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ICCR

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Kieran Hartsough, Public Health Research Associate, ICCR
Daniel E. Rosan, Program Director for Public Health, ICCR
Lisa Sachs, Public Health Research Associate, ICCR

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Disclaimer

This report is the result of a long-term collaborative process among investor-members of the Interfaith Center on Corporate Responsibility. The findings, interpretations, and conclusions expressed may not necessarily reflect the views of all the institutional investors involved. The report is intended for informational purposes only. It is not intended to provide, and should not be relied on for, accounting or legal advice, or investment recommendations. We have made every effort to ensure the information provided is reliable, but make no guarantee that it is accurate or complete.

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EXECUTIVE SUMMARY

We are facing some of the worst plagues in human history. Over forty million people in the world are living with human immunodeficiency virus (HIV). An estimated six million people need treatment today with antiretroviral drugs or they will soon die, and the remaining millions will require treatment within the next ten years. AIDS currently kills about three million people each year. Tuberculosis, in turn, takes the lives of two million people. An additional three million succumb to malaria. These are deaths that can be avoided, lives that can be extended, and people who can be saved, if we choose to save them.

Providing widespread access to HIV/AIDS treatment can only be done in the context of a broader response to the public health crisis in emerging markets. This crisis includes not only AIDS but also TB, malaria, and other infectious diseases which primarily afflict poor countries. Addressing the crisis requires responsible actions by a number of sectors, only one of which is pharmaceuticals.

Pharmaceutical companies face particular risks for two fundamental reasons: failure to develop new medicines which address diseases of poverty, and poor patients' lack of access to existing medicines. In the first case, the problem is largely market failure. The markets for medicines addressing diseases of poverty are insufficient to give the return today's investors demand. In the second case, the problem is insufficient attention. Today's social contract demands companies take creative, wide-ranging steps to increase access to medicines. Fortunately for pharmaceutical shareholders and patients, neither problem is insurmountable.

Risks to pharmaceutical companies include:

- Risks to the social contract on which drug companies depend to finance innovation and protect intellectual property;
- Risks that emerging markets will withdraw from or undermine international intellectual property agreements;
- Threats to the economic development of emerging markets;
- Risks that rich-country regulatory environments will undermine pricing power in profitable markets;
- Adverse impacts on staff morale and recruitment prospects; and
- A potential inability to successfully secure new markets.

This report will measure how effectively companies are addressing these two fundamental problems by comparing actual pharmaceutical responses against industry best practices. We can conclude that companies whose practices approach best practices are more effectively managing these risks than their peers. The companies addressed in this report include any drug company that controls or produces – or is planning to produce – products which address at least one of the three pandemic diseases, and any other company with global revenues among the top ten in the industry.

Best Practices

We judged each company according to each recommended practice on a five-point scale (5 being highest, 1 lowest). The current status of each practice and the recommended best practices (for which a company would receive a 5) are as follows:

- Research: Fixed-Dose Combinations (FDCs)
  Current Status: Thus far, drug companies have created fixed-dose combinations of antiretrovirals only for pairs of their own products, allowing concerns about brand-share to outweigh undeniable public health benefits of therapeutically appropriate fixed-dose combinations.
  Best Practice: Company is taking a leading role in the development or production of FDCs with other companies.

- Research: Neglected Diseases
  Current Status: There has long been an industry-wide neglect of these severe public health threats. There is little market-driven research and development on diseases of poverty, and the available drugs are not universally accessible, are unaffordable to the most affected populations, or are only available in inconvenient or ineffective formulas.
  Best Practice: Company has robust programs to research and develop drugs for a range of neglected diseases.

- Pediatric Needs: Formulations
  Current Status: Clinicians treating children with HIV/AIDS have an urgent need for improved formulations, including child-friendly delivery systems such as chewable tablets, smaller pills, and improved syrups that do not require refrigeration.

QUICK REFERENCE CHART

Approach	Issue	ABT	AZN	BI	BMY	GILD	GSK	JNJ	LLY	MRK	NVS	PFE	ROG	SNY	SGP	WYE	Industry Mean
Research	Fixed Dose Combination	2	N/A	1	5	5	2	N/A	N/A	4	N/A	N/A	1	N/A	N/A	N/A	2.9
	Neglected Diseases	1	3	1	1	1	5	4	1	3	5	3	3	5	1	1	2.5
Pediatric Needs	Formulations	3	N/A	2	4	3	3	N/A	N/A	4	N/A	2	4	N/A	N/A	N/A	3.1
	Price Cuts	5	N/A	5	3	1	4	N/A	N/A	3	N/A	N/A	2	N/A	N/A	N/A	3.3
Accessibility	Licensing	1	N/A	3	2	2	4	2	5	2	N/A	1	2	N/A	N/A	N/A	2.4
	Patent Relaxation	1	N/A	1	3	1	1	1	N/A	1	3	1	3	N/A	N/A	N/A	1.6
	Differential Pricing	3	N/A	4	4	4	4	N/A	N/A	5	4	N/A	3	4	N/A	N/A	3.9
	Registration	2	N/A	4	5	2	5	N/A	N/A	2	N/A	N/A	5	N/A	N/A	N/A	3.6
Reporting to Shareholders		3	4	2	3	3	5	4	4	4	4	3	3	4	1	1	3.2
Philanthropy		4	2	3	4	N/A	4	4	4	5	4	3	4	4	N/A	1	3.5
Political Engagement	Political Contributions	2	1	1	2	1	1	4	4	4	1	4	2	3	4	1	2.3
	Trade Association	1	1	1	1	5	1	1	1	1	1	1	1	1	1	1	1.3

Best Practice: Company produces a range of child-friendly formulations for children in each age group for its entire clinically appropriate product line.

- Pediatric Needs: Price Cuts
  Current Status: Typically, child formulations are much more expensive than adult formulations.
  Best Practice: Pediatric treatment costs per patient per year are equivalent to adult treatment costs.

- Accessibility: Licensing & Technology Transfer
  Current Status: Voluntary licensing is largely unused by American drug companies. Even when granted, many voluntary licenses are granted to one or two companies only and contain unduly restrictive terms. Many voluntary licenses also lack sufficient technology transfer.
  Best Practice: Company has issued three or more non-exclusive licenses for its full range of products, allowing for sales in a wide range of markets. The company provides training and technology to licensees and encourages co-formulation with other brands to develop appropriate fixed-dose combinations.

- Accessibility: Patent Enforcement Relaxation
  Current Status: Global intellectual property rules are becoming more restrictive, and few companies have relaxed their patents in least developed countries (LDCs) or major generic exporting countries.
  Best Practice: The company has no patents in countries that are major generic exporters and no patents in LDCs.

- Accessibility: Differential Pricing
  Current Status: Most companies have differential pricing schemes only in sub-Saharan Africa, while middle-income nations are regularly excluded from differential pricing schemes or treated on an ad-hoc basis.
  Best Practice: Low-income country prices are affordable and predictable. Middle income country prices are affordable and predictable.

- Accessibility: Registration
  Current Status: Pharmaceutical companies have often failed to obtain registration for all the available dosages and formulations of their products with national drug regulatory agencies in poor countries or have done so on a delayed basis, delaying access to the newest medicines.
  Best Practice: Company has obtained registration for all available dosages and formulations in all relevant markets. (We give companies the benefit of the doubt on this topic, and assume registration except where there is specific information available to the contrary.)

- Reporting To Shareholders:
  Current Status: Many reports tend to be anecdotal, and corporate reporting on HIV/AIDS often focuses solely on philanthropy. Because philanthropic responses are not linked to business strategy and development, reporting on philanthropy does not adequately discuss the business risks of these pandemics nor does it explain how the firm's approach effectively and maximally addresses these risks.
  Best Practice: Company's reporting includes an articulation of the business case for action, an assessment of the options for action, systematic reporting of the company's goals and activities, and evidence of leadership at the board level. The report also has pricing schemes and timetables for its access to medicines goals.

- Sustainable Philanthropy:
  Current Status: Philanthropic programs are the single most popular form of pharmaceutical companies' responses to the HIV/AIDS pandemic. But purely philanthropic responses to the pandemics (gifts of money or products) are not systemic solutions.

Best Practice: Company's philanthropic programs are well integrated into its overall access to medicines programs. They are wide-reaching and sustainable. The programs are built into the company's business strategy and reported to shareholders as such. The activities and impacts of the programs are continuously monitored.

- Political Engagement: Political Contributions
  Current Status: There is a wide-spread lack of transparency in political contributions in the industry.
  Best Practice: Company reports on all political contributions, providing individual rationales for each candidate and group to whom it contributes. The company has board oversight of political contributions.

- Political Engagement: Trade Associations
  Current Status: Most pharmaceutical firms that choose to participate in trade associations do not report their dues or the political activities which their dues fund.
  Best Practice: Company fully discloses its trade association dues and payments to third-party organizations, as well has how those dues are directed. Its dues and payments are consistent with its public position on public health issues. Or, the company is not a member of trade organizations so does not need to report separately on dues.

Key Findings

Our analysis demonstrates that, by and large, pharmaceutical companies are not in compliance with current best practices in responding to HIV/AIDS and neglected diseases. This leads to a number of potential impacts for public health and for institutional investors exposed to the pharmaceutical sector.

KEY FINDINGS		
For Investors	*Strategies Vary*	Individual responses vary substantially by company: the industry can not be judged monolithically.
	Reporting Is Sub-Standard	Most companies are not reporting on material useful to either shareholders.
	Substantial Risks Remain	Depending on product mix and policies, some companies continue to face substantial downside risks.
	Improve Public Health, Reduce Company Risk	The soundest way to reduce risk is to address, as much as possible, sthe underlying public health crisis.
For Public Health	*Neglected Disease R&D*	Some companies are distinguishing themselves, but the majority are taking little action.
	Pediatric AIDS	Children with AIDS continue to have unmet medical needs.
	Second-Line AIDS Drugs	Second-line drugs are less likely to be affordable or available generically.
	AIDS Drug Access Beyond Africa	Company policies are overwhelmingly focused on Africa. Companies may not be prepared to address the spread of AIDS to other regions.

- We found a wide disparity between companies in approaches selected to respond to the public health crisis in emerging markets and in the success of these approaches. Investors would be well served by evaluating responses to the crisis on a company by company basis.
- Almost without exception, we found that company reporting on the public health crisis is poor from an investment value perspective. It appears that the majority of companies are driving their reporting from their public relations or marketing functions. Reporting tends not to contain useful information to make public health judgments. Investors are advised to seek more robust pharmaceutical industry reporting.
- We found little that reassures us that companies are responding adequately to address the industry-wide risks posed by the public health crisis and company-specific regulatory and headline risks.
- The number of public – private partnerships and intensive neglected disease research programs is larger today than it was several years ago. But the range of company responses on this topic is quite wide. Neglected disease R&D may offer companies the greatest opportunity for substantial public health impact. Only a small number of companies appear to recognize this.
- There is an urgent need for pharmaceutical companies to increase resources devoted to making and distributing affordable pediatric AIDS medicines. We found that the gap between best practices and current company practices is wide.
- We found that second-line AIDS drugs continue to be much more expensive and less likely to be licensed or available generically. Additionally, we found that firms have one patent, licensing, and pricing strategy for sub-Saharan Africa and another for the rest of the developing world, thus failing to prepare for the rapid expansion of the AIDS pandemic beyond Africa.

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INTRODUCTION

In June of 2005, the Interfaith Center on Corporate Responsibility published a short monograph on pediatric AIDS.[1] On the cover was Sudi, a thirteen-year-old patient at the AIDS Research and Family Care Clinic in Mombasa, Kenya who was responding well to treatment. Sudi died in May 2006, as we sent this report to press. He lived with HIV his entire life.

We are facing some of the worst plagues in human history. Over forty million people in the world are living, as Sudi did, with human immunodeficiency virus (HIV). An estimated six million people need treatment today with antiretroviral drugs or they will soon die, and the remaining millions will require treatment within the next ten years. AIDS currently kills about three million people each year. Tuberculosis, in turn, takes the lives of two million people. An additional three million succumb to malaria. These are deaths that can be avoided, lives that can be extended, and people who can be saved, if we choose to save them.

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The Interfaith Center on Corporate Responsibility (ICCR) is a coalition of 275 faith-based institutional investors with collective assets under investment of $110 billion. Since 2000, ICCR members have engaged the pharmaceutical industry on responses to the HIV/AIDS-TB-Malaria pandemics. We seek to uphold the *Principles For Global Corporate Responsibility,* specifically that every person has the right of access to health care.[2]

As faith-based and socially responsible institutional investors, we ground our actions securely in our fiduciary duty to our beneficiaries. Retirees, parents saving for college, philanthropies, and health care providers do not have the luxury of sacrificing returns. It is clear that the HIV-TB-Malaria pandemics have actual or potential impacts on the developing economies in which we invest.

Failure to respond to global expectations on access to medicines could undermine the current business model for branded drugs.

Pharmaceutical shareholders in particular face a wide variety of risks from the failure to adequately respond to the HIV-TB-Malaria pandemics. As one investment firm wrote, "failure to respond to global expectations on access to medicines could undermine the current business model for branded drugs."[3] The Pharmaceutical Shareowners Group (PSG) went further, articulating the following risks in a recent report:[4]

- Risks to the social contract on which drug companies depend to finance innovation and protect intellectual property;
- Risks that emerging markets will withdraw from or undermine international intellectual property agreements;
- Threats to the economic development of emerging markets;
- Risks that rich-country regulatory environments will undermine pricing power in profitable markets;
- Adverse impacts on staff morale and recruitment prospects; and
- A potential inability to successfully secure new markets.

Pharmaceutical companies face these risks for two fundamental reasons: failure to develop new medicines which address diseases of poverty, and poor patients' lack of access to existing medicines. In the first case, the problem is largely market failure. The markets for medicines addressing diseases of poverty are insufficient to give the return today's investors demand. In the second case, the problem is insufficient attention. Today's social contract demands companies take creative, wide-ranging steps to increase access to medicines. Fortunately for pharmaceutical shareholders and patients, neither problem is insurmountable.

This report will measure how effectively companies are addressing these two fundamental problems by comparing actual pharmaceutical responses against industry best practices. We can conclude that companies whose practices approach best practices are more effectively managing these risks than their peers.

CONTEXT

Our dialogues with pharmaceutical companies on this topic began in 2000, when the cost of treating one patient with AIDS for one year with the latest life-extending drugs approached $10,000. That year, pharmaceutical companies revived a previously filed lawsuit seeking to overturn South Africa's newly amended Medicines and Related Substance Control Act. The Act, among other things, could have brought cheaper AIDS drugs through utilization of lawful intellectual property flexibilities, including parallel importation. At the time, skepticism about the feasibility of treatment access was widespread. In 2001, USAID head Andrew Natsios, famously told the U.S. House of Representatives' International Relations Committee "People [in Africa] do not know what watches and clocks are."[5] (He later apologized.)

Natsios' comment was indicative of the attitude among donor governments and international development agencies. Providing widespread access to treatment was considered unfeasible. At the same time, risks to pharmaceutical companies were growing. AIDS activists in rich countries were expanding their long-time work on access to treatment in their own countries

to include the developing world. More importantly, civil society and the faith community in many developing countries began advocating for treatment access.

Civil society and the faith community in many developing countries began advocating for treatment access.

In the years since, the international community has reached a new consensus. Generic production of AIDS drugs has led to a remarkable drop in the cost of treatment from 2000 to 2006. People living openly with HIV and AIDS, and civil society and the faith community generally, have been relentless in their advocacy for health care for all. And the public health community has recognized that treatment is an integral part of preventing new infections and changing high-risk behavior.

Today, antiretroviral treatment for people with AIDS in poor countries is accepted as both economically feasible and morally imperative.[6] Meanwhile, the business and investment communities have explored the economic impacts of the HIV-TB-Malaria pandemics. Research on the economic impact of AIDS and other infectious diseases has expanded, and found impacts on the household, regional, and national levels. Businesses and investors have begun to respond, motivated by their fiduciary duty.

Providing widespread access to HIV/AIDS treatment can only be done in the context of a broader response to the public health crisis in emerging markets. This crisis includes not only AIDS but also TB, malaria, and other infectious diseases which primarily afflict poor countries. Addressing the crisis requires responsible actions by a number of sectors, only one of which is pharmaceuticals. This chart describes our view of the roles played by the state, the private sector, and civil society.

RESPONSIBILITIES	ACTORS						
	Developing Country Governments	Donor Governments	Branded Pharmaceutical Sector	Generic Pharmaceutical Sector	Other Private Sector	Faith Community	Civil Society
Advocate for access to health care	✓	✓	✓	✓	✓	✓	✓
Implement health care services	✓				✓	✓	✓
Discover medicines		✓	✓				
Distribute medicines			✓	✓			
Provide incentives for drug discovery		✓					✓
Responsibly fund health care delivery	✓	✓			✓	✓	✓

ICCR leads the investment community response. During our dialogues with drug-makers, ICCR members are often asked for guidance in responding to the HIV-TB-Malaria pandemics. In response, we produced "Big Pharma & Small Patients: Recommendations for

Pharmaceutical Company Responses to the HIV/AIDS, Tuberculosis, and Malaria Pandemics"[7] in June 2005.

This first attempt at articulating best practices came from the existing literature and our own membership, which has extensive experience on the ground working with people living with HIV.

