those hardest hit by the epidemic, in the context of a broader framework of care, treatment and support.

[7] Accelerating Access Initiative (AAI) - Fact Sheet, December 31, 2005.

developed such exacting analytic and methodological standards to account for delivery of medicines.

Responsibilities/Actors Chart (page 15)

Both the private and public sector have a role to play in the delivery of medicines.

Comprehensive literature of best practices (page 16)

These reports, such as the Ethical Investment Research Service inventory of best practices, echo many presumptive claims, asserting that the industry is accountable for the access challenges they propose that the remedy is the elimination of patent protection for pharmaceuticals. It would be valuable to review the R&D industry's perspective, which is summarized in the IFPMA booklets, "Research and Development for Neglected Diseases: Lessons Learned and Remaining Challenges" and "The Pharmaceutical Innovation Platform."

Methodology (pages 17-18)

MSF Pricing of ARVs (page 17)

A study by the Hudson Institute, *Myths and Realities on Prices of AIDS Drugs*, reveals that most single- and fixed-dose ARV patent drugs are either less expensive or competitively priced against their copy drug counterparts. This is mainly due to the details of price tenders. R&D companies normally include the cost of transportation and supply chain quality controls in their prices, while copy producers do not. Such costs are often 10 per cent or more of the ex-factory price and if this differential is added in, the prices of R&D companies are actually quite competitive.

Price bids by copy producers also normally contain many conditions, such as guarantees that the purchaser agree to contract for a large volume of product. For example, agreements negotiated by the Clinton Foundation have required as conditions:

1. Large irrevocable orders over a five year period;
2. Executed only on formal Letters of Credit; and
3. Contingency to obtain starting materials at a discount sufficient to justify the proposed price.

Best Practices (pages 18-32)

Many presumptions are made in the subsections on best practices despite the fact that there is no consensus among stakeholders on what are "best practices" – those often depend on individual settings and circumstances. We would have appreciated a discussion on these issues, linked to the environmental context and a company's own assessment, to find common ground.

Research: Neglected Diseases (page 20-21)

Effective solutions to combat the research gap require a holistic approach with contributions from all stakeholders coupled with favorable regulatory treatment and government policy support. This includes all elements along the medicines development chain, from adequate private and public funding for basic medical research, private R&D incentives, to increased access and improved health care infrastructure.

A key allegation made by industry critics -- that only 10 percent of health R&D (private and public) is spent on developing treatments for 90 percent of the world's health problems -- is misleading. Non-communicable diseases such as cardiovascular diseases, cancers, psychiatric disorders and diabetes account for roughly 60 percent of global mortality and this ratio is due to increase as these diseases become more prominent in developing countries. It seems reasonable to conclude that the bulk of pharmaceutical R&D ought rightly to be concentrated on these priority indications, where cures are desperately needed.

Nor is the R&D industry neglecting the major neglected diseases. R&D-based pharmaceutical companies alone have more than 185 new medicines in development to address infectious diseases, including AIDS, TB and Malaria. Additionally, innovative medicines first developed for relatively wealthy countries have subsequently found valuable medical uses in developing countries, not only for the conditions for which they were first approved, but also for other diseases endemic to resource-deprived regions (see Table below).

Developing-Country Uses for Developed-Country Medicines

Drug	First Indication	Subsequent Indication
Azithromycin	Inner Ear	Trachoma/Bacterial Blindness
Miltefosine	Breast Cancer	Leishmaniasis
Eflornithine	Cancer	Sleeping Sickness
Ivermectin	Intestinal Worms	River Blindness
Doxycycline	Travelers Diarrhea	Malaria/Resistant Strain
Fluconazole	Yeast Infection	AIDS/Opportunistic Fungi
TMP-SMX	Cystitis	AIDS-Related Pneumonia

The past few years also have seen the acceleration of public-private collaboration, with the creation of several disease-focused product development public-private partnerships (PPPs):

Examples of Product Development PPPs for Neglected Diseases[8]

Malaria	Medicines for Malaria Venture (MMV) Malaria Vaccine Initiative (MVI) European Malaria Vaccine Initiative (MMV) Japanese Pharmaceutical, Ministry of Health, WHO Malaria Drug Partnership (JPMW) Lapdap™ Antimalarial Product Development (Lapdap)
Tuberculosis	Global Alliance for TB Drug Development (TB Alliance) Global TB Vaccine Foundation (Aeras) Foundation for Innovative New Diagnostics (FIND)
African trypanosomiasis **Leishmaniasis** **Chagas disease**	Drugs for Neglected Diseases Initiative (DNDi) Gates Foundation/University of Carolina Partnership (GFUNC) Infectious Disease Research Institute (IDRI) Institute for One World Health (IOWH)