In 2001, Oxfam and other NGOs were already articulating a series of policy steps pharmaceutical companies could take to alleviate the crisis and their exposure to it.[8] In 2003, Henderson Global Investors released an initial report warning of a "mismatch between pharmaceutical business strategies and global health needs" among other corporate responsibility and sustainability challenges.[9] Henderson and thirteen other institutional investors then formed the Pharmaceutical Shareowners Group (PSG) to focus specifically on the public health crisis in emerging markets; they published their report in September 2004.[10] PSG included F&C Asset Management, an ICCR Associate Member. Ethical Investment Research Services followed with general best practice indicators in May 2005.[11]

INSTITUTION	TITLE	TOPIC	YEAR
Oxfam	Formula For Fairness	Company briefing paper on Pfizer	2001
Ecumenical Council for Corporate Responsibility	GSK: Getting Better?	Company briefing paper on GlaxoSmithKline	2003
Henderson Global Investors	Fulfilling its Potential	Broad report covering sustainability and ethics in the pharmaceutical industry	2003
Pharmaceutical Shareowners Group	The Public Health Crisis in Emerging Markets	Industry-wide risks from the public health crisis, and some industry responses.	2004
Ethical Investment Research Services	Access to Medicines for the Developing World and the Pharmaceutical Industry	Social and environmental risk analysis applied to drug-makers.	2005
Interfaith Center on Corporate Responsibility	Big Pharma & Small Patients	Recommendations for pharmaceutical company responses to global AIDS crisis	2005
Interfaith Center on Corporate Responsibility	Benchmarking AIDS	Analysis of pharmaceutical company responses to global AIDS crisis	2006

Our report "Big Pharma & Small Patients" contained specific policy recommendations and was the first such report from the U.S.-based investment community. We sent "Big Pharma & Small Patients" to pharmaceutical Boards of Directors in July 2005. Only one company responded specifically to our recommendations at the time. Subsequently an independent board member described "Big Pharma & Small Patients" in conversation as a "cogent and reasonable" argument for further action by pharmaceutical companies.

These evolving investor reports reflect a consensus that a range of approaches is required, and companies should not approach the HIV-TB-Malaria crisis from only one perspective.

In this report, we return to, and update, the policy recommendations in "Big Pharma & Small Patients." Then we evaluate pharmaceutical company actions in light of those recommendations.

METHODOLOGY

Rationally choosing a peer group of pharmaceutical companies for this study was not straightforward. The top ten companies by global revenue exclude important players such as Boehringer-Ingelheim, Gilead, Eli Lilly, and Roche.[12] S&P 500 and Dow Jones listings companies exclude European firms.[13] On the other side, the membership list of a trade association such as the Pharmaceutical Research and Manufacturers Association (PhRMA) membership list is too broad.[14]

We decided to include any drug company that controls or produces – or is planning to produce – products which address at least one of the three pandemic diseases. We then added any other company with global revenues among the top ten in the industry. We believe addressing the disease burden of the developing world is essential to retaining a social license to operate, regardless of the particular product mix at a specific company.

The chart below lists the companies included and the reasons we did so:

COMPANY	COUNTRY	GLOBAL TOP 10	RELEVANT PRODUCTS: EXISTING COMMERCIAL				RELEVANT PRODUCTS: PIPELINE			
			HIV	TB	Malaria	Neglected Diseases	HIV	TB	Malaria	Neglected Diseases
Abbott	US	✓	✓							
Astra Zeneca	UK	✓						✓		
Boehringer-Ingelheim	Germany		✓				✓			
Bristol-Myers Squibb	US	✓	✓				✓			
Gilead Sciences	US		✓				✓			
GSK	UK	✓	✓					✓	✓	✓
Johnson & Johnson	US	✓					✓	✓		
Eli Lilly	US			✓						
Merck	US	✓	✓			✓	✓			✓
Novartis	Switzerland	✓		✓	✓	✓		✓		✓
Pfizer	US	✓	✓				✓		✓	✓
Roche	Switzerland		✓			✓	✓			
sanofi-aventis	France	✓		✓	✓	✓	✓		✓	✓
Schering-Plough	US						✓			
Wyeth	US	✓					✓			✓

We judged each company according to each recommended practice on a five-point scale (5 being highest, 1 lowest). The description of best practices and the meaning of each score are described below. Not all indicators are applicable to all companies. The grades themselves are developed from our research, academic and nongovernmental sources, and company materials. For pricing data, we used the Medecins Sans Frontieres report "Untangling the Web of

Price Reductions, 8th Edition."[15] For registration data, we used the World Health Organization database, which tracks national regulatory approval,[16] except where companies provided additional data in their responses to drafts of this report. We refer to pharmaceutical products by their non-proprietary name (i.e. ritonavir, not Norvir).

After we collected the initial research, we sent this report to a panel of experts drawn from the investment, academic, and NGO sectors. We also sent the relevant materials to each company directly. Reviewers and the companies who chose to respond are listed in our acknowledgements.

Companies are graded individually in each best practice category, not against their peer group. (And not on a curve). We have then summed up our evaluation in a short narrative as each company's "Bottom Line."

Currently, ICCR members are engaged in dialogue or shareholder resolution filings with Abbott Laboratories, Bristol-Myers Squibb Co., Gilead Sciences, GlaxoSmithKline, Eli Lilly, Johnson & Johnson, Merck & Co., Novartis, Pfizer, Roche, and Schering-Plough. Occasionally, those dialogues include information that is not yet publicly available. Needless to say, we have not included such information in this report.

Finally, we ended our research on April 15th, 2006. Information released after that date has not been included.

THE BEST PRACTICES

Research: Fixed-Dose Combinations (FDCs)

- *Public Health Benefits:* Fixed-dose combinations of antiretroviral drugs, which are available generically, combine multiple medicines into a single pill. This greatly reduces the complexity of supplying, tracking, and, most importantly, taking antiretroviral drugs. They may reduce the pill burden for some patients to one pill per day. Improved patient compliance also reduces the likelihood of disease mutation.
  - Often, FDCs are less expensive than their equivalent products to produce, and the reduced number of pills lowers logistical costs.
  - In this report, we have focused specifically on FDCs of anti-AIDS drugs. But fixed-dose combinations of drugs for other diseases are also important. Malaria FDC treatments can reduce the treatment course to only a single daily administration of the drug for three days. FDCs of malaria drugs, as with antiretroviral drugs, are necessary to prevent drug resistance, which is caused by providing sub-optimal therapies or when patients do not finish a full course of treatment. This is particularly important for artemisin-based combination therapy.
- *Current Status:* Thus far, drug companies have created fixed-dose combinations of antiretrovirals, such as lamivudine+zidovudine (Combivir) or emtricitabine+tenofovir (Truvada), only for pairs of their own products. Our experience is that patients most value combinations of the drugs they are most likely to take, even if those drugs are produced by different companies. The recent efforts by Gilead, Bristol-Myers Squibb, and Merck to develop a once-a-day fixed-dose combination of tenofovir+emtricitabine (Truvada) and efavirenz (Sustiva) is a positive development, but for far too long, major drug companies have allowed concerns about brand-share to outweigh the undeniable public health benefits of therapeutically appropriate fixed-dose combinations.

APPROACH	ISSUE	BEST PRACTICE RECOMMENDATION (SCORE: 5)
Research	Fixed Dose Combination	Company is taking the leading role in the development or production of FDCs with other companies.
	Neglected Diseases	Company has robust programs to research and develop drugs for a range of neglected diseases.
Pediatric Needs	Formulations	Company produces a range of child-friendly formulations for children in each age group for its entire clinically appropriate product line.
	Price Cuts	Pediatric treatment costs per patient per year are equivalent to adult treatment costs.
Accessibility	Licensing	The company has issued non-exclusive licenses for its full range of products to three or more licensees and has provided training and technology. The licenses are not unduly restrictive, allow for sales in a wide range of markets, and explicitly allow co-formulations with other brands.
	Patent Relaxation	The company has no patents in countries that are major generic exporters and no patents in LDCs.
	Differential Pricing	Low-income country prices are affordable and predictable. Middle income country prices are affordable and predictable.
Registration		We are not aware of any registration problems. (Companies are given the benefit of the doubt.)
Reporting to Shareholders		The company's reporting includes an articulation of the business case for action, an assessment of the options for action, systematic reporting of the company's goals and activities, and evidence of leadership at the board level. The report also has pricing schemes and timetables for its goals.
Philanthropy		The company's philanthropic programs are well integrated into its overall access to medicines programs. They are wide-reaching and sustainable. The programs are built into the company's business strategy and reported to shareholders as such. The activities and impacts of the programs are continuously monitored.
Political Engagement	Political Contributions	The company reports on all political spending, providing individual rationales for each candidate and group to whom it contributes. The company has Board oversight of political contributions.
	Trade Associations	The company fully discloses its trade association dues and payments to third-party organizations, as well has how those dues are directed. Its dues and payments are consistent with its public position on public health issues. Or, the company is not a member of trade organizations so does not need to report separately on dues.

- Generic companies have produced FDCs across patents, improving available treatment regimes. FDCs are now the standard first line treatment as recommended by the World Health Organization.[17]

- *Best Practice Recommendations:* Firms should collaborate with each other to develop clinically appropriate FDC products. While development takes place, firms should rapidly rollout co-packaging (i.e. packaging medicines according to how they will be consumed, instead of according to which company manufacturers them) to simplify the logistics of providing triple drug cocktails to patients in resource poor settings.

- *Pharmaceutical Company Benefits and Opportunities:*
  - Improves company reputation;
  - Allows company to share costs of innovation and infrastructure with other companies;
  - Products developed may have high value in rich countries;
  - Helps prevent drug resistance to existing products;
  - Improves company morale and recruitment prospects.

- *Pharmaceutical Company Risks and Costs:*
  - Research and development expense;
  - Reputation risk due to the possibility of research failure on a high-profile project;
  - Possibility of complicated legal or licensing agreements with partner companies.

Scoring:

5= Company is taking a leading role in the development or production of FDCs with other companies.

4= Company is collaborating with other companies in the distribution of FDCs but is not taking a leading role in the development process.

3= Company has expressed intent to collaborate with other firms to develop and distribute FDCs.

2= Company is developing its own FDCs via proprietary products.

1= Company is not engaged in any FDC development or distribution.

N/A= Company does not have any antiretrovirals for the treatment of HIV.

Note: While this report focuses mostly on the development of FDCs of AIDS drugs, companies that are highly focused on developing treatments for malaria are scored in this category as well.

• Top Rated Companies: Bristol-Myers Squibb (5), Gilead (5)

• Average Rating: 2.9

Research: Neglected Diseases

- *Public Health Benefits:* Neglected diseases such as tuberculosis, malaria, trypanosomiasis, leishmaniasis, schistosomiasis, and dengue fever, account for more than 12% of the global disease burden. They primarily affect populations in poor countries. These diseases also cause most of the deaths among people with HIV. Developing treatments for these diseases would have substantial public health benefits, saving and prolonging millions of lives. As diseases increasingly cross borders, there are benefits to both rich and poor markets. For example, malaria is today moving to previously non-malarial areas and leishmaniasis has been spreading to Southern Europe.

- *Current Status:* There has long been an industry-wide neglect of these severe public health threats. One-third of the world's population is currently infected with tuberculosis bacilli, and every second a new person is infected with TB.[18] Yet, no new tuberculosis drug has been developed in the past forty years, and the vaccine currently in use was developed in 1923 and is considered substandard.[19]
  - There is little market-driven research and development on diseases of poverty; the vast majority of global drug research is focused on conditions primarily impacting rich countries.[20]

Of the 1,556 new drugs developed between 1975 and 2004, only 21 new drugs were developed for tropical diseases and tuberculosis.[21] Additionally, there has been little interest in women's health in developing countries – research into microbicides for HIV prevention, for example, is driven primarily by private philanthropy.

- There are drugs and vaccines available for several of these neglected diseases, including TB, malaria and polio, but the available drugs are not universally accessible, are unaffordable to the most affected populations, or are only available in inconvenient or ineffective formulas. There is a growing risk of drug resistance to the available drugs, particularly when the complexity or cost of the treatment prevents patients from completing a full course of treatment.
- Recently, several public-private partnerships have been developed with leadership from private philanthropies. This has successfully increased the resources going to neglected disease research.[22] However, most research is at an early stage, making the specific public health benefit unclear.

• *Best Practice Recommendations:* Pharmaceutical firms should be investing substantial research and development resources in neglected diseases. Firms can also respond by allowing non-profit partnerships engaged in developing drugs for these diseases, such as the Drugs For Neglected Diseases Initiative (DNDi) or the International Microbicide Project, unfettered access to molecular libraries and scientists.[23] These partnerships are focusing their research exclusively on diseases of poverty.

• *Pharmaceutical Company Benefits and Opportunities:*
- Builds goodwill;
- Attracts high-quality researchers;
- Improves relationships with emerging market regulators;
- Better positions company to take advantage of unforeseen opportunities such as infectious disease pandemics that reach rich markets;
- Protects potential future markets;
- Several multilateral aid agencies and international philanthropies have discussed "pull mechanisms" which would reward research and development of drugs for diseases which do not have viable rich country markets, such as pediatric AIDS and other infectious diseases. Companies that have already invested in these areas will have some advantage in securing these rewards.[24]

• *Pharmaceutical Company Risks and Costs:*
- Research and development is costly;
- "Pull-mechanisms" and rich country donations may be unreliable, making it difficult to recoup research and development costs;
- Partnering with third parties can create legal and regulatory costs.

Scoring:

Our score is based on the level of involvement in neglected disease research.

5= Company has robust programs to research and develop drugs for a range of neglected diseases.

4= Company has programs for a narrow range of neglected diseases; or the company has small internal programs and partners with NGOs.

3= Company has programs for a narrow range of neglected diseases or partners in research with NGOs.

2= Company does not have any established program but is involved on a limited basis in neglected disease research.

1= Company is conducting little or no research into neglected diseases.

N/A= This category is applicable to every company.

• Top Rated Companies: GlaxoSmithKline (5), Novartis (5), Sanofi-aventis (5)

• Average Rating: 2.5

Pediatric Needs: Formulations

- *Public Health Benefits:* Child-friendly formulations of HIV/AIDS treatment are necessary to treat the 2.3 million children living with HIV/AIDS. Children require different doses and formulations than do adults for safe and effective treatment.
- *Current Status:* Clinicians treating children with HIV/AIDS have an urgent need for improved formulations. These include child-friendly delivery systems such as chewable tablets, smaller pills, and improved syrups that do not require refrigeration. While syrups or solutions are clearly needed for very young children, providers in the field are desperately calling for better solid formulations for non-infant children.[25] Syrups are more costly than pills, harder to ship, often taste bitter, require large amounts for effective dosage, are difficult to dose correctly, and require refrigeration, which is often unavailable in poorer countries. Crushing adult pills for children makes dosing difficult and can result in dangerous over- or under-dosing.[26]

  Clinicians also require formulations that simplify treatment and improve adherence, such as fixed-dose combinations. Co-packaging and packaging organized around dispensing practices would be useful in the interim.
- *Best Practice Recommendations:* Firms should devote all necessary resources to developing products that meet these needs and do so transparently (including providing timetables). When developing new product lines, pediatric needs should be included in the development process.
- *Pharmaceutical Company Benefits and Opportunities:*
  - Improves its reputation;
  - Gains experience in pediatric formulations transferable to other products;
  - Attracts researchers;
  - Improves relationships with poor country regulators and policymakers;
  - Improves relationships with NGOs;
  - Pediatric AIDS may be included in reward incentives or "pull mechanisms" offered by aid agencies and international philanthropies.[27]
- *Pharmaceutical Company Risks and Costs:*
  - Research and development costs;
  - Risk to reputation if the production costs of pediatric products make those products unaffordable even when sold at cost.

Scoring:

5= Company produces a range of child-friendly formulations for children in each age group for its entire clinically appropriate product line.

4= Company produces several pediatric formulations, but not the complete range of formulations for children of all ages or not the complete range for all clinically appropriate products.

3= Company produces one formulation and is engaged in development of additional formulations for the same drug.

2= Company produces only one formulation.

1= Company does not have any pediatric formulations of drugs that are clinically appropriate for children, or company has not researched whether its current drugs would be appropriate for children.

N/A= Company does not have any antiretroviral drugs that are clinically appropriate for use in children.

Note: Where appropriate, pediatric formulations of malaria treatments are also discussed.

- Top Rated Companies: Bristol-Myers Squibb (4), Merck (4), Roche (4)
- Average Rating: 3.1

Pediatric Needs: Price Cuts

- *Public Health Benefits:* Half of all children born with HIV die before age two. One key reason is the inability of health care providers to afford the high cost of pediatric AIDS medicines.[28]
- *Current Status:* Typically, child formulations are much more expensive than adult formulations. It is more difficult to achieve economies of scale for pediatric products. They are sometimes also more expensive to produce.
- *Best Practice Recommendations:* Pharmaceutical firms should alter the pricing for their pediatric formulations to ensure that the cost of treating a child never exceeds the cost of treating an adult with the same medicine.
- *Pharmaceutical Company Benefits and Opportunities:*
  - Improves its reputation;
  - Boosts its staff morale and recruitment prospects;
  - Simplifies its sales and access programs.
- *Pharmaceutical Company Risks and Costs:*
  - If the cost exceeds the production price, the company may lose some marginal value on sales.

Scoring:

5= Pediatric treatment costs per patient per year are equivalent to adult treatment costs.
4= Pediatric treatment costs are in line with adult treatment costs but not equivalent.
3= Pediatric treatment costs are significantly different.
2= Pediatric formulations are unaffordable.
1= Pediatric formulations are not marketed in developing countries.
N/A= Company does not have any antiretrovirals clinically approved for children.
Note: Scores are given by company, not by product.
• Top Rated Companies: Abbott (5), Boehringer-Ingelheim (5)
• Average Rating: 3.3

Accessibility: Licensing & Technology Transfer

- *Public Health Benefits:* Non-exclusive, voluntary licenses are vital tools in the expansion of access to essential medicines. Such licenses are typically for sales in developing country markets, include a reasonable rate of royalty, and provide for technology transfer or training. Licenses create multiple suppliers for a given drug, and the resulting competition lowers the cost of medicines. Multiple suppliers also reduce the chance that a given market would face a drug shortage. Finally, they can also encourage the production of fixed-dose combinations. Licenses come in two forms: voluntary or compulsory. (Some voluntary licenses are also the result of litigation). Compulsory licenses may provide greater public health benefits, but they are politically difficult to acquire and litigious.
- *Current Status:* Recent changes in international trade policies make voluntary licensing – on reasonable terms and conditions – even more important. For instance, India recently amended patent regulations to allow pharmaceutical product patents for the first time.[29] Other major pharmaceutical exporting nations are making similar changes in their patent laws. Increasingly, bilateral trade agreements are including additional intellectual property protections such as data exclusivity, known as "TRIPS plus."[30] These provisions are encouraged by the pharmaceutical industry but not required by the World Trade Organization. These rules have reduced the ability of generic producers to enter the market in a timely fashion, unless they have compulsory or voluntary licenses.

There are few barriers to using voluntary licenses to increase generic production, and the benefits are substantial. Nonetheless, voluntary licensing is largely unused by American drug companies.[31] Even when granted, many voluntary licenses are granted to one or two companies only and contain unduly restrictive terms such as geographical restrictions, market-segment restrictions (e.g., government sales only), price maintenance and active pharmaceutical ingredient procurement terms, and restrictions on co-formulating with other brands (i.e. no fixed-dose combinations). Many voluntary licenses also lack sufficient technology transfer.

- *Best Practice Recommendations:* Widespread voluntary licensing to all applicants meeting clear, predetermined quality standards, for the company's full range of products.
  - The guiding principle is that multiple licensees should be granted licenses for manufacturing, sale, and distribution in aggregated developing country markets. Non-exclusivity is essential so that robust competition and multiple redundant sources of supply are available from licensees producing at efficient economies of scale. Public health benefits only come when licenses end monopolies, not when they reproduce them. Similarly, these licenses should explicitly allow and encourage the development of therapeutically appropriate fixed-dose combinations.
- *Pharmaceutical Company Benefits and Opportunities:*
  - Lowers the opportunity cost of producing drugs which sell at non-profit prices;
  - Creates good relationships with other generic companies;
  - Reduces the political pressure which comes from being the sole supplier;
  - Gives the patent holder increased ability to control the risk of diversion (compared to compulsory licenses). This can be done by setting clear, consistent guidelines and standards for licensees;
  - Is more predictable for companies than government-issued compulsory licenses.
- *Pharmaceutical Company Risks and Costs:*
  - There is a risk of diversion of drugs into rich countries, though compulsory licensing and differential pricing create similar or greater risks.

Scoring:

This best practice has previously been identified by other investors.[32] Licensing is scored based on the following factors:

a) Company's licenses are non-exclusive.

b) Company licenses its full range of products.

c) Company's licenses are not unduly restrictive (e.g. price maintenance, active pharmaceutical ingredient purchasing restrictions, etc…).

d) Company's licenses allow for sales in a wide range of markets.

e) Company provides training and technology to licensees.

f) Company explicitly allows and encourages co-formulation with other brands to develop appropriate fixed-dose combinations.

5= Company's licenses satisfy all of the above criteria for three or more licensees.

4= Company's licenses satisfy four or five of the above criteria for three or more licensees.

3= Company's licenses satisfy three or fewer of the above criteria for three or more licensees.

2= Company has fewer than three licensees.

1= Company has not issued any licenses.

N/A= Company does not have any antiretrovirals for the treatment of HIV/AIDS.

Note: Companies are only scored for the licensing of antiretrovirals. Nevertheless, we encourage companies to issue voluntary licenses for other treatments for diseases of poverty as well.

• Top Rated Companies: Eli Lilly (5)

• Average Rating: 2.4

Accessibility: Patent Enforcement Relaxation

- *Public Health Benefits:* While forgoing patent protections in emerging markets will not solve the problem of insufficient access to drugs alone, a recent report by the World Health Organization's Commission on Intellectual Property Rights identifies patent relaxation as an important component of efforts to increase access to medicine. Relaxing patents lowers the barriers to entry for generic drug makers.[33, 34] The production of generic drugs in poor nations has been proven to drive down the cost and increase availability of essential medicines, especially antiretrovirals.[35]
- *Current Status:* Under World Trade Organization rules, least developed countries are not required to have pharmaceutical patent protection in place until 2016, and many middle-income countries were to have it in place by 2005. However, as described above, global intellectual property rules are becoming more restrictive.
- *Best Practice Recommendations:* In order to eliminate legal uncertainty around generic production in emerging markets, patent holders can simply inform generic suppliers they would not face civil enforcement actions from the patent-holder for production or sale in least developed countries (LDCs), sub-Saharan Africa or major generic exporting countries. Companies could also undertake a formal filing and delisting or repudiation of a patent with the patent office. The underlying principle is lowering the barrier to entry for generic producers. However, companies should continue to supply all markets, even where they do not have patents, if there is a public health need.[36]
- *Pharmaceutical Company Benefits and Opportunities:*
  - Improves reputation;
  - Can be combined with licensing and technology transfer to reduce the chances of government-issued compulsory licenses;
  - Simplifies messaging around company patent policy;
  - Sends message to emerging market governments that increased intellectual property protections need not adversely impact public health.
- *Pharmaceutical Company Risks and Costs:*
  - Diversion of product from poor to rich markets;
  - Patent relaxation is not typically sufficient to ensure generic production, so company must combine with additional access strategies.

Scoring:

5= Company has no patents in countries that are major generic exporters and no patents in LDCs.

3= Company has a policy of not patenting its drugs in LDCs and sub-Saharan African countries.

1= Company has no global patent policy.

N/A= Company has no antiretrovirals for the treatment of HIV/AIDS.

Note: This report focuses on patents on antiretrovirals primarily, with exceptions for companies focusing on malaria treatments. Nonetheless, companies are encouraged to relax patents on other essential medicines in LDCs.

- Top Rated Companies: Bristol-Myers Squibb (3), Novartis (3), Roche (3)
- Average Rating: 1.6

Accessibility: Differential Pricing

- *Public Health Benefits:* The price of a drug is not the only barrier to access to that drug. However, an affordable price is a prerequisite to addressing the other barriers (such as infrastructure and so on). Pricing drugs differentially in different markets allows patients in those

diverse markets access to the drug. Additionally, drug resistance emerges when patients do not take their full regime of drugs, cycle on and off medicines, or are otherwise noncompliant. High drug costs can be a driver for noncompliance.

- *Current Status:* Every maker of antiretroviral drugs has committed to charging lower prices in markets comprised of purchasers with a reduced ability to pay. Often those prices are referred to as 'not for profit' or 'at cost,' and in theory match the cost of production without profit-taking. These claims are difficult to verify because company financial data is not available to third party reviewers.

Although the HIV epidemic is expanding globally, many companies have limited their policies to sub-Saharan Africa only. Middle-income nations are regularly excluded from differential pricing schemes, or their concerns are addressed on an ad-hoc basis.[37] It is clear, however, that poor patients in Haiti, Thailand, Guatemala and elsewhere have the same right to affordable medicines as individuals in Mozambique and other countries in sub-Saharan Africa.

- *Best Practice Recommendations:* Companies' differential pricing policies must be strengthened in four ways.
  - First, they should be expanded geographically, so that patients in regions other than sub-Saharan Africa and those in middle-income countries can also have affordable access to treatment.
  - Second, the prices must be available in both private and public sectors. There should not be complicated procedural barriers associated with differential pricing programs.
  - Third, differential prices in both low- and middle-income countries should be systemic, not determined on an ad hoc basis.
  - Fourth, differential prices should be regularly reviewed for their impact on drug access. Prices that are significantly higher than generic prices should trigger a review and reduction. In addition, people living with HIV/AIDS and health care providers should be regularly consulted when determining prices.

Differential pricing must be combined with other access strategies. Multiple-source products are preferable to single-source drugs, even when priced affordably, because single-source supplies are dependent on the political whims, supply chain, and distribution capacities of a single firm.

- *Pharmaceutical Company Benefits and Opportunities:*
  - Improves reputation;
  - Improves staff morale and recruitment prospects;
  - Improves relationships with emerging market regulators;
  - Increases predictability of sales and access programs;
  - Increases ability to control potential diversion of products to rich markets.
- *Pharmaceutical Company Risks and Costs:*
  - Increased pricing pressure in rich markets;
  - Some risk of diversion.

Scoring:

5= Low-income country prices are affordable and predictable. Middle-income country prices are affordable and predictable.

4= Low-income country prices are affordable and predictable. Middle-income country prices are affordable, but are not predictable (i.e. are case by case).

3= Low-income country prices are not affordable, but are predictable. Middle-income country prices are not affordable, and may or may not be predictable.

2= Low-income country prices are not predictable but, on a case by case basis, are affordable for some countries.

1= Company does not offer differential pricing which is affordable in any country.

N/A= Company does not have antiretroviral drugs for HIV/AIDS.

Note: While differential pricing strategies should be used for a variety of products, we have focused on antiretrovirals because of the availability of pricing data.

- Top Rated Companies: Merck (5)
- Average Rating: 3.9

Accessibility: Registration

- *Public Health Benefits:* Registered drugs ensure that patients have access to all available treatments. The drugs and treatments required vary among patients, so complete access to all available products is necessary.
- *Current Status:* Drug registration in poor countries can be difficult because of a lack of human and technical capacity in national drug regulatory authorities, corruption, or other factors. Nonetheless, pharmaceutical companies have often failed to obtain registration for all the available dosages and formulations of their products with national drug regulatory agencies. Some fail to register their products altogether in smaller and poorer countries. Even when companies do register their products, they often do so on a delayed basis, delaying access to the newest medicines. These delays and outright failure to register make price discounts offered to developing nations illusory – because drugs cannot be prescribed in nations where they are not registered.
- *Best Practice Recommendations:* In an ideal world, drug registration would not be a burden. Stakeholders are actively working with governments to reduce that burden. Nonetheless, drug companies must work to ensure that patients all over the world have access to their products through universal drug registration. Companies should also pre-qualify their products with the World Health Organization.
  - Similarly, when entering into licensing agreements, companies should specifically agree to give material and technical assistance for drug registration. When compulsory licenses are issued, companies should give explicit reference rights and registration data access rights to licensees for purposes of facilitating registration or marketing approval of the generic products. Finally, companies should ensure that their products are marketed in all necessary countries.
- *Pharmaceutical Company Benefits and Opportunities:*
  - Improves relationships with emerging market regulators;
  - Helps protect markets;
  - Reduces reputation risk.
- *Pharmaceutical Company Risks and Costs:*
  - Registration often takes time and effort;
  - Company may risk political backlash if it discloses a submitted dossier in a country which nonetheless does not grant market approval.

Scoring:

We give companies the benefit of the doubt on this topic, and assume registration except where there is specific information from stakeholders, governments, or multilateral institutions to the contrary. Scores are then given based on the severity of the problem and the company's speed and transparency in responding.

5= We are not aware of any registration problems.

4= Company has registered all products in most - but not all – markets.

3= Company has registered only some products, or has registered in only some markets, but has made specific commitments to improve.

2= Company has registered only some products, or has registered in only some markets.

1= Company has been strongly criticized for consistent and widespread failure to register its drugs.

N/A= Company does not have any antiretrovirals on the market.

Note: We have only scored companies based on their registration of antiretrovirals. Companies are encouraged to ensure that their other essential medicines are registered and marketed widely as well.

- Top Rated Companies: Bristol-Myers Squibb (5), GlaxoSmithKline (5), Roche (5)
- Average Rating: 3.6

Reporting To Shareholders:

- *Public Health Benefits:* Companies with clear, transparent processes and policies for responding to the public health crisis in emerging markets are, quite frankly, likely to be better at doing so.

  But our concern as stockowners of pharmaceutical firms extends beyond the public health benefits of company actions. Potentially, the global intellectual property regime coming into force today could be undermined by the lack of movement from drug companies on this crisis. More concretely, potential markets are being decimated by the pandemics. Measuring and mitigating that impact, with regular public reporting to shareholders, should be at the forefront of company responses to the pandemic.

  Public health would benefit from improved reporting by all companies with exposure to infectious disease threats such as HIV, but the unique role of pharmaceutical products makes reporting by drug makers especially important.

- *Current Status:* Investor groups such as the Interfaith Center on Corporate Responsibility, the Pharmaceutical Shareowners' Group, and Ethical Investment Research Services have been calling for strengthened reporting for many years. PSG found that "Since reporting is not systematic or linked to discussions of investment value, this makes it difficult for investors to assess whether companies are effectively optimizing opportunities and minimizing risk."[38]

  There is no standard for shareholder reports. Many reports tend to be anecdotal, and corporate reporting on HIV/AIDS often focuses solely on philanthropy. Because philanthropic responses are not linked to business strategy and development, reporting on philanthropy does not adequately discuss the business risks of these pandemics nor does it explain how the firm's approach effectively and maximally addresses these risks.

- *Best Practice Recommendations:* In addition to ensuring that company policies are aligned with these best practices, pharmaceutical companies must demonstrate leadership at the highest levels, with regular board involvement on developing HIV/AIDS, Tuberculosis and Malaria policies. We suggest that reporting include:
  - An articulation of the business case for action;
  - Evidence of leadership at the board level;
  - An objective assessment of the options available for expanding access to medicines;
  - Systematic reporting of goals, objectives, and activities so that performance can be transparently evaluated by stakeholders.[39]

- *Pharmaceutical Company Benefits and Opportunities:*
  - Better corporate governance;
  - Better risk management;
  - Improved stakeholder relations;
  - Better internal communication.

- *Pharmaceutical Company Risks and Costs:*
  - Cost of compiling the requisite information;
  - Legal and regulatory costs inherent in public companies issuing such reports.

Scoring:

5= Company's reporting includes an articulation of the business case for action, an assessment of the options for action, systematic reporting of the company's goals and activities, and evidence of leadership at the board level. The report also has pricing schemes and timetables for its access to medicines goals.

4= Company's reporting shows evidence of leadership and specific commitments to address the public health crisis. However, there is minimal discussion of business risks and the company's case for corporate responsibility activities. The report also does not include impact statements or timetables for its goals.

3= Company's reporting includes information about the company's AIDS and other pandemic activities but focuses on philanthropic activities. The report does not address the business risks and opportunities the company faces from the public health crisis. There is no information about leadership at the board level or policy statements.

2= Company's reporting does not include a discussion of business risks and opportunities, nor a specific discussion of commitments, goals and options for activities related to essential medicines. There is no information about leadership at the board level or policy statements.

1= Company's reporting does not have any information about the business risks of the HIV-Malaria-TB pandemics, and the information about its policies, leadership, activities and commitments is minimal or diffuse and hard to find.

- *Top Rated Companies:* GlaxoSmithKline (5)
- *Average Rating: 3.2*

Sustainable Philanthropy:

- *Public Health Benefits:* The sustainability of a philanthropic project is critical to its success as an effective response to the HIV-TB-Malaria pandemics. A sustainable philanthropic initiative ensures that the benefits of the philanthropy - donations, money, technology - will not be subject to untimely termination when the resources are depleted. Instead, a sustainable philanthropic approach will remain available to its target population, increase the capacity of local health care providers and civil society, and flexibly address the evolving needs of the recipient population.

- *Current Status:* Philanthropic programs are the single most popular form of pharmaceutical companies' responses to the HIV/AIDS pandemic. But purely philanthropic responses to the pandemics (gifts of money or products) are not systemic solutions. They are largely reactive measures. Often they fail to consider and prepare for the future of the pandemics: the spread of these pandemics to different populations, the increasing incidence rates, the evolving strains and emergence of drug resistant strains, and the expected long-term demand for these drugs, particularly in the absence of focused prevention and treatment plans. PSG found that few companies took account of future demand and access issues when developing and marketing new products.[40]

  Furthermore, companies often do not adequately assess the drivers and impacts of their philanthropic initiatives as they do with initiatives that are integrated in their core business strategy. Companies often do not monitor their philanthropic programs with sufficient consistency, rigor or transparency.

- *Best Practice Recommendations:* Where philanthropic programs have been established, companies have an obligation to ensure self-sufficiency, and to coordinate with national governments and other donors such as the Global Fund to Fight AIDS, Tuberculosis, and Malaria. They have a particular obligation to ensure that patients already started on antiretroviral treatment have access to those drugs for the rest of their lives.

  Companies should monitor the impacts of these programs, particularly through outside auditing and third-party reporting. They should continue to adapt to the evolution of these pandemics to ensure effectiveness and sustainability. Companies should also report openly and comprehensively to their shareholders about their philanthropic initiatives, indicating how these programs sufficiently and effectively address the risks posed by the pandemics.