In July 2001, a joint working group comprised of experts from the World Health Organization (WHO) and the research-based pharmaceutical industry found that only three diseases were truly "neglected": African trypanosomiasis, leishmaniasis, and Chagas disease as many of the less prominent infectious diseases can be effectively treated with inexpensive, off-patent medicines such as those contained on the WHO Essential Drugs List. The R&D industry has responded with offers to engage in public private partnerships to address these particular ailments, and Pfizer would welcome a discussion with ICCR on how to move these initiatives forward.

A similar conclusion was drawn by a group of experts from the WHO's Special Program for Research and Training in Tropical Diseases (TDR) in a study published in 2002 comparing global daily mortality of major diseases affecting developing countries, including the three "neglected" diseases. According to WHO, the key factors behind the excessive mortality caused by these diseases include endemic poverty, disenfranchisement by gender, unavailability of basic primary health services and failure to apply prevention and treatment strategies, rather than the unavailability of medicines[9].

[8] Initiative for Public Private Partnerships for Health (IPPPH), online database accessed at http://www.ippph.org/index.cfm?page=/ippph/partnerships

[9] WHO, Report on Infectious Diseases: Removing Obstacles to Healthy Development. WHO 1999.

Accessibility: Licensing & Technology Transfer (page 23-24)

India's adoption of TRIPS-consistent legislation covering pharmaceuticals will not prevent the production and export of generic copies of patented products to the developing world. An amendment to its patent law allows Indian producers to manufacture generic drugs for export to countries with insufficient production capacity, as endorsed by the November 2001 WTO Declaration on TRIPS and Public Health and subsequently clarified by the August 2003 Chairman's consensus statement on implementing Paragraph Six of the Declaration.

The Declaration and the Chairman's statement reaffirmed the importance of intellectual property protection in creating incentives for pharmaceutical innovation and clarified the ability of WTO member countries to use compulsory licensing and other flexibilities in cases of national emergency to gain access to medicines for humanitarian or non-commercial public use. It also exempted the 49 least developed countries from obligations to enforce patent protection for pharmaceuticals until at least 2016.

In addition, more than 90 per cent of the 319 medicines on WHO's Essential Drugs list are off-patent; and of those that are patented, few extend to the developing world or are enforced by the patent holder in those markets. We would also like to point out that the US and other industrialized nations have introduced an informal, indefinite moratorium in taking WTO action to enforce TRIPS protections, if such enforcement actions affect public health interests.

Finally, licensing is but one of many practical options that can be considered in expanding access. Licenses, similar to other access strategies, should be placed into context regarding the relevant medicine and disease of focus. The point is that there is no "one-size-fits-all" solution. And because of the variety of obstacles developing countries face in delivering medicines to patients, there is a need for creative solutions. The private sector has played a significant role in this area.

Accessibility: Patent Enforcement Relaxation (page 25)

The reference to the report of the WHO Commission on Intellectual Property, Public Health and Innovation is misleading. There was no consensus by the Commission members on anything related to patents and intellectual property. As a result, three members dissented. For example, one member concludes that "patents are not the issue but the overwhelming poverty of individuals, absence of state healthcare financing, lack of medical personnel, transport and distribution infrastructure plus supply chain charges which can make affordable originator or generic products unaffordable," while another states that "the report should have provided more evidence-based analyses of different patent policy options for developing countries, considering both their short and long-term consequences."[10]

[10] The Report of the Commission on Intellectual Property Rights, Innovation, and Public Health. 2006. Download the report at http://www.who.int/intellectualproperty/documents/thereport/en/index.html.

The report itself concludes that "conditions for ensuring access to medicines requires a multifaceted approach ranging from pricing to human and financial resources and the general level of infrastructure."

It would be a mistake to regard patent abrogation or the application of compulsory licensing as the solution to the health problems in developing countries. Delivering medicines to patients in these countries does not automatically mean patients get treated, because many of these countries lack the necessary infrastructure to deliver medicines or the diagnostic tools that ensure such medicines have the desired prophylaxis effect. In countries without patent protection there is still a dramatic lack of treatment for those with HIV/AIDS. In India, for example, only 14,000 out of 770,000 people with HIV/AIDS and in need of antiretroviral treatment received it in 2003.[11]

The reality is that life-saving medicines made available for free or at not-for-profit prices often do not reach patients in less developed countries where other basic infrastructure challenges present barriers to drug access. By the WHO's own admission, at least one-third of the population of developing countries still have no access to the cheap generic medicines that dominate the Essential Drug List. And according to a 2001 World Bank study, three million people die unnecessarily each year of communicable diseases for which off-patent medicines are readily available.[12]

To ensure that people in developing countries can enjoy the benefits of good health, all groups involved in healthcare provision – national governments, pharmaceutical companies, medical professionals, NGOs and aid agencies, as well as employers and other domestic and international sources of funding – need to work together to build capacity for healthcare delivery and secure the increased financial resources needed to address pandemic diseases such as HIV/AIDS, tuberculosis, and malaria. Inexpensive medicines alone cannot guarantee good health in developing countries.

Accessibility: Differential Pricing (page 25-26)

Kevin De Cock, Head of the WHO HIV Division, stated recently that it is not the current price of drugs, but crumbling infrastructure and massive healthcare worker shortages that are undermining efforts to deliver antiretroviral drugs to Africa.

The "current status" section is unsoundly cynical toward industry's efforts to lower prices. It is known that the prices of branded products are for the most part equal or less costly than generics. The Accelerated Access Initiative estimates that over half of the 1.3 million treated in developing countries use branded medicines (716,000, December 2005).

Fluctuating prices depend on the cost of other healthcare alternatives and the institutional structure of healthcare benefits, which differ from country to country, and even within countries. Hence the industry has been practicing "differential pricing" throughout its history – it is not new.

[11] WHO Regional Office for South-East Asia, HIV/AIDS Facts and Figures, http://w3.whosea.org/EN/section10/Section18/Section348.htm.
[12] World Bank. Immunization at a Glance, Washington, DC (2001).

An IFPMA report[13] provides detail on factors in addition to those above that contribute to price variations, including:

- Exchange rates – fluctuations in rates have a dramatic impact on international price comparisons, rendering such comparisons statistically misleading.
- Local taxes and tariffs – value-added taxes vary from 0 to 25 per cent in OECD countries, while developing countries often impose punitively high customs duties on imported medicines, driving up their cost to the consumer. Tariffs are even imposed on free or donated medicines.
- Costs and margins through the distribution system – in many markets, upwards of a third or more of the retail price consists of margins paid to wholesalers, pharmacists and other stakeholders. In many industrialized markets, the manufacturer has effectively lost control of the price to other participants in the supply chain who rely on close ties to government payers.

Philanthropy (page 29-30)

There is an implication in this section that the industry may not be committed to philanthropic partnership programs for the long term. This is belied by the evidence: many industry donations and public health partnerships have been in operation for more than a decade. For example, Merck's Mectizan program to treat River Blindness has been in place for almost twenty year. In addition, Pfizer's International Trachoma Initiative to eliminate blinding trachoma was established in 1998 and is committed to fund and administer the program for as long as there is a demonstrated public health need.

Pfizer (pages 60-63)

Introduction (page 60)

There should be two corrections noted: the text repeats that *maraviroc* is in late stage development and Pfizer holds patent rights to Viracept in the US, Canada, Puerto Rico, Japan and Korea.

Pfizer has reached out to a variety of stakeholders including MLOs, NGOs, bilateral agencies and private institutions to formulate a developing country strategy for *maraviroc*. This process has been guided by the following principles:

1) Leverage core assets -- protect Pfizer's engine for innovation through pricing that reflects our investments in developed economies, where there is available capacity to pay
2) Improve and adjust our pricing approach through consultation, trial and learning
3) Set realistic expectations
4) Maintain a transparent intent
5) Engage with others consistently

[13] IFPMA. The Health Care Implications of International Price Variations. 2000.

6) Partner to be a part of the solution -- leverage existing Pfizer partnerships, e.g., Infectious Disease Institute in Uganda

One of the main challenges of this new drug is that a diagnostic test to appropriately identify patients infected with R5-type virus will be required. Today, only one US based diagnostics company can conduct the test; costs could range up to $700-800/test, take 3-5 weeks for processing, and requires dry ice to ship.