- *Pharmaceutical Company Benefits and Opportunities:*
  - Sustainable philanthropic programs are important to maintain a positive reputation;
  - When integrated as part of a business strategy, sustainable philanthropic programs can further the business goals of the company;
  - Company can improve stakeholder relations by showing stakeholders that it is addressing the health crisis with long-term, well-integrated activities;
  - Company can play a role in protecting the development of emerging markets;
  - Sustainable programs will reduce the risk that a charitable program will backfire.
- *Pharmaceutical Company Risks and Costs:*
  - Planning a sustainable philanthropic program may be more expensive than a shorter-term or one-time donation;
  - Sustainable philanthropy often entails partnerships which may bring specific legal or regulatory risks;
  - Partnerships sometimes entail complicated government relations.

Scoring:

5= Company's philanthropic programs are well integrated into its overall access to medicines programs. They are wide-reaching and sustainable. The programs are built into the company's business strategy and reported to shareholders as such. The activities and impacts of the programs are continuously monitored.

4= Company's philanthropic programs are well integrated into its overall access to medicines programs, wide-reaching, and sustainable. The company does not, however, integrate the philanthropic programs into its business strategy. The company reports to shareholders about the programs but does not openly assess options or provide indicators to evaluate impacts.

3= Company's philanthropic programs are part of its overall access to medicines program, but the programs are not systemic or sustainable. Shareholder reporting is limited to descriptions of the programs.

2= Company's philanthropic programs are not presented as part of its overall access to medicines program, and the company provides only anecdotal information about the programs.

1= Company's philanthropic programs are scattered or are not on a scale commensurate with the resources of the company.

N/A= Company has made an affirmative decision to use non-philanthropic means to respond to access to medicines- a choice we see as legitimate.

- Top Rated Companies: Merck (5)
- Average Rating: 3.5

Political Engagement: Political Contributions

- *Public Health Benefits:* In a highly regulated industry such as pharmaceuticals, companies must have a transparent and accountable voice in the political process. However, public health is increasingly impacted by political decisions which are influenced by pharmaceutical companies. Therefore, transparency and accountability from pharmaceutical firms, especially in regards to political spending, may have a positive public health impact. Transparency and accountability are also important to ensure that political spending and influence are consistent with the companies' stated positions and commitments to access to medicines.
- *Current Status:* The wide-spread lack of transparency in political contributions in the industry has been partially addressed by new policies from a small number of firms. In general, however, political giving is difficult to track. Campaign finance reform in the United States, which limited corporate political contributions at the federal level, has actually made corporate political spending more diffuse and difficult to track, according to Institutional Shareholder Services.[41] Investors are increasing concerned about this issue: a recent survey of investors found 90% backed greater disclosure.[42]

- *Best Practice Recommendations:* Current best practice in this area is clear: frequent disclosures of corporate contributions to political candidates, parties, and third-party organizations (such as so-called '527' organizations), regular oversight at the board level of such spending, and a clear rationale ensuring that corporate managers are acting in the interests of both shareholders and patients.[43]
- *Pharmaceutical Company Benefits and Opportunities:*
  - Improves company's ability to ensure its spending is in line with its policies on access to medicines issues;
  - Improves internal controls and corporate governance;
  - Increases transparency for stakeholders.
- *Pharmaceutical Company Risks and Costs:*
  - If the company has not been effectively managing political spending, it may face legal and reputational risks which can threaten shareholder value.

Scoring:

5= Company reports on all political spending, providing individual rationales for each candidate and group to whom it contributes. The company has board oversight of political contributions.

4= Company reports on all political contributions with general rationales, or the company has chosen to forgo contributions, or contributions must be approved by shareholders. The company has board-level oversight.

3= Company reports on all political contributions with general rationales, or the company has chosen to forgo contributions, or contributions must be approved by shareholders. The company has not assigned board-level oversight.

2= Company discloses some of its political contributions, or it discloses aggregate contributions without specific contribution details. Or the company has agreed to disclose all contributions but has not yet implemented its commitment.

1= Company does not disclose any corporate political contributions, and there is no board-level oversight of the contributions.

- Top Rated Companies: Johnson & Johnson (4), Eli Lilly (4), Merck (4), Pfizer (4), Schering-Plough (4)
- Average Rating: 2.3

Political Engagement: Trade Associations

- *Public Health Benefits:* Public health is increasingly impacted by political decisions which are influenced by pharmaceutical companies. The primary vehicle for such influence today is trade associations. Full disclosure of a company's involvement in trade organizations, particularly where payments are used for political purposes, holds companies accountable for their public positions. Transparency is also important to ensure that trade association behavior is consistent with companies' stated positions on access to medicines.
- *Current Status:* Most pharmaceutical firms choose to participate in trade associations such as the Pharmaceutical Research and Manufacturers of America (PhRMA) and the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA). Rarely do companies report their payments or the organizations to which their payments are directed.
- *Best Practice Recommendations:* Companies that participate in such trade organizations should disclose their payments to – and the expenses of – such organizations that are used for political purposes. Public policy positions taken by the organization should be transparent. Payments to third-party organizations, such as think tanks, advocacy groups, and so on, should be kept to a minimum and disclosed.

- *Pharmaceutical Company Benefits and Opportunities:*
  - Improves internal controls and corporate governance;
  - Improves external controls over trade association activities.
- *Pharmaceutical Company Risks and Costs:*
  - Where trade associations are violating campaign finance laws or engaged in other risky behavior, member companies will incur risks.

Scoring:

5= Company fully discloses its trade association payments, and payments to third-party organizations, as well has how those payments are directed. Its payments are consistent with its public position on public health issues. Or, the company is not a member of trade organizations so does not need to report separately on such payments.

4= Company fully discloses all trade association payments but does not disclose how those dues are used for political purposes.

3= Company discloses most, but not all, of its trade association payments but it does not disclose how those payments are used for political purposes.

2= Company discloses only some of its trade association payments and does not disclose how they are used for political purposes.

1= Company is a member of one or more trade association but does not disclose its payments or how they are used for political purposes.

- Top Rated Companies: Gilead (5)
- Average Rating: 1.3

COMPANY PROFILES

Abbott Laboratories

Abbott Laboratories (NYSE: ABT) engages in the discovery, development, manufacture, and sale of health care products. It is a top ten global pharmaceutical company, with three segments: Pharmaceutical Products, Diagnostic Products, and Ross Products (nutritional products). Abbott manufacturers and markets antiretrovirals ritonavir (Norvir) and lopinavir+ritonavir (Kaletra).

Abbott Laboratories (NYSE: ABT)			
COUNTRY: United States		**TOP 10:** ✓	
COMMERCIAL PRODUCTS HIV: ritonavir (Norvir), lopinavir+ritonavir (Kaletra)		**PIPELINE PRODUCTS**	
Approach	Issue	Score	Industry Mean
Research	Fixed Dose Combination	2	2.9
	Neglected Diseases	1	2.5
Pediatric Needs	Formulations	3	3.1
	Price Cuts	5	3.3
Accessibility	Licensing	1	2.4
	Patent Relaxation	1	1.6
	Differential Pricing	3	3.9
	Registration	2	3.6
Reporting to Shareholders		3	3.2
Philanthropy		4	3.5
Political Engagement	Political Contributions	2	2.3
	Trade Association	1	1.3
BOTTOM LINE: Abbott's lack of collaboration with generic pharmaceutical companies or other branded companies is troubling. There is an urgent clinical need for a number of products Abbott could provide: improved pediatric formulations, heat-stable ritonavir, additional FDCs containing ritonavir boosting, and low cost generic lopinavir+ritonavir. The new heat-stable version of lopinavir+ritonavir is a key second line drug. Abbott must ensure that it is universally registered, available, and affordable in adult and pediatric formulations.			

Research: Fixed-Dose Combinations

Abbott's lopinavir+ritonavir (Kaletra) is a fixed-dose combination protease inhibitor. A new tablet formulation of the product, using a technology called Meltrex, does not require refrigeration and may be taken without food. Abbott is applying Meltrex technology to develop a non-refrigerated formulation of ritonavir, but has not given a timeline.[1]

Abbott does not collaborate with other companies to produce additional FDCs, despite the fact that a number of other ARVs must be taken with ritonavir in order to be effective. In response to this report, Abbott stated that it "is open to exploring opportunities for co-formulations with other companies that would represent an advancement over existing treatments for patients."[2] No such opportunities appear to be on the horizon. Abbott could collaborate with companies such as Bristol-Myers-Squibb, whose atazanavir requires ritonavir boosting, among other possibilities.[3] Rating: 2

Research: Neglected Diseases

Abbott's public disclosures of its pipeline do not include any research into neglected diseases.[4] Abbott donates artesunate to the Institute for OneWorld Health, which is developing a low-cost antimalarial medicine.[5] Rating: 1

Pediatric Needs: Formulations

Liquid formulations, which require refrigeration, are available for both Abbott products. However, the company has not produced low-dose pills or granulated medicine that could be mixed with food. Adult pills cannot be scored because they are soft-gel capsules (also requiring refrigeration). The company states that it invested in clinical studies in children for its existing HIV drugs at the same time as they were studied in adult formulations.[6]

WHAT WE DIDN'T INCLUDE

No report can be comprehensive: below are two additional areas we identified as in need of further research and evaluation into corporate practices.

Diagnostics

Bringing effective, affordable tools for the diagnosis of HIV infection and the monitoring of HIV treatment to market in poor countries is an essential and neglected piece of the access to medicines issue. For children under two, the crisis is even more acute. These children carry the antibodies produced by their HIV-positive mothers, meaning the cheap tests used for adults are not reliable. Instead, more expensive viral load tests are required. This is a primary reason children account for a disproportionate share of AIDS deaths.[1]

In early 2004, the Clinton Foundation announced an agreement with several companies to lower the cost of some diagnostic tools.[2] However, additional research is needed to evaluate the degree to which diagnostic companies are appropriately responding to the global AIDS crisis.

Shareholders in the following companies should monitor the situation closely:

Abbott Laboratories (NYSE: ABT), Abbott Park, IL.

Applera, traded as Applied Biosystems (NYSE: ABI), and Celera Genomics Group (NYSE: CRA), Norwalk, CT.

Bayer (NYSE: BAY), Leverkusen, Germany.

Beckman Coulter (NYSE: BEC), Fullerton, CA.

Becton, Dickinson & Company, (NYSE: BDX), Franklin Lakes, NJ.

BioMérieux, (Paris: BIM.PA), Marcy l'Etoile, France.

OraSure (NASDAQ: OSUR), Bethlehem, PA.

Roche (VTX: ROG), Basel, Switzerland.

Clinical Trials Ethics

Many social investment analysts and academics rank clinical trial ethics as one of the top social risks facing pharmaceutical companies, in addition to access to medicines and drug safety. In the case of HIV/AIDS, where participants who become infected during vaccine and prophylaxis trials will require life-long treatment, the issues are particularly acute. As this report was being completed, the *Wall Street Journal* explored the issues facing Gilead Sciences, makers of tenofovir - which may be useful in the prevention of HIV in high-risk populations—in a front page story.[3]

Impacted communities, pharmaceutical companies, public and private agencies which implement clinical trials, and international donors who fund such trials will need renewed collaboration in order to effectively manage these issues.

1 More information is included in the UNICEF "Global Consultation: Reaching out to children in the WHO 3x5 initiative: pediatric HIV care and treatment summary report," 2-3 September 2004.

2 Celia Dugger, "Clinton gets five companies to reduce the cost of AIDS tests," 15 January 2004, New York Times.

3 David Hamilton and Marilyn Chase, "Despite Hope, Decade of Delay Afflicts Drug to Prevent AIDS," 18 May 2006, Wall Street Journal.

The company is developing a low-dose pediatric tablet formulation of lopinavir+ritonavir and of ritonavir with the goals of eliminating the need for refrigeration and providing dosing option flexibility.[7] It has not released a timetable for bringing them to market. Rating: 3

Pediatric Needs: Price Cuts

The cost of lopinavir+ritonavir syrup for least developed countries is $152/patient/year. Ritonavir syrup costs $79/patient/year. Both of these prices are in line with adult formulation prices offered by Abbott.[8] Abbott has not announced the expected cost of the new pediatric formulations. Rating: 5

Accessibility: Licensing & Technology Transfer

Abbott does not issue any voluntary, non-exclusive licenses and has not stated plans to do so. It consistently rejected licensing requests from Brazil. (In March 2006, after Brazil threatened to issue a compulsory license, Abbott lowered the price of lopinavir+ritonavir to $0.63 per pill from $1.17).[9] Rating: 1

Accessibility: Patent Enforcement Relaxation

Abbott does not have patents on its products in many sub-Saharan African markets, with the exception of South Africa. It has indicated that it will not enforce its patent on the current ritonavir capsule formulation in South Africa for five years, yet it notes that no generic manufacturer has produced this product in South Africa.[10] Abbott made no statements about patents on the new formulations of lopinavir+ritonavir and ritonavir. Abbott has a patent monopoly on lopinavir until 2016.[11] The company feels "Abbott's HIV patents are not preventing access to HIV treatment in developing countries."[12] Rating: 1

Accessibility: Differential Pricing

Generic versions of Abbott products are not widely available. Abbott prices tend to be higher than competitor products in similar therapeutic categories. Lopinavir+ritonavir costs $500/patient/year in Africa and the least developed countries (LDCs). Ritonavir costs $83/patient/year. In middle-income countries, "Abbott's approach is to work with governments to address country-specific needs."[13] Middle-income country prices are not predictable or transparent.

When the new formulation of lopinavir+ritonavir becomes available in Africa and LDCs, the price will remain the same. Some observers have estimated the newer formulation is cheaper to produce than its predecessor.[14,15]

Abbott was one of the founding partners of the Accelerating Access Initiative (AAI), a UN-brokered program of branded drug manufacturers with the purpose of accelerating access to care and treatment for HIV/AIDS.[16] Some non-government organizations criticize AAI for insufficient price cuts, geographical restrictions, and an emphasis on public relations.[17] Rating: 3

Accessibility: Registration

Abbott has said that it is making its HIV medicines available in sixty-nine of the world's poorest countries most affected by HIV, including all of Africa and LDCs.[18] Abbott has filed for registration in every sub-Saharan African market except Eritrea, yet as of March 2006, the old formulation of lopinavir+ritonavir is only registered in fifty-four countries.[19]

Some NGOs have complained of a lack of registration or availability in some markets outside Africa. MSF-China has been contacting Abbott since June 2004 about the "growing and urgent" need for access to second line drugs such as Abbott's lopinavir+ritonavir drug. Neither the old nor new formulation of that drug is available in China despite the fact that the old formulation has been registered in China since 2003, and Abbott has not made ritonavir capsules available in China despite its registration in 2002.[20] Abbott did not reply to several requests in 2004 and 2005 for these existing formulas and has not responded to recent requests for the new formula, approved by the FDA in October 2005.[21]

To date, Abbott has not yet registered its new, improved Kaletra formulation in any developing country. However, it recently announced that South Africa has granted fast-track review of the new product.[22] Abbott has said it will actively pursue registration in other African countries, but it is waiting for EU approval before filing dossiers in any of those countries. We are unclear as for the reasons for these delays, and they have left Abbott open to criticism. [23,24] Rating: 2

Reporting To Shareholders

Abbott makes a wide variety of documents, most of them developed from a public relations perspective, available to shareholders. It reports on the results of its programs addressing HIV in several of these documents. It does not articulate business risks or discuss core business issues such as fixed-dose combinations or drug pricing. There is little discussion of the impact HIV/AIDS has on Abbott's business–despite substantial impacts from sometimes tense negotiations over AIDS drugs between Abbott and emerging markets such as Brazil. Rating: 3

Philanthropy

Abbott has made a $100 million commitment to address barriers to testing, treatment and support services for HIV-positive populations in developing countries, including a partnership with the government of Tanzania to improve testing and treatment in Tanzania. It also funds a network of pediatric AIDS clinics run by Baylor College of Medicine. Rating: 4

Political Engagement: Political Contributions

Abbott has agreed to disclose political contributions, including those to 527 groups, beginning in the second quarter of 2006. The company has not assigned board-level responsibility for oversight, nor does it have a political contributions policy statement explaining the procedures and policies that regulate corporate contributions.[25] Rating: 2

Political Engagement: Trade Associations

Abbott is a member of several trade associations and does not disclose dues paid which are used for political purposes. Rating: 1

Abbott's Bottom Line

Abbott's lack of collaboration with generic pharmaceutical companies or other branded companies is troubling. There is an urgent clinical need for a variety of products Abbott could provide: improved pediatric formulations, heat-stable ritonavir, additional FDCs containing ritonavir, and low-cost generic lopinavir+ritonavir. The heat-stable formulation of lopinavir+ritonavir is a key second-line ARV. Abbott must ensure it is universally registered, available, and affordable in adult and pediatric formulations.

AstraZeneca

AstraZeneca (NYSE: AZN) is a top ten pharmaceutical company with 64,000 employees, headquartered in London, with R&D based in Sodertalje, Sweden. Formed via a merger of the UK's Zeneca with Astra of Sweden in 1999, the company is focused on six therapeutic areas: cancer, cardiovascular, gastrointestinal, infection, neuroscience, and respiratory and inflammation. AstraZeneca's leadership is changing: 2005 ended with the deferred retirement of Sir Tom McKillop as chief executive of AstraZeneca. His successor is David Brennan, formerly the Executive Vice-President, North America.[26]

Research: Fixed-Dose Combinations

Currently, AstraZeneca has no antiretrovirals for the treatment of HIV.

Fixed-dose drug combinations can also reduce pill burden, increase patient compliance and reduce the emergence of drug-resistant strains for other infectious diseases besides HIV.
Rating: N/A

Research: Neglected Diseases

Most AstraZeneca products do not address diseases prevalent in the developing world, but in 2003, the firm opened a research facility in Bangalore, India with over seventy scientists, dedicated to developing medicines for drug-resistant tuberculosis and reducing the complexity and duration of treatment regimes. It plans to have a candidate drug for development identified by 2006/2007.[27]

For both developed-world and developing-world public health needs, the company's drug pipeline is weak. [28]
Rating: 3

Pediatric Needs: Formulations

Currently, AstraZeneca has no antiretrovirals for the treatment of HIV.

All essential medicines clinically appropriate for children should be available in a range of pediatric formulations. Rating: N/A

Pediatric Needs: Price Cuts

Currently, AstraZeneca has no antiretrovirals for the treatment of HIV.

Pediatric formulations of essential medicines should be sold at costs in line with adult formulations on a per-patient per-treatment course basis. Rating: N/A

Accessibility: Licensing & Technology Transfer

In regards to its potential TB treatment, AstraZeneca states that it will apply for patent protection when new drugs are developed, but will seek partnership arrangements with appropriate global and local organizations to make treatment available at affordable prices to those in need in the poorest countries.[29] We expect that commitment to include substantial licensing and technology transfer programs. Rating: N/A

AstraZeneca (NYSE: AZN)

COUNTRY: United Kingdom	TOP 10: ✓
COMMERCIAL PRODUCTS TB: candidate drug for drug-resistant TB	**PIPELINE PRODUCTS**

Approach	Issue	Score	Industry Mean
Research	Fixed Dose Combination	N/A	2.9
	Neglected Diseases	3	2.5
Pediatric Needs	Formulations	N/A	3.1
	Price Cuts	N/A	3.3
Accessibility	Licensing	N/A	2.4
	Patent Relaxation	N/A	1.6
	Differential Pricing	N/A	3.9
	Registration	N/A	3.6
Reporting to Shareholders		4	3.2
Philanthropy		2	3.5
Political Engagement	Political Contributions	1	2.3
	Trade Association	1	1.3

BOTTOM LINE: With its immense resources, AstraZeneca has the potential to make a significant contribution to finding new treatments for tuberculosis. We would like to see increased activity in other disease areas. The company has done a decent job of articulating policies, but without products it is difficult to say what it would do in practice.

Accessibility: Patent Enforcement Relaxation

Currently, AstraZeneca has no antiretrovirals for the treatment of HIV.

Companies selling patented essential medicines in emerging markets should consider patent relaxation as a method of increasing generic production of their products. Rating: N/A

Accessibility: Differential Pricing

In its Corporate Responsibility Priority Action Plan, AstraZeneca states its objective is to consider access to medicines when defining pricing and market access strategies for new brands. The company supports the idea of differential pricing in some poor countries, provided appropriate anti-diversion safeguards are in place. However, AstraZeneca does not give any examples of particular products or countries where it has agreed to differential pricing.[30] Rating: N/A

Accessibility: Registration

Currently, AstraZeneca has no antiretrovirals for the treatment of HIV.

Other essential medicines should also be pre-qualified by the WHO, and registered and available in all relevant emerging markets. Rating: N/A

Reporting To Shareholders

In January 2004, an Access to Medicines Director position was created that reports directly to the CEO. The Access to Medicines Director is responsible for directing how access to medicines should be considered for new products both during development and after launch. The company has corporate guidelines on pricing and market access, currently targeted at cancer and infection therapy areas, but with plans to broaden to other therapy areas.[31]

Nonetheless, the company does not articulate the business case for its corporate responsibility activities, and there is little discussion of the risks posed to the company by pandemic diseases.[32] Rating: 4

Philanthropy

AstraZeneca has several locally-based charitable programs, such as a partnership with the Red Cross and Red Crescent in a tuberculosis program in Kyrgyzstan and Turkmenistan,[33] and a sanitation and health education program in parts of India.[34] We found the scope of AstraZeneca's developing-country philanthropy to be lagging behind competitors, given the company's size. Rating: 2

Political Engagement: Political Contributions

Like all U.K. companies, AstraZeneca shareholders must approve in advance political spending in the European Union. At the annual meeting on April 28, 2005, shareholders authorized the company to make donations or incur expenditure in the EU up to $150,000.[35, 36]

In the United States, AstraZeneca is not a major giver ($323,000 in 2004). On its website, the company says that "any political contributions...must be...approved under procedures laid down by the board or governing body of the Company concerned," but the company does not disclose its political contributions or require board-level oversight. Rating: 1

Political Engagement: Trade Associations

AstraZeneca is a member of several trade associations, including PhRMA (Pharmaceutical Research and Manufacturers of America), EFPIA (European Federation of Pharmaceutical Industries and Associations), and IFPMA (International Federation of Pharmaceutical Manufacturers and Associations), but it does not disclose dues paid which are for political purposes. Rating: 1

AstraZeneca's Bottom Line

With its immense resources, AstraZeneca has the potential to make a significant contribution to finding new treatments for tuberculosis. We would like to see increased activity in other disease areas. The company has done a decent job of articulating policies, but without products it is difficult to say what it would do in practice.

Boehringer-Ingelheim

Boehringer-Ingelheim (BI) is the only private, family-owned company among the world's major pharmaceutical companies. BI is headquartered in Ingelheim, Germany with nearly 36,000 employees worldwide. BI business consists of Prescription Medicines, Consumer Health Care and Animal Health. BI's traditional expertise is in cardiovascular, central nervous system, and respiratory issues. In recent years, BI has also increased its focus on HIV/AIDS, arthritis and urological disorders. BI makes the antiretroviral drugs tipranavir (Aptivus) and nevirapine (Viramune). Nevirapine is especially important in the prevention of mother-to child transmission (MTCT) of HIV.

Research: Fixed-Dose Combinations

BI launched tipranavir, a protease inhibitor licensed from Pfizer (then Pharmacia), in 2005. The drug provides options to patients with resistance to multiple protease inhibitors. It is late-stage therapy and is today only available in the West. As patients in the developing world develop resistance to first and second line treatments, tipranavir may become more important for those patients as well. As tipranavir must be co-

Boehringer-Ingelheim (BI)

COUNTRY: Germany	**TOP 10:** No
COMMERCIAL PRODUCTS HIV: tipranavir (Aptivus), nevirapine (Viramune)	**PIPELINE PRODUCTS** HIV: new non-nucleoside reverse transcriptase inhibitor (NNRTI)

Approach	Issue	Score	Industry Mean
Research	Fixed Dose Combination	1	2.9
	Neglected Diseases	1	2.5
Pediatric Needs	Formulations	2	3.1
	Price Cuts	5	3.3
Accessibility	Licensing	3	2.4
	Patent Relaxation	1	1.6
	Differential Pricing	4	3.9
	Registration	4	3.6
Reporting to Shareholders		2	3.2
Philanthropy		3	3.5
Political Engagement	Political Contributions	1	2.3
	Trade Association	1	1.3

BOTTOM LINE: BI's robust licensing policy could provide a firm foundation on which to build. Yet unlike peer companies, BI has given no indication it will entertain further voluntary licenses. BI must take large steps forward to improve transparency around pricing in middle-income countries and respond aggressively to HIV/AIDS as a compelling business issue.

administered with ritonavir for the drug to be effective, we recommend research into fixed-dose combinations of these drugs.[37]

The company is also conducting clinical trials into combination therapy for the prevention of mother-to-child transmission (MTCT) of HIV infection, with nevirapine and lamivudine+zidovudine.[38] In July 2004, BI and GlaxoSmithKline announced that they had "signed a letter of intent" to co-package BI's nevirapine and GSK's lamivudine+zidovudine.[39] GSK informed us that "it was decided that the fastest way to get such a co-package to patients would be to work through one of our licensees, Aspen Pharmacare in South Africa." According to GSK, this co-package is already on the market in Africa and has been approved by the FDA.[40] At a meeting with people living with AIDS, BI stated that it decided not to move forward with research on an FDC because it "turns into a regulatory nightmare" and that it doesn't know "how to make it happen, given the anti-trust laws."[41]

BI has additional research and development in HIV focusing on treatment-experienced patients and has identified a potential new non-nucleoside reverse transcriptase inhibitor (NNRTI) to follow-on nevirapine. Rating: 1

Research: Neglected Diseases

There is no additional neglected disease research we are aware of. Rating: 1

Pediatric Needs: Formulations

BI manufactures nevirapine in an oral suspension, which is registered in most countries for use in children. The company states that in all of its HIV research activities, special care is given to pediatric indications. Currently, nevirapine is not available in scored or low-dose tablets, which would be welcomed by clinicians.[42] Tipranavir clinical trials in children are in progress.[43,44] Rating: 2

Pediatric Needs: Price Cuts

The First Category price (least developed countries) for liquid nevirapine is USD $400 per patient per year. This compares to the First Category price of tablet (adult) nevirapine of USD $438.[45] The cost of pediatric formulations is equivalent to the cost of the adult tablets. However, the cost of both formulations is higher than generic equivalents. Rating: 5

Accessibility: Licensing & Technology Transfer

After a yearlong inquiry by the South African Competition Commission into accusations of excessive pricing, in December 2003 BI agreed to issue licenses to generics companies to import or manufacture and market nevirapine with a 5% royalty.[46] In 2003, BI issued a voluntary license to South African's Aspen Pharmacare to manufacture and market nevirapine in the public sector in fourteen Southern Africa Development Community (SADC) nations.[47, 48] BI has since issued four more voluntary licenses to companies in South Africa, Nigeria, Egypt and Kenya, including at least one without royalties.[49] We were unable to determine the geographic scope of these licenses, but they include the license to export to at least the countries of the SADC and probably to all sub-Saharan African countries. Rating: 3

Accessibility: Patent Enforcement Relaxation

The company has no statements relaxing its patent rights in least developed countries. This is particularly important as it has patents in many countries that could benefit from fixed-dose combinations containing nevirapine. Rating: 1

Accessibility: Differential Pricing

BI offers nevirapine at reduced prices in select countries, including all World Bank low-income countries and sub-Saharan Africa. Other countries are on a case-by-case basis, which makes pricing unpredictable and less transparent.[50] Tablet prices in particular are much higher than generic equivalents. The First Category price (least developed countries) for liquid nevirapine is USD $400 per patient per year and $438 for the tablet formulation. Generic equivalents range from $82 to $411 for the liquid formulation and from $73 to $255 for the tablet formulation.[51]

BI was one of the founding partners of the Accelerating Access Initiative (AAI), a UN-brokered program of branded drug manufacturers with the purpose of accelerating access to care and treatment for HIV/AIDS. Some non-government organizations criticize AAI for insufficient price cuts, geographical restrictions, and an emphasis on public relations. [52,53] Rating: 4

Accessibility: Registration

BI has not often been criticized for registration lags, but it does not market liquid nevirapine suspension in China. Lack of nevirapine suspension makes treatment of children very difficult, as adult tablets have to be broken to approximate the proper dosage.[54] Rating: 4

Reporting To Shareholders

BI is a private company and does not share the same fiduciary duty and disclosure requirements as peer companies. Nonetheless, BI has an interest in robust reporting to stakeholders to maintain a social license to operate.

BI endorses the concept of corporate social responsibility[55] and claims to have an early recognition system for business risk.[56] However, HIV/AIDS is not identified as a risk, despite BI's immense exposure and recent litigation (in South Africa, for example, as discussed above).

It would also be beneficial to BI and stakeholders for BI to report on the extent to which its voluntary licenses have resulted in increased access to essential medicines in developing countries. Rating: 2

Philanthropy

Since 2000, BI has given free access to single-dose nevirapine through its Viramune Donation Program for the prevention of mother-to-child transmission (MTCT) of HIV. Nevirapine is to be used alone or in combination with other drugs, to prevent the transmission of the HIV virus during birth.[57] Currently, the company is donating the product to 140 programs in fifty-eight countries, with more than 634,000 mother and child doses supplied.[58, 59]

The company has offered nevirapine for free only for the use of MTCT prevention in the public sector and not for an antiretroviral treatment program. Antiretroviral donation programs are controversial - some observers argue that by giving away the drug for MTCT programs, the company may be undermining the generic market for nevirapine, complicating procurement systems, and even contributing to stigma by distinguishing between "innocent" newborns and other AIDS patients.

The company also has relatively small-scale education, training, and capacity-building programs in South Africa, Swaziland, Botswana, Malawi, Cambodia, and Papua New Guinea. Rating: 3

Political Engagement: Political Contributions

BI does not report its political contributions or any oversight procedures. Rating: 1

Political Engagement: Trade Associations

BI is a member of several trade organizations and does not disclose dues paid which are for political purposes. Rating: 1

Boehringer-Ingelheim's Bottom Line

BI's robust licensing policy could provide a firm foundation on which to build. Yet unlike peer companies, BI has given no indication it will entertain further voluntary licenses. BI must take large steps forward to improve transparency around pricing in middle-income countries and respond aggressively to HIV/AIDS as a compelling business issue.

Bristol-Myers Squibb

Founded in 1887, Bristol-Myers Squibb Company (NYSE: BMY) is a top ten pharmaceutical company which engages in the discovery, development, licensing, manufacture, marketing, distribution, and sale of pharmaceutical products. The company primarily operates in three segments: Pharmaceuticals, Nutritionals, and Other Healthcare. The Pharmaceuticals segment provides branded pharmaceutical products for cardiovascular, virology, including human immunodeficiency virus, infectious diseases, oncology, and affective disorders.

The company manufactures and markets atazanavir, didanosine, stavudine, and manufactures and markets efavirenz in the United States (Merck markets efavirenz globally).

Research: Fixed-Dose Combinations

In a joint venture with Gilead Sciences, maker of tenofovir and emtricitabine, Bristol is developing a three-in-one pill which will be efavirenz+tenofovir+emtricitabine. This will be the first fixed-dose combination

Bristol-Myers Squibb (NYSE: BMY)

COUNTRY: United States	**TOP 10:** ✓
COMMERCIAL PRODUCTS HIV: atazanavir (Reyataz), didanosine (Videx), stavudine (Zerit), efavirenz (Sustiva)	**PIPELINE PRODUCTS**

Approach	Issue	Score	Industry Mean
Research	Fixed Dose Combination	5	2.9
	Neglected Diseases	1	2.5
Pediatric Needs	Formulations	4	3.1
	Price Cuts	3	3.3
Accessibility	Licensing	2	2.4
	Patent Relaxation	3	1.6
	Differential Pricing	4	3.9
	Registration	5	3.6
Reporting to Shareholders		3	3.2
Philanthropy		4	3.5
Political Engagement	Political Contributions	2	2.3
	Trade Association	1	1.3

BOTTOM LINE: Bristol-Myers Squibb shows some much needed flexibility on licensing and patents, continues to make significant research commitments, and has created effective partnerships with Gilead Sciences and International Partnership for Microbicides. Its core need is more effective reporting with quantitative goals and measures, especially on emerging products such as the new FDC.

developed by branded drug companies. Merck, which has a license from Bristol to sell efavirenz outside of North America, is also involved.[60]

Bristol's drug atazanavir is a relatively new AIDS drug that is considered especially effective when used in a cocktail with ritonavir, manufactured by Abbott Laboratories.[61] Bristol should collaborate with Abbott to create an FDC of these two drugs. Rating: 5

Research: Neglected Diseases

While Bristol has a substantial research commitment in the area of $200 million per year to HIV/AIDS, there is no similar commitment to other diseases of poverty.[62] Rating: 1

Pediatric Needs: Formulations

We found conflicting information about available pediatric formulations of Bristol's drugs. An IFPMA report says that both stavudine and didanosine are available as powders used to make liquid solutions, and that didanosine is also available in chewable tablets (a new formulation of didanosine, Videx EC, has no pediatric version). The report also says that BMS makes a pediatric solution of efavirenz.[63] However, MSF reports that there are no pediatric formulations of didanosine, but that low-dose capsules are available for stavudine. The report does not mention pediatric versions of efavirenz.[64]

Bristol should clear up this confusion by improving its own reporting. In addition, the company should develop pediatric formulations of atazanavir. There is no public timetable for bringing new pediatric formulations to market. [65] Rating: 4

Pediatric Needs: Price Cuts

The prices of stavudine and didanosine powders are $358/patient/year and $133/patient/year, respectively. Stavudine prices remain significantly different from adult formulation prices. Rating: 3

Accessibility: Licensing & Technology Transfer

Bristol recently announced an agreement for royalty-free voluntary licenses and technology transfers for atazanavir with two generic manufacturers: South Africa's Aspen PharmaCare Holdings Ltd. and India's Emcure Pharmaceuticals Ltd.[66] Both companies can make and sell the drug to sub-Saharan Africa, and Emcure can sell in India. Bristol will also provide training at the South African and Indian facilities, and will provide support for regulatory filings.[67] It is laudable that the license came less than two years after the US launch of the drug; however, BMS will need to increase the number of licensees to come into full compliance with the best practice.

The company also issued a royalty-free license to the International Partnership for Microbicides (IPM) for a novel compound that inhibits the entry of HIV into healthy cells. Rating: 2

Accessibility: Patent Enforcement Relaxation

In 2001, following civil society action, Bristol was the first drug company to publicly declare that "The company will ensure that its patents do not prevent inexpensive HIV/AIDS therapy in Africa."[68] Bristol aggressively defended legal action in Thailand threatening its didanosine patent. (After several years and losses in court, BMS ended the suit by relinquishing the patent). Rating: 3

Accessibility: Differential Pricing

Stavudine is available for $55/patient/year. Didanosine varies from $198 to $310/patient/year, depending on the dosage purchased. This is in line with competitor products and generic versions. We were unable to find data on atazanavir, which concerned us.

Middle-income countries are handled on a case-by-case basis and are not treated uniformly and transparently. Bristol has not yet announced a discount price for its new fixed-dose combination antiretroviral.

BMS was one of the founding partners of the Accelerating Access Initiative (AAI), a UN-brokered program of branded drug manufacturers with the purpose of accelerating access to care and treatment for HIV/AIDS.[69] Some non-government organizations criticize AAI for insufficient price cuts, geographical restrictions, and an emphasis on public relations.[70] Rating: 4

Accessibility: Registration

Bristol data provided to ICCR shows registration of stavudine and didanosine in approximately seventy low and middle-income countries, with buffered didanosine (a new formulation) registered in sixty-eight countries and pending in another twenty-three. We were unable to locate data on atazanavir in WHO records and were not provided data from Bristol on that product. Rating: 5

Reporting To Shareholders

Bristol, like most pharmaceutical companies, has a wide range of brochures and websites discussing its AIDS initiatives, with a focus on philanthropic initiatives. In 2001 BMS hired the International Association of Physicians in AIDS Care to do an evaluation of its then two-year-old philanthropic program, which is branded Secure The Future. It has continued to report robustly on Secure The Future since then, although another full-scale evaluation has not been completed.

Nonetheless, the company's reporting on grant making does not substantially address the additional best practices included here. Nor does it assist shareholders in determining the risks and opportunities BMS uniquely faces from the public health crisis in emerging markets.

We are also concerned about the lack of information on the development and accessibility of Bristol's new FDC, including pricing schemes, registration efforts and timelines for new pediatric formulations. Rating: 3

Philanthropy

Bristol's $150 million Secure The Future program supports a range of activities, with a focus on orphans and vulnerable children. In addition, the company has taken the lead in creating a Pediatric AIDS Corps, a program where pediatricians spend time abroad treating children with AIDS, and their medical school loans and so on are covered by the program. Rating: 4

Political Engagement: Political Contributions

The company discloses its political contributions and regularly reports such contributions to the board of directors. This is a new policy and the company has yet to report on its implementation. Rating: 2

Political Engagement: Trade Associations

The company does not disclose trade association dues which are spent on political activity. In fiscal year 2007, CEO Peter Dolan will become Chair of PhRMA. Rating: 1

Bristol-Myers Squibb's Bottom Line

Bristol-Myers Squibb shows some much needed flexibility on licensing and patents, continues to make significant research commitments, and has created effective partnerships with Gilead Sciences and International Partnership for Microbicides. Its core need is more effective reporting with quantitative goals and measures, especially on emerging products such as the new FDC.

Gilead Sciences

Gilead (NASDAQ: GILD) is a biopharmaceutical company specializing in discovering, developing, and commercializing small molecule therapeutics to treat infectious diseases. Founded in 1987, the company developed and distributes antiretrovirals tenofovir (Viread), emtricitabine (Emtriva), and a combination therapy of the two products (Truvada). In addition, Gilead developed oseltamivir, commonly known as Tamiflu, which may be effective against the H5N1 flu strain currently infecting birds and widely feared for a human epidemic centered in Southeast Asia. Oseltamivir is marketed by Roche.

Research: Fixed-Dose Combinations

In a joint venture with Bristol-Myers Squibb, maker of efavirenz, Gilead Sciences is developing a three-in-one pill which will be efavirenz+tenofovir+emtricitabine. This will be the first fixed-dose combination developed by branded drug companies. Merck, which has a license from Bristol to sell efavirenz outside of North

Gilead Sciences (NASDAQ: GILD)	
COUNTRY: United States	**TOP 10:** No
COMMERCIAL PRODUCTS HIV: tenofovir (Viread), emtricitabine (Emtriva), tenofovir+emtricitabine (Truvada) • Flu: oseltamivir (Tamiflu)	**PIPELINE PRODUCTS** HIV: GS 9137, efavirenz+tenofovir+emtricitabine

Approach	Issue	Score	Industry Mean
Research	Fixed Dose Combination	5	2.9
	Neglected Diseases	1	2.5
Pediatric Needs	Formulations	3	3.1
	Price Cuts	1	3.3
Accessibility	Licensing	2	2.4
	Patent Relaxation	1	1.6
	Differential Pricing	4	3.9
	Registration	2	3.6
Reporting to Shareholders		3	3.2
Philanthropy		N/A	3.5
Political Engagement	Political Contributions	1	2.3
	Trade Association	5	1.3

BOTTOM LINE: Gilead is a nimble company that has shown leadership in developing a new fixed dose combination product. It has awakened to criticisms of its lack of pediatric formulations and lack of registration, but must do better to lay those concerns to rest. Better reporting, including clear statements on the status of its efforts, would go a long way towards addressing concerns.

America, is also involved. Gilead is the lead company. In addition, Gilead has partnered with Aspen Pharmacare, a generic company that will offer co-packaging of the three medicines in the interim period.[71] Rating: 5

Research: Neglected Diseases

With a focus solely on infectious disease, Gilead is well positioned to be a major player in combating diseases of poverty. The company has focused a great deal on hepatitis and has additional pre-clinical research into new HIV therapies. However, we do not see a concerted neglected disease focus by the company. Rating: 1

Pediatric Needs: Formulations

Gilead has an oral solution of emtricitabine, but it is not available in developing countries. It has not yet come to market with pediatric formulations of tenofovir or its combination drug.[72]

Gilead told us that a liquid formulation of tenofovir is not feasible because of its unpalatable taste, and that it is attempting "to develop a new 'coated sprinkle' formulation that will take approximately one year to

complete."[73] The company is conducting clinical studies of tenofovir in adolescents. Gilead has not released a timetable for when pediatric formulations of emtricitabine and its other drugs may be available in developing countries, and we are not aware of any research into low-dose or scored tablets. Rating: 3

Pediatric Needs: Price Cuts

Gilead has not yet come to market with pediatric formulations in developing countries. Rating: 1

Accessibility: Licensing & Technology Transfer

Gilead has issued a marketing, technology transfer and distribution license to Aspen Pharmacare, for tenofovir and tenofovir+emtricitabine (but not emtricitabine alone, or the tenofovir+emtricitabine+efavirenz FDC in development). It is open to additional licensees but maintains that reaching the economies of scale required for low prices requires consolidated production - at the very least, of the active pharmaceutical ingredient.[74] Rating: 2

Accessibility: Patent Enforcement Relaxation

Gilead has made no statements relaxing its patent rights. Gilead has applied for a patent of tenofovir in India under India's new patent laws. Indian AIDS advocacy groups, including the Delhi Network of Positive People and Indian Network for People living with HIV/AIDS, are vehemently opposing the application, in one of the first major challenges to the new Indian legislation.[75] A generic version, tenvir, is already being produced by Cipla. An Indian patent could give Gilead twelve-year market exclusivity in India. Rating: 1

Accessibility: Differential Pricing

Gilead prices for tenofovir are $204 per patient per year; tenofovir+emtricitabine is $315. These prices are in line with similar products from other companies. In addition, Gilead prices are published on its website. Other companies required us to use third-party reports.

However, middle-income countries are forced to negotiate with Gilead on a case-by-case basis, with no predictable or transparent pricing. Gilead has been engaged in relatively high profile negotiations with Brazil, for example. The company should have a consistent, transparent formula for determining middle income pricing for all sectors.

The price for the new FDC has not been published, but Gilead should ensure that this valuable drug is affordable in all markets to ensure wide-spread access.

Gilead is one of the partners of the Accelerating Access Initiative (AAI), a UN-brokered program of branded drug manufacturers with the purpose of accelerating access to care and treatment for HIV/AIDS.[76] Some non-government organizations criticize AAI for insufficient price cuts, geographical restrictions, and an emphasis on public relations.[77] Rating: 4

Accessibility: Registration

Gilead has been harshly criticized by health care providers for a lack of product registration in developing countries.[78] New WHO guidelines add tenofovir to the Essential Drugs List. But Gilead has filed for registration of tenofovir in only fifty-four of ninety-seven countries eligible for reduced prices under the Gilead Access Program. Tenofovir+emtricitabine is filed in only forty-seven countries. Gilead reports that, to date, tenofovir and tenofovir+emtricitabine are registered in ten and four Access countries respectively.[79]

The company has responded by requiring generic licensee Aspen Pharmacare to register the product in sub-Saharan African markets and by committing to register the product itself in other markets. Gilead should report frequently on the status of these registration efforts and ensure that the new FDC in development is not stymied by a similar delay. Rating: 2

Reporting To Shareholders

Gilead's reporting to shareholders focuses on its access programs, with transparent pricing information for low-income countries. We found little basis for evaluating risks or opportunities available to the company. We also would have been more comfortable, given the criticism on registration, to see more information on how the company is responding. Recently, Institutional Shareholder Services found that Gilead "does not appear to provide the level of detail or discussion on the issue found at many other companies."[80] Rating: 3

Philanthropy

Gilead does not appear to have significant charitable activities. This report takes an all-or-nothing approach to philanthropy. Companies which engage in it must engage fully, but those who choose not to, such as Gilead, are not penalized. Rating: N/A

Political Engagement: Political Contributions

Gilead does not disclose its corporate political contributions and does not have oversight of the political contributions at the board level. Disclosure is particularly important because Gilead has high-profile political figures as current (George Schultz) or former (Donald Rumsfeld) Directors. Rating: 1

Political Engagement: Trade Associations

Gilead is not a member of the major pharmaceutical trade associations and so does not need to report separately on trade association dues used for political purposes. Rating: 5

Gilead's Bottom Line

Gilead is a nimble company that has shown leadership in developing a new fixed-dose combination product. It has awakened to criticisms of its lack of pediatric formulations and lack of registration, but must do better to lay those concerns to rest. Better reporting, including clear statements on the status of its efforts, would go a long way towards addressing concerns.

GlaxoSmithKline

GlaxoSmithKline (NYSE: GSK) is one of the world's largest pharmaceutical companies, following the merger in 2001 of Glaxo Wellcome and SmithKline Beecham. It is the market leader in HIV therapies.[81] GSK has four main therapeutic areas: anti-infectives, central nervous system, respiratory and gastrointestinal/metabolic. The company also has a Consumer Healthcare portfolio comprising over-the-counter (OTC) medicines, oral care products and nutritional healthcare drinks.

Its current medicines for HIV are amprenavir (Agenerase), lamivudine+zidovudine (Combivir), lamivudine (Epivir), lamivudine+abacavir (Epzicom), fosamprenavir (Lexiva), zidovudine (Retrovir), abacavir+lamivudine+zidovudine combination tablet (Trizivir) and abacavir (Ziagen). GSK is also an industry leader in vaccine development.

Research: Fixed-Dose Combinations

GSK produces lamivudine+zidovudine (Combivir), abacavir+lamivudine+zidovudine (Trizivir) and lamivudine+abacavir sulfate (Epzicom). However, although GSK has a strong internal product line, it does not collaborate with outside companies to manufacture fixed-dose combinations.

In July 2004, BI and GSK announced that they had "signed a letter of intent" to co-package BI's nevirapine and GSK's lamivudine+zidovudine.[82] GSK informed us that "it was decided that the fastest way to get such a co-package to patients would be to work through one of our licensees, Aspen Pharmacare in South Africa." According to GSK, this co-package is already on the market in Africa and has been approved by the FDA.[83] GSK has not stated plans to research a fixed-dose combination with BI. Rating: 2

Research: Neglected Diseases

GSK has the most substantial neglected disease program in the industry. It has created a group within its R&D organization "to focus on diseases of the developing world." To date, GSK has thirteen clinical development programs targeting eight diseases particularly relevant to developing countries.[84] It is the only pharmaceutical company with vaccines and drugs for malaria, tuberculosis and HIV in its pipeline.

In June 2005, GSK announced plans to launch five vaccines over the next five years, for rotavirus, cervical cancer, pneumococcal disease, influenza and meningitis. It has brought Rotarix, for rotavirus, to market in several developing countries. Rotavirus is the leading cause of severe diarrhea in infants, killing 500,000 children annually, mostly in developing countries.

GSK is in clinical trials with vaccines against dengue fever and hepatitis C, and it also has an HIV recombinant vaccine, a combination vaccine for measles, mumps, rubella and varicella, and a TB vaccine in the pipeline.[85] GSK has announced a new joint TB drug discovery partnership with the Global Alliance for TB Drug Development.[86]

GSK is in the early stages of testing a malaria vaccine, Mosquirix, for children.[87] It is also in phase III trials of an "affordable fixed-dose artemisinin combination treatment for malaria in Africa, ...likely to be effective against drug resistant *P falciparum* malaria as found in Africa."[88]

GSK is also in phase II trials of a protease inhibitor for HIV treatment and of a new oral treatment for visceral leishmaniasis, which affects over half a million people a year in the developing world.[89] Rating: 5

GlaxoSmithKline (NYSE: GSK)

COUNTRY: United Kingdom

TOP 10: ✓

COMMERCIAL PRODUCTS
HIV: amprenavir (Agenerase), lamivudine+zidovudine (Combivir), lamivudine (Epivir), lamivudine+abacavir (Epzicom), fosamprenavir (Lexiva), zidovudine (Retrovir), abacavir+lamivudine+zidovudine (Trizivir), abacavir (Ziagen) • Malaria: atovaquone and proguanil hydrochloride (Malarone), chlorproguanil-dapsone (Lapdap)

PIPELINE PRODUCTS
HIV: candidate vaccine, candidate protease inhibitor TB: candidate vaccine • Rotavirus: candidate vaccine Influenza: candidate vaccine • Malaria: Mosquirix vaccine, candidate drug for drug resistant malaria • Dengue Fever: candidate vaccine • Leishmaniasis: candidate drug

Approach	Issue	Score	Industry Mean
Research	Fixed Dose Combination	2	2.9
	Neglected Diseases	5	2.5
Pediatric Needs	Formulations	3	3.1
	Price Cuts	4	3.3
Accessibility	Licensing	4	2.4
	Patent Relaxation	1	1.6
	Differential Pricing	4	3.9
	Registration	5	3.6
Reporting to Shareholders		5	3.2
Philanthropy		4	3.5
Political Engagement	Political Contributions	1	2.3
	Trade Association	1	1.3

BOTTOM LINE: GSK is an industry leader in reporting, licensing, and research, but also has points of vulnerability. We suggest GSK improve transparency around political spending, both directly and through trade associations; improve its middle-income pricing strategy; collaborate with other companies to produce fixed-dose combinations; and issue licenses to additional generic companies, particularly for second-line drugs and in middle-income markets, such as China.

Pediatric Needs: Formulations

GSK has oral solutions of abacavir, amprenavir, lamivudine and zidovudine, a syrup formulation of zidovudine and syrup and dry syrup formulations of lamivudine. GSK is currently assessing the development of scored tablets for use in children for the company's key ARVs: lamivudine, abacavir, and lamivudine+zidovudine.[90] There is an urgent need for a pediatric version of lamivudine+zidovudine. Rating: 3

Pediatric Needs: Price Cuts

Pediatric prices are listed as abacavir: $382 for oral solution; lamivudine: $82 for oral solution/syrup/dry syrup; zidovudine: $223 for oral solution/syrup.

This compares to adult formulations for abacavir: $887 for tablets; lamivudine: $69 for tablets; zidovudine: $117-212 for capsules/tablets, depending on the dosage.[91] GSK has almost closed the gap between pediatric and adult formulation prices. Rating: 4

Accessibility: Licensing & Technology Transfer

GSK states that it supports voluntary licensing "as a specific response to a particular set of circumstances" and not as "a universal solution."[92] GSK has issued seven licenses to date. As a result of legal pressure, GlaxoSmithKline licensed zidovudine and lamivudine to four South African producers, including Thembalami, the now-defunct joint venture of India's Ranbaxy and South Africa's Adcock Ingram; neither Ranbaxy nor Adcock has been able to secure licenses following Thembalami's demise. Cipla-Medpro (now part of Enaleni Pharmaceuticals) and Aspen are licensed in South Africa. GSK has also licensed to Cosmos Limited and Universal Corporation in Kenya.[93]

GSK also has a technology transfer, supply and license arrangement in place with the Brazilian government for the production of the measles, mumps and rubella vaccine. Rating: 4

Accessibility: Patent Enforcement Relaxation

GSK has not made any statements in regards to refraining from enforcing patents in developing countries. GSK is currently seeking a patent in India for lamivudine+zidovudine; lamivudine+zidovudine (Combivir) is the first ARV to be reviewed by the Indian patent office under India's new patent laws. GSK also has a monopoly on lamivudine in China but has not made the drug available in the dosages required.[94]

In response to this report, GSK said "having a policy that states that patents will not be enforced in certain markets does not necessarily make it easier for generics to become available. In fact, blanket 'relaxations' could mean that companies 'wash their hands' of the issue and do not register new products...or provide technology transfer."[95] GSK argues that patents do not contribute to lack of access to medicines, and without adequate intellectual property protection, many life-saving medicines would not be developed. The company supports the health safeguards of the TRIPS agreement. Rating: 1

Accessibility: Differential Pricing

GSK sells its AIDS medicines and antimalarials at not-for-profit prices to public sector customers and other organizations in sixty-four countries, including all of sub-Saharan Africa.[96] The company has explicit statements of support for preferential pricing, voluntary licensing, and public-private partnerships. Preferential pricing offers for developing countries for relevant medicines are on its website.

For LDCs, prices for abacavir are $887 per patient per year; lamivudine, $69; lamivudine+zidovudine+abacavir, $1241; lamiduvine+zidovudine, $237; zidovudine, $241, $117, $212, depending on the dosage.[97] For middle-income countries, prices vary on a case-by-case basis.[98] In response to this report, GSK said that it is only able to offer not-for-profit prices to the LDCs if wealthier and middle-income countries contribute to the ongoing cost of R&D.[99]

GlaxoSmithKline offers the lowest price available to all projects fully funded by the Global Fund to Fight AIDS, TB and Malaria and PEPFAR, regardless of location. This is an improvement over peer companies, whose best prices do not apply to Global Fund projects if they are in middle-income countries.

The Clinton Foundation recently announced that it had negotiated lower prices with Indian generic Cipla to manufacture abacavir, an important second-line drug, for $447, with volume requirements.[100, 101, 102] GSK

currently sells abacavir for $887 per patient per year in least developed countries and sub-Saharan Africa.

GSK was one of the founding partners of the Accelerating Access Initiative (AAI), a UN-brokered program of branded drug manufacturers with the purpose of accelerating access to care and treatment for HIV/AIDS.[103] Some non-government organizations criticize AAI for insufficient price cuts, geographical restrictions, and an emphasis on public relations.[104] Rating: 4

Accessibility: Registration

GSK first-line products are widely registered. The company must ensure second-line products are as well. Rating: 5

Reporting To Shareholders

GSK has the best reporting in the industry on this subject. There is a designated board member responsible for external stakeholder issues. Its CSR report includes specific information on medicines for the developing world, community investment, and R&D. There is a detailed description of supported projects. In addition, GSK articulates its business interest in responding to HIV/AIDS.[105] We would like to see more specific performance measures on access to medicines issues, which the company is developing and promises for its next report. Rating: 5

Philanthropy

Much of GSK's response to the AIDS-TB-Malaria pandemics comes via its core business, but GSK has charitable initiatives as well. Through its partnership with the WHO's Global Alliance to Eliminate Lymphatic Filariasis, GSK has donated 136 million treatments of its drug, albendazole, to thirty-six countries to prevent transmission of the tropical disease. GSK has also assisted the Global Alliance to Eliminate LF through grants and assistance with advocacy, research and education initiatives.[106] GSK also has an African Malaria Partnership that supports education and behavior change programs in eight African countries. It has invested $1.5 million dollars over three years to this partnership.[107] GSK's executive responsible for community involvement reports directly to the CEO. Rating: 4

Political Engagement: Political Contributions

Donations to organizations in the EU must be made in accordance with the Political Parties, Elections and Referendums Act of 2000 which requires U.K. companies to seek shareholder approval for political spending in the EU. The company has occasionally disclosed political spending in aggregate in its annual report but does not report American, Canadian, or other country donations in detail. Internal oversight procedures and board responsibility are also not disclosed. Rating: 1

Political Engagement: Trade Associations

GSK is an active member of pharmaceutical trade organizations but does not disclose dues paid which are for political purposes. Rating: 1

GlaxoSmithKline's Bottom Line

GSK is an industry leader in reporting, licensing, and research, but also has points of vulnerability. We suggest GSK improve transparency around political spending, both directly and through trade associations; improve its middle-income pricing strategy; collaborate with other companies to produce fixed-dose combinations; and issue licenses to additional generic companies, particularly for second-line drugs and in middle-income markets, such as China.

Johnson & Johnson

Johnson & Johnson (NYSE: JNJ), is a broadly based manufacturer of health care products for the consumer, pharmaceutical, and medical devices markets. J&J has over 200 operating companies employing 115,000 in fifty-seven countries. Worldwide sales in 2004 were $47.3 billion. Johnson & Johnson's Tibotec subsidiary is developing three novel antiretroviral drugs (TMC114, TMC125, and TMC278) and a novel tuberculosis treatment (TMC207).

Johnson & Johnson (NYSE: JNJ)			
COUNTRY: United States		**TOP 10:** ✓	
COMMERCIAL PRODUCTS		**PIPELINE PRODUCTS** HIV: TMC114, TMC125, TMC278 • TB: TMC207	
Approach	Issue	Score	Industry Mean
Research	Fixed Dose Combination	N/A	2.9
	Neglected Diseases	4	2.5
Pediatric Needs	Formulations	N/A	3.1
	Price Cuts	N/A	3.3
Accessibility	Licensing	2	2.4
	Patent Relaxation	1	1.6
	Differential Pricing	N/A	3.9
	Registration	N/A	3.6
Reporting to Shareholders		4	3.2
Philanthropy		4	3.5
Political Engagement	Political Contributions	4	2.3
	Trade Association	1	1.3
BOTTOM LINE: Tibotec is off to a good start, with an early partnership with International Partnership for Microbicides and research into neglected diseases such as tuberculosis. The company must keep up the momentum with aggressive pediatric research and registration of its products. Partnerships with generic companies will be essential to ensure new products are widely available.			

Research: Fixed-Dose Combinations

Tibotec, a wholly owned subsidiary of Johnson & Johnson, is bringing to market several novel HIV therapies that may be appropriate components of a fixed-dose combination. However, the products have not yet been approved. Rating: N/A.

Research: Neglected Diseases

In addition to HIV, Tibotec is also bringing a multi-drug-resistant TB product to market. This would be the first new product for this disease in several decades. Rating: 4

Pediatric Needs: Formulations

The company has explored pediatric options for its products still in development, and has created a low-dose formulation that could be used for children. It is unclear at this time what the results will be. Rating: N/A

Pediatric Needs: Price Cuts

Johnson & Johnson has no relevant products on the market.

Pediatric formulations of essential medicines should be sold at costs in line with adult formulations on a per-patient per-treatment course basis. Rating: N/A.

Accessibility: Licensing & Technology Transfer

The company has no products on the market but has expressed openness to partnering with generic companies to expand procurement options. In addition, the company has granted a royalty-free license to the International Partnership for Microbicides.[108] Rating: 2

Accessibility: Patent Enforcement Relaxation

The company has made no statements regarding patent relaxation. Rating: 1

Accessibility: Differential Pricing

The company will not announce pricing policies until its products come to market.

Differential pricing policies should be predictable and transparent for any essential medicines sold in emerging markets. Rating: N/A

Accessibility: Registration

The company has no products on the market.

All essential medicines should be pre-qualified by the WHO, and registered and available in all relevant emerging markets. Rating: N/A

Reporting To Shareholders

J&J's reporting is done via a website which integrates charitable grants, research, intellectual property licenses, and workplace programs. This is superior to the typical philanthropy-driven reporting at peer companies.[109]

Nonetheless, we were seeking a more explicit discussion of core business risk, especially given J&J's dual exposure to HIV/AIDS risk via its substantial global consumer product operations and via sector-specific pharmaceutical risk. Rating: 4

Philanthropy

Johnson & Johnson has a modest philanthropy program tied to HIV/AIDS initiatives. The program is one of four HIV/AIDS goals at the company (the others are developing products, making products accessible, and implementing HIV/AIDS workplace programs). J&J also has a specific program to enable countries to better leverage Global Fund grants. We support the integrated approach of J&J's philanthropy, although more explicit evaluation and monitoring would be valuable. Rating: 4

Political Engagement: Political Contributions

The company has committed to disclosing political contributions and those contributions are overseen at the board level.[110] This is a new policy and the reports have recently been released. Rating: 4

Political Engagement: Trade Associations

The company does not disclose political contributions made to trade associations for political purposes. Johnson & Johnson CEO William Weldon was the Chair of PhRMA in fiscal year 2006. Rating: 1

Johnson & Johnson's Bottom Line

Tibotec is off to a good start, with an early partnership with International Partnership for Microbicides and research into neglected diseases such as tuberculosis. The company must keep up the momentum with aggressive pediatric research and registration of its products. Partnerships with generic companies will be essential to ensure new products are widely available.

Eli Lilly

Eli Lilly and Company (NYSE: LLY) is a research-based pharmaceutical corporation based in Indianapolis. Lilly's core research competencies tend towards mental health and diabetes, although the company has products for severe sepsis and osteoporosis as well. Two Lilly products, capreomycin (Capastat) and cycloserine (Seromycin), are used to treat multi-drug resistant tuberculosis (MDR-TB).

Eli Lilly (NYSE: LLY)			
COUNTRY: United States		**TOP 10:** No	
COMMERCIAL PRODUCTS TB: capreomycin (Capastat), cycloserine (Seromycin)		**PIPELINE PRODUCTS**	
Approach	Issue	Score	Industry Mean
Research	Fixed Dose Combination	N/A	2.9
	Neglected Diseases	1	2.5
Pediatric Needs	Formulations	N/A	3.1
	Price Cuts	N/A	3.3
Accessibility	Licensing	5	2.4
	Patent Relaxation	N/A	1.6
	Differential Pricing	N/A	3.9
	Registration	N/A	3.6
Reporting to Shareholders		4	3.2
Philanthropy		4	3.5
Political Engagement	Political Contributions	4	2.3
	Trade Association	1	1.3
BOTTOM LINE: Lilly's MDR-TB program is a rare bright spot in the world of tuberculosis, a disease which is underfunded on every level, from research to patient care. Lilly has shown leadership in creating generic, local production capacity, and has reported strongly on the results and its plans moving forward. Given this record, it is a disappointment Lilly research priorities are unlikely to yield new drugs useful against diseases of poverty.			

Research: Fixed-Dose Combinations

Lilly has no antiretrovirals for the treatment of HIV.

Fixed-dose combinations can also reduce pill burden, increase patient compliance and reduce the emergence of drug-resistant strains for other infectious diseases besides HIV. Rating: N/A

Research: Neglected Diseases

Lilly's clinical strengths do not lend themselves to neglected diseases. However, the company has a long history with MDR-TB and Lilly staff continue to work closely with the Global Alliance for TB Drug Development and MEND, both nonprofit public private partnerships focused upon development of drugs

for neglected diseases. Nonetheless, Lilly does not have an internal neglected disease program. Rating: 1

Pediatric Needs: Formulations

Lilly has no antiretrovirals for the treatment of HIV.

All essential medicines clinically appropriate for children should be available in a range of pediatric formulations. Rating: N/A

Pediatric Needs: Price Cuts

Lilly has no antiretrovirals for the treatment of HIV.

Pediatric formulations of essential medicines should be sold at costs in line with adult formulations on a per-patient per-treatment course basis. Rating: N/A

Accessibility: Licensing & Technology Transfer

Lilly has taken the extraordinary step of transferring manufacturing technology needed to produce cycloserine and capreomycin to several generic firms around the world, including Shasun in India, Aspen in South Africa, and Hisun in China. These drugs for multi-drug resistant tuberculosis (MDR-TB) no longer have patent protection and so no actual license was necessary. Nonetheless, Lilly made a $70 million technology transfer and support commitment, and matched it with academic and non-governmental partnerships that increase the capacity of health systems to treat MDR-TB. We do not believe there would be significant generic production of these products without Lilly's engagement.[111] Rating: 5

Accessibility: Patent Enforcement Relaxation

Lilly has no antiretrovirals for the treatment of HIV, and its MDR-TB drugs are no longer patent protected.

Companies selling patented essential medicines in emerging markets should consider patent relaxation as a method of increasing generic production of their products. Rating: N/A

Accessibility: Differential Pricing

Lilly has no antiretrovirals for the treatment of HIV.

Differential pricing policies should be predictable and transparent for any essential medicines sold in emerging markets. Rating: N/A

Accessibility: Registration

Lilly has no antiretrovirals for the treatment of HIV.

Other essential medicines should also be pre-qualified by the WHO, and registered and available in all relevant emerging markets. Rating: N/A

Reporting To Shareholders

Lilly's reporting on its MDR-TB program is valuable to readers because it includes commitments Lilly has made moving forward and a timetable for implementation of those commitments. However, the company does not evaluate business risks or provide evidence of board-level engagement. Rating: 4

Philanthropy

Lilly's philanthropic commitments are closely matched to its partnerships with generic firms and appear structured to advance its core business objective of creating a well-managed, well-supplied system of access to care for MDR-TB. There is a high level of coordination with the World Health Organization. Rating: 4

Political Engagement: Political Contributions

Lilly discloses corporate political contributions and they are overseen at the board level.[112] Rating: 4

Political Engagement: Trade Associations

The company does not disclose political contributions made to trade associations for political purposes. Rating: 1

Eli Lilly Bottom Line

Lilly's MDR-TB program is a rare bright spot in the world of tuberculosis, a disease which is under-funded on every level, from research to patient care. Lilly has shown leadership in creating generic, local production capacity, and has reported strongly on the results and its plans moving forward. Given this record, it is a disappointment Lilly research priorities are unlikely to yield new drugs useful against diseases of poverty.

Merck

Merck & Co. (NYSE: MRK) is a global research-based pharmaceutical company. Established in 1891, Merck discovers, develops, manufactures and markets vaccines and medicines in more than twenty therapeutic categories. Merck manufactures and markets indinavir (Crixivan) and controls the international rights to efavirenz (Stocrin), a product developed by Bristol-Myers Squibb. WHO recommends efavirenz "as a first-line treatment and as a preferred treatment for HIV-positive patients co-infected with tuberculosis."[113]

In February 2006, Merck announced that it is researching a new HIV drug, MK-0518, and as of March 2006, is in phase three trials. It hopes to file this new drug with the FDA in 2007.[114]

Merck (NYSE: MRK)

COUNTRY: United States	**TOP 10:** ✓
COMMERCIAL PRODUCTS HIV: indinavir (Crixivan), efavirenz (Stocrin) Rotavirus: Rotateq • Worm infections: ivermectin (Stromectol)	**PIPELINE PRODUCTS** HIV: MK-0518, HIV vaccine

Approach	Issue	Score	Industry Mean
Research	Fixed Dose Combination	4	2.9
	Neglected Diseases	3	2.5
Pediatric Needs	Formulations	4	3.1
	Price Cuts	3	3.3
Accessibility	Licensing	2	2.4
	Patent Relaxation	1	1.6
	Differential Pricing	5	3.9
	Registration	2	3.6
Reporting to Shareholders		4	3.2
Philanthropy		5	3.5
Political Engagement	Political Contributions	4	2.3
	Trade Association	1	1.3

BOTTOM LINE: Merck's history responding to neglected diseases is strong, but the company's HIV/AIDS response appears to be overly driven by philanthropy. While those programs are strong, Merck should be bringing the full force of its core business strengths to bear to overcome registration lags, pediatric formulation challenges, and a still-tentative licensing approach.

Research: Fixed-Dose Combinations

In a joint venture with Gilead Sciences, maker of tenofovir and emtricitabine, Bristol-Myers Squibb and Merck are developing a three-in-one pill which will be efavirenz+tenofovir+emtricitabine. This will be the first fixed-dose combination developed by branded drug companies. Merck, which has a license from Bristol-Myers Squibb to market efavirenz internationally, is not playing a development role but will be involved in distributing the final product. Rating: 4

Research: Neglected Diseases

Merck has a relatively long history of neglected disease research, often through its substantial vaccine development programs. Rotateq, a new vaccine against rotavirus, is particularly promising. Rotavirus causes 500,000 deaths annually in children under five, almost all in developing countries.[115] Rating: 3

Pediatric Needs: Formulations

Efavirenz is available in a syrup formulation and in low-dose (50 mg) tablets. Clinicians have called for additional solid formulations of efavirenz, such as granulated powders which can be mixed with food. In addition, clinical trials are needed to study efavirenz in children under three years old. The company has not responded to calls for additional research and has released no timetable for new product improvements. Indinavir is not clinically appropriate for children. Rating: 4

Pediatric Needs: Price Cuts

The syrup formulation of efavirenz is expensive: $309 per patient per year in least developed countries and $496 per patient per year in middle-income countries.[116] Rating: 3

Accessibility: Licensing & Technology Transfer

Merck issued a license to South African generic company Aspen Pharmacare.[117,118] Originally, Merck also issued a license to Thembalami, a joint venture of South African Adcock and Indian Ranbaxy. When Thembalami dissolved, observers expected the two parent companies to be issued licenses by Merck, but that has not happened. The company is "exploring the potential" for additional licenses.[119] In addition, Merck has donated investigational products to the International Partnership for Microbicides.[120]

Merck will be under increasing pressure to issue voluntary licenses because several generic companies recently lowered prices on efavirenz in an agreement with the Clinton Foundation. Making those price cuts widely available may require additional licenses.[121, 122, 123] Rating: 2

Accessibility: Patent Enforcement Relaxation

Merck has no statements relaxing its patent rights. In its 2004-2005 Corporate Responsibility Report, Merck states that currently South Africa is the only country in Africa where efavirenz and indinavir are both patented. Indinavir is also patented in the Democratic Republic of Congo. In the other fifty-one countries in Africa, neither product is patented.[124] Rating: 1

Accessibility: Differential Pricing

Merck prices its products according to a country's HIV prevalence rate and the country's Human Development Index (HDI) ranking. (The HDI is released annually by the UNDP and ranks countries according to life expectancy, education, and real income). Merck prices its products lowest in low human development index countries or other countries with an HIV prevalence rate exceeding 1%. In March 2006, Merck reduced its price in these countries, so treatment for one year on efavirenz would cost $277 for 600 mg tablets, $394.20 for 200mg capsules, and $600 for indinavir.[125,126]

In middle HDI countries with HIV prevalence below 1%, treatment will cost $697 for efavirenz 600mg tablets, $821.25 for efavirenz 200mg capsules, and $1029 for indinavir.[127] Merck does have a transparent middle-income country pricing policy, something most peer companies lack, but we feel the gap between first and second tier pricing is high. Merck makes these prices available to all stakeholders "responsible for the provision of HIV/AIDS care and treatment...who can provide reasonable assurance of their capacity to ensure increased patient access," including both private and public sector stakeholders.[128]

The Clinton Foundation recently announced that it had negotiated lower prices for efavirenz. Four companies - Cipla, Ranbaxy Laboratories, Strides Arcolab and Aspen Pharmaceuticals - will make efavirenz for no more than $240 per patient per year.[129, 130, 131]

Merck was one of the founding partners of the Accelerating Access Initiative (AAI), a UN-brokered program of branded drug manufacturers with the purpose of accelerating access to care and treatment for HIV/AIDS.[132] Some non-government organizations criticize AAI for insufficient price cuts, geographical restrictions, and an emphasis on public relations.[133] Rating: 5

Accessibility: Registration

International aid groups have claimed efavirenz is not always registered in developing country markets. Merck faced public criticism, including a short *Wall Street Journal* piece, because of the long time lag between a 2002 announcement of a price cut for 600 mg efavirenz and registration of 600 mg efavirenz in hard-hit countries.[134,135] As late as July 2005, Merck had registered the 600 mg and older, 200 mg formulation of efavirenz in 25 sub-Saharan African countries. There are about forty sub-Saharan African low or mid-range HDI countries.[136] Rating: 2

Reporting To Shareholders

Merck's inaugural corporate responsibility report includes discussion of the company's philanthropic programs, research programs, and pricing and patent policies. Reporting on each of these elements in an integrated fashion is positive. Merck has also posted its pricing policy on its website, including specific prices for both low- and middle-income countries.[137]

The company reported 307,000 patients on treatment regimes using Merck products in March 2005, but without information on trends or the total unmet medical need. Both the ivermectin donation program and the public-private partnership in Botswana have been reported on and studied by public health authorities.[138] Merck has not brought a similar focus, however, to its core business functions addressing HIV/AIDS.

The company articulates a general business case for action by saying "Acting in a responsible manner over the long term serves the best interests of the people our programs benefit, as well as our shareholders. By doing the right thing, we further enhance our Company's reputation, our ability to play a constructive role in advancing good public policy, customer trust and, as a result, the opportunity to achieve our business goals."[139] We would like to see this line of reporting explored further. Rating: 4

Philanthropy

Merck's HIV/AIDS philanthropic programs, which take the form of large-scale public private partnerships in Botswana, the People's Republic of China, and Romania are among the strongest in the industry. They involve significant commitments of funding and a strong emphasis on treatment and evidence-based prevention programs. Merck has committed $50 million in cash and donations of efavirenz over five years to Botswana.[140] The $30 million China program is newer and its scope and scale remain to be seen. The company's ivermectin donation program for river blindness, which is almost twenty years old, is often held up as a model for drug company donation programs. However, it is important to understand ivermectin requires only a single annual dose, making it better suited for donation than more complicated treatment regimes needed for tuberculosis or AIDS. Rating: 5

Political Engagement: Political Contributions

The company discloses its political contributions. Merck's Board has a Committee on Public Policy and Social Responsibility; the Committee's charter states that it must "[m]onitor and evaluate the Company's corporate citizenship programs and activities including, but not limited to, the support of charitable, political and educational organizations..."[141] According to the company's code of conduct, political contributions must receive the prior approval of the CEO.[142] Rating: 4

Political Engagement: Trade Associations

The company does not disclose political contributions made to trade associations for political purposes. Rating: 1

Merck's Bottom Line

Merck's history responding to neglected diseases is strong, but the company's HIV/AIDS response appears to be overly driven by philanthropy. While those programs are strong, Merck should be bringing the full force of its core business strengths to bear to overcome registration lags, pediatric formulation challenges, and a still-tentative licensing approach.

Novartis AG

Novartis (NYSE: NVS) is a top ten global pharmaceutical company headquartered in Basel, Switzerland. It is primarily engaged in the development and manufacture of health care products via Novartis Pharmaceuticals; Sandoz, a generic pharmaceutical firm; and Novartis Consumer Health, for over-the-counter (OTC) medicines and animal health. Novartis is currently in the process of acquiring the Chiron Corporation, a biopharmaceutical company that focuses on infectious diseases and cancer.

Novartis AG (NYSE: NVS)

COUNTRY: Switzerland

TOP 10: ✓

COMMERCIAL PRODUCTS
Malaria: artemether+lumefantrine (Coartem) • TB: rifampicin (Rimactane) • Leprosy: clofazimine (Lamprene), rifampicin (Rimactane)

PIPELINE PRODUCTS
TB: candidate drug • Dengue Fever: candidate drug

Approach	Issue	Score	Industry Mean
Research	Fixed Dose Combination	N/A	2.9
	Neglected Diseases	5	2.5
Pediatric Needs	Formulations	N/A	3.1
	Price Cuts	N/A	3.3
Accessibility	Licensing	N/A	2.4
	Patent Relaxation	3	1.6
	Differential Pricing	4	3.9
	Registration	N/A	3.6
Reporting to Shareholders		4	3.2
Philanthropy		4	3.5
Political Engagement	Political Contributions	1	2.3
	Trade Association	1	1.3

BOTTOM LINE: Novartis could make a significant contribution to the fight against neglected diseases with the Novartis Institute for Tropical Diseases. The company has worked to improve its sustainability reporting. Novartis must ensure that its products, especially for malaria and tuberculosis, reach those in need. We would like to see a multi-pronged accessibility agenda combining licensing, technology transfer, differential pricing, and other tactics.

Research: Fixed-Dose Combinations

Novartis has no antiretrovirals for the treatment of HIV, yet it plays a role in developing FDCs for the treatment of malaria, TB and leprosy (see below). Rating: N/A

Research: Neglected Diseases

Novartis has played a leading role in developing antimalarial FDCs. The company manufactures Coartem, a combination of artemether (an artemisinin derivative) and lumefantrine, for *falciparum* malaria, which is resistant to many other drugs. Coartem is the only WHO pre-qualified, fixed-dose artemisinin-based combination therapy.[143] In 2002, Coartem was added to the WHO's Essential Medicines list.

Sandoz developed a rifampicin-based fixed-dose combination for TB treatment.[144] Rifampicin shortens the duration of treatment from eight to six months and is recommended for areas with widespread HIV co-infection.[145]

Novartis has also developed two of the three products in the multi-drug therapy used in WHO's leprosy elimination strategy and has committed to ensure that "leprosy patients around the world have access to high-quality multi-drug therapy free of charge" under an agreement recently extended to 2010.[146]

The Novartis Institute for Tropical Diseases (NITD) is a public-private partnership between Novartis and the Singapore Economic Development Board aiming to discover innovative treatments for major tropical diseases. NITD is focused on dengue fever and tuberculosis, with the goal of two drugs in trials by 2008 and one on the market by 2012. NITD will "make treatments readily available and without profit to poor patients."[147, 148] Rating: 5

Pediatric Needs: Formulations

Novartis has signed an agreement with the Medicine for Malaria Venture (MMV) to develop a new pediatric formulation of artemether+lumefantrine (Coartem). The target date for availability of the new pediatric formulation is 2007.[149] Rating: N/A

Pediatric Needs: Price Cuts

Novartis has no antiretrovirals for the treatment of HIV.

Pediatric formulations of essential medicines should be sold at costs in line with adult formulations on a per-patient per-treatment course basis. Rating: N/A

Accessibility: Licensing & Technology Transfer

Novartis has no antiretrovirals for the treatment of HIV. It is not clear if NITD-developed drugs will be licensed as the research at NITD is still in early stages. However, licensing for generic production may be a useful tool for additional patented essential medicines beyond anti-retroviral drugs. Rating: N/A

Accessibility: Patent Enforcement Relaxation

Company policy states that Novartis will not obtain patents in the least developed countries.[150] Most LDCs do not provide patent protection (under TRIPS, they have until 2016 to do so), regardless. Novartis has made statements in support of TRIPS flexibilities. Rating: 3

Accessibility: Differential Pricing

Novartis provides its antimalarial drugs at cost ($2.40 per dose) for public sector use in Africa, Asia, and Latin America. Rating: 4

Accessibility: Registration

Novartis has no antiretrovirals for the treatment of HIV.

Other essential medicines should also be pre-qualified by the WHO, and registered and available in all relevant emerging markets. Rating: N/A

Reporting To Shareholders

Novartis does some reporting on performance regarding access for the developing world, and reports using

Global Reporting Initiative frameworks. The company summarizes its projects, objectives, focus regions and costs, as well as the number of new patients reached in a particular year and the total number so far. The board reports that it regularly undertakes a review of sector specific social issues. Novartis also opines that improving access in the developing world is the right thing to do and good for business although a clear business case is not well-articulated.[151,152] Rating: 4

Philanthropy

In 2005, Novartis contributed $696 million and reached 6.5 million patients worldwide through its access-to-medicines programs for the fight against neglected diseases. This represents 2.2% of the company's 2005 sales.[153] Novartis promotes charitable work and community projects, and has collaborated in several long-term public-private partnerships, such as World Health Organization's (WHO) Roll Back Malaria initiative.

Novartis' Global Alliance to Eliminate Leprosy (GAEL) had committed to provide free leprosy treatment for all patients worldwide from 1999 until the end of 2005. The agreement is now to be extended to 2010. Novartis also donates TB drugs to the Global Fund to Fight AIDS, Tuberculosis and Malaria. Rating: 4

Political Engagement: Political Contributions

Novartis reports very little on political contributions, with neither donations nor procedures or oversight disclosed to shareholders. Rating: 1

Political Engagement: Trade Associations

Novartis is a member of several trade associations and does not disclose dues paid which are for political purposes. Rating: 1

Novartis's Bottom Line

Novartis could make a significant contribution to the fight against neglected diseases with the Novartis Institute for Tropical Diseases. The company has worked to improve its sustainability reporting. Novartis must ensure that its products, especially for malaria and tuberculosis, reach those in need. We would like to see a multi-pronged accessibility agenda combining licensing, technology transfer, differential pricing, and other tactics.

Pfizer

Pfizer (NYSE: PFE), one of the world's largest pharmaceutical companies, develops, manufactures, and markets prescription medicines, over-the-counter consumer health care products, and animal health products. Pfizer has the novel HIV therapy maraviroc in late-stage development and is exploring azithromycin as part of combination therapies for malaria. Pfizer is the developer of antiretrovirals nelfinavir (Viracept) and delavirdine (Rescriptor). The company distributes nelfinavir in the United States (Roche does so overseas) and delavirdine globally. Maraviroc is in late-stage development. One challenge: maraviroc only works against the R5-type HIV virus, and the blood test to determine virus type costs up to $800 per test.[154]

Research: Fixed-Dose Combinations

The company is not involved in the development of fixed-dose combination products. Nelfinavir and delavirdine are not clinically appropriate for FDCs. The company has announced no plans to develop FDCs based on maraviroc because the drug has not completed necessary trials. Rating: N/A

Research: Neglected Diseases

The company is testing an existing antibiotic, azithromycin, (which lost market exclusivity in May 2006) for several neglected diseases, including as a malaria combination therapy with chloroquine or artesunate and quinine in areas of high drug resistance.[155]

Pfizer collected and sequenced a large number of parasites from the malaria studies, and it has shared the data with the Gates Foundation.[156] It is also supplying compounds to the WHO Special Programme for Research Training in Tropical Diseases for screening against anti-parasitic agents, including trypanosomiasis, Chagas disease and dengue fever.[157]

There are no further neglected disease products in the company pipeline.[158] Pfizer points out that many drugs developed for rich country diseases have subsequently been used for diseases of poverty.[159] Rating: 3

Pediatric Needs: Formulations

Delavirdine is not typically clinically appropriate for children. Nelfinavir is available as an oral powder but is not available in low-dose capsules, and the adult tablets are not scored for easier breaking. As the drug's developer, Pfizer is the party responsible for improved pediatric formulations of nelfinavir. Pfizer says that it will consider a pediatric formulation for maraviroc once the initial set of clinical trials confirms its safety and efficacy.[160] Rating: 2

Pediatric Needs: Price Cuts

Delavirdine is not typically clinically appropriate for children. Nelfinavir prices are determined by Roche. Rating: N/A

Pfizer (NYSE: PFE)

COUNTRY: United States	**TOP 10:** ✓
COMMERCIAL PRODUCTS HIV: nelfinavir (Viracept), delavirdine (Rescriptor) Trachoma: azithromycin (Zithromax) • Opportunistic infections: fluconazole (Diflucan)	**PIPELINE PRODUCTS** HIV: Maraviroc • Malaria: candidate combination drug with azithromycin

Approach	Issue	Score	Industry Mean
Research	Fixed Dose Combination	N/A	2.9
	Neglected Diseases	3	2.5
Pediatric Needs	Formulations	2	3.1
	Price Cuts	N/A	3.3
Accessibility	Licensing	1	2.4
	Patent Relaxation	1	1.6
	Differential Pricing	N/A	3.9
	Registration	N/A	3.6
Reporting to Shareholders		3	3.2
Philanthropy		3	3.5
Political Engagement	Political Contributions	4	2.3
	Trade Association	1	1.3

BOTTOM LINE: Pfizer has immense resources which could bring research-based and market-based solutions to the access to essential medicines crisis. However, the firm has relatively little research investment in the developing world (especially considering its size). Pfizer is heavily dependent on traditional philanthropic approaches to health problems. There is an emphasis on public relations. Given Pfizer's disproportionate influence on the industry we find these issues especially troubling.

Accessibility: Licensing & Technology Transfer

In 2003, European drug company Pharmacia created an innovative program, which granted licenses for delavirdine to an NGO to pass on to generic producers. (Delavirdine is third-line therapy, not a commonly used product). The International Dispensary Association (IDA) facilitated the license, only for use in nations with less than $1,200 per capita GDP. At the time, Pharmacia executives called the program "a practical, consensus approach" satisfying "the only focus that matters from a humanitarian perspective - the urgent needs of the patients."[161] [162]

Pfizer's acquisition of Pharmacia later that year gave the company control of delavirdine and Pfizer ended the program before it was implemented. In response to this report, Pfizer claimed that "Pfizer and the International Dispensary Association (IDA) concluded jointly that Rescriptor is not the appropriate medicine for the proposed pilot program."[163] However, an IDA consultant who negotiated on IDA's behalf with Pfizer said, "I would have taken it, if they would give it to me."[164] The model of cooperation remains, but Pfizer has made no commitments to use it for any potential new or other existing drugs. Rating: 1

Accessibility: Patent Enforcement Relaxation

The company has made no statements demonstrating patent flexibility. In response to this report, Pfizer said that "under threat of a patent violation, Pfizer will evaluate the circumstances on infringement and make decisions on enforcement on a case-by-case basis."[165] Rating: 1

Accessibility: Differential Pricing

Pfizer has no commonly used HIV/AIDS products sold in developing countries.

Differential pricing policies should be predictable and transparent for any essential medicines sold in emerging markets. Rating: N/A

Accessibility: Registration

Pfizer does not control the rights to any commonly used antiretrovirals sold in developing countries.

Other essential medicines should also be pre-qualified by the WHO, and registered and available in all relevant emerging markets. Rating: N/A

Reporting To Shareholders

The sheer volume of materials that Pfizer generates is astounding. In the past year alone, Pfizer has released a Corporate Citizenship Report,[166] a report on philanthropic programs,[167] and CEO Dr. Henry (Hank) McKinnell has authored a book,[168] not to mention numerous articles, web updates, brochures, and press releases.

Some of this reporting is valuable. The philanthropic fluconazole (for opportunistic infections) and azithromycin (for trachoma) programs are well covered.[169] Public policy issues such as intellectual property, lobbying positions, and drug pricing are discussed in some detail.

Pfizer clearly sees a core business case for action because of the immense public relations resources they have devoted to addressing access to medicines issues. However, it does not articulate that case in its materials. There is no assessment of the various policy options available and explanation of why Pfizer chose one over another. There are occasional goals and objectives (i.e. eliminate trachoma by 2020) but they are not extended to all programs. Finally, there are specific commitments about environmental performance and other issues, but there are not comparable commitments about access to medicines. Rating: 3

Philanthropy

Pfizer has a number of philanthropic programs, including employee volunteer programs and support of health-care infrastructure development in Uganda. The most notable and controversial program is its fluconazole donation program. Fluconazole is an anti-fungal drug used to treat several opportunistic infections that are fatal in people with AIDS if left untreated. It recently lost patent protection in most countries. South