Research: Neglected Diseases (page 60)

Preliminary results from a phase-2 trial sponsored by Pfizer for the treatment of Falciparum malaria and conducted in Thailand demonstrates that combination therapy with the Pfizer medicine *azithromycin* can be used with artesunate and adequate doses of quinine in areas of high drug resistance. Confirmation of efficacy and safety in additional patient populations is under consideration.

Pfizer's chloroquine/Zithromax malaria trial has generated interesting data. We have seen a dose response in our phase II studies, upon which further clinical trials are continuing. Studies are ongoing and we expect results from our African-based trial shortly.

Pfizer has collected a large number of parasites from the program that have been sequenced. We can now correlate the parasitic genotype with the patient phenotype and clinical outcomes. We are sharing data on these organisms with the Gates Foundation in order to improve our collective understanding of treatment approaches to malaria.

Pediatric Needs: Formulations (page 61)

Viracept was the first agent in HIV to gain simultaneous approval for an adult and a pediatric formulation at time of launch. Safety and efficacy have been established for the pediatric formulation in patients from 2 to 13 years of age. In children 2 years of age and older, the recommended oral dose of Viracept oral powder or 250mg tablets is 45–55mg/kg twice daily or 25–35mg/kg three times daily.

The powder formulation is recommended for use in children who are unable to swallow tablets or for adults unable to take tablets. Patients unable to swallow the tablets may dissolve the tablets in water for easier administration. As to the lack of tablet scores, even a small child (weight 10 kg) medically requires at least the equivalent of a single 250 mg tablet with each dose (25 mg/ kg three times / day) or (45-55 mg / kg bid).

Of the two Pfizer drugs applicable to communicable diseases that Pfizer holds patent rights to in developing countries – Diflucan and Zithromax -- pediatric formulations do exist. These formulations are dispensed through our access programs.

Pfizer will consider a pediatric formulation for *maraviroc* once the initial set of clinical trials confirms its safety and efficacy.

Accessibility: Licensing & Technology Transfer (page 62)

At the time of discussions regarding Rescriptor (delavirdine), the non-exclusive licensing concept, as an access methodology, captured everyone's imagination, and understandably so. But it is our contention that Rescriptor would have been the wrong compound for this venture. As a public relations matter, it might be easy to see us as thwarting progress on access, but that is a very narrow view of the situation considering what all of our responsibilities are in delivering appropriate, high-quality medicines to patients in developing countries.

In short, Pfizer was asked to make available Rescriptor to developing countries as a possible first-line treatment, but the fact is that the US Department of Health and Human Services (DHHS) does not recommend Rescriptor as a first-line treatment "because of inferior antiretroviral potency and three times daily dosing."[14] Furthermore, the complex dosing regimen increases risk of resistance, which negates the therapeutic benefit of the entire NNRTI class as it is susceptible to cross-resistance from a single mutation. Finally, Rescriptor has a contra-indication for women of child-bearing age -- a key demographic for ARV treatment. Under these circumstances, we did not believe it medically appropriate to license this particular therapy for this purpose.

Pfizer is committed to expanding access to medicines and will continue to work with IDA and other partners on innovative access programs that work.

Accessibility: Patent Relaxation (page 62)

Under threat of a patent violation, Pfizer will evaluate the circumstances on infringement and make decisions on enforcement on a case-by-case basis.

Reporting to Shareholders (page 62)

Corporate Citizenship and Access, in addition to financial performance, have been added as key performance standards to our Annual Report as of 2004.

Philanthropy (page 62-63)

This analysis ignores all feedback from our April response to the draft report. Most notably, it does not update numbers for the Diflucan Partnership Program (***from 21 countries to 47 countries***). In addition, the analysis on philanthropy fails to identify in any detail Pfizer's three other major international flagship programs – the **International Trachoma Initiative**, the **Infectious Diseases Institute** and the **Global Health Fellows** – but rather only mentions in passing. Finally, it does not address the seven principles we use in outlining our approach to philanthropy initiatives.

[14] Department of Health and Human Services. Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents. May 4, 2006

Instead, the report mischaracterizes Pfizer's vision and efforts in addressing access issues in the developing countries as "traditional philanthropic approaches." This is a limited perspective on Pfizer's work in developing countries. Our access programs, the Diflucan Partnership Program (DPP) and the International Trachoma Initiative (ITI), encompass many wrap-around activities to best facilitate delivery and treatment for patients in need. For example, as part of the ITI, Pfizer works in concert with governments, NGOs and MLOs to implement a comprehensive approach to eliminate blinding Trachoma -- the SAFE strategy (surgery, antibiotic treatment, facial hygiene and environmental change). These programs clearly provide benefits that go well beyond delivery and treatment of medicines for the respective diseases.

The ITI was included in the Center for Global Development's "Millions Saved: Proven Successes in Global Health" as a case study for global public health programs that yielded tangible, measurable gains in terms of health outcomes and improved quality of life. Pfizer's works in cooperation with a coalition of stakeholders including World Vision, UNICEF, the Edna McConnell Clark Foundation and the World Health Organization to incorporate Zithromax treatment as part of the SAFE strategy. To date, Pfizer has contributed $760 million in cash and donations in 13 countries and as of November 2003, Pfizer committed to increase Zithromax donations to ***135 million treatments*** over five years, to 2008. This comprehensive approach has proved to be very successful. Morocco – the ITI's first partnership country – has met all of WHO's criteria to enter the process that will certify that the country has eliminated blinding trachoma as a public health problem.

The Diflucan Partnership Program not only provides medicines, but also trains to healthcare workers and builds supply chain management skills to ensure that inventories are properly accounted for so medicines are always available for patients. These are skills that provide a sustainable setting for delivery of health services. The concept of sustainability is a key tenet in all philanthropic programs we initiate.

Pfizer has worked diligently in partnership to address criticisms of the DPP, designing a program that serves ***over 1,100 facilities*** *in* ***47 countries.*** The program to date has treated over ***200,000 patients*** for life-threatening fungal infections and Pfizer has provided training to nearly ***20,000 healthcare providers*** on diagnosis and management of fungal infections. Diflucan is made available free of charge to governments and non-governmental organizations for HIV patients who lack basic healthcare.

Learning from our experiences on the ground, we have developed seven principles guiding these initiatives, which include:

1) Commit for the long-term
2) Focus on outcomes and impact
3) Utilize the full resources of the company
4) Identify scalable and sustainable solutions
5) Demonstrate leadership
6) Work in partnership
7) Engage in projects that can add the greatest value

Through these principles, we learn from each of the initiatives in order to make the subsequent program stronger and more effective.

Pfizer has provided approximately $30 million in financial support to the **Infectious Diseases Institute (IDI).** The Institute serves as a regional center of excellence for HIV training, care and treatment. Care is currently being provided to ***approximately 18,000 adult*** and ***4,000 pediatric patients*** each quarter through the IDI and ***1,000 health professionals*** have been trained from 22 countries in Africa. Partners include the Academic Alliance Foundation, Pangaea Global AIDS Foundation, the Infectious Diseases Society of America, Makerere University, Mulago Hospital and the AIDS Support Organization (TASO).

The **Global Health Fellows Program**, since its inception in 2003, has sent ***117 Fellows*** to work with ***23 nongovernmental organizations*** in ***29 countries,*** delivering healthcare and health system support to those in need around the world. Approximately 70% of the Fellows have been involved in HIV/AIDS programs.

Pfizer's Bottom Line (page 63)

Pfizer was recently identified as "the most generous company" by the Philanthropy Chronicle, and has been for several years running. We have brought new life-saving medicines in various therapeutic areas to the world for several decades, a record supplemented by access initiatives for thousands of patients in various parts of the world. Our track record speaks for itself – through our research, products and related services, we add years to life and quality of life to years.

In terms of the report, it seems not to acknowledge the range of responses, the variety of programs and the creativeness represented by companies involved in the fight against endemic diseases. Quite apart from the patient successes companies have facilitated, the initiatives demonstrate flexibility in design, extend to multiple partnerships around every disease, encompass robust research and development programs and, in general, a willingness to fail and start again to achieve important public health outcomes.

In sum, we wish the report were less damning and more challenging, acknowledging that work has begun in earnest but that more effort among all stakeholders is needed. That the report has more comparative rigor associated with how little companies are doing than there is in evaluating the effectiveness and need for coordination and support for this voluntary work seems an ineffectual methodology to encourage more activities of the very kind that ICCR frequently asks the R&D-based industry to undertake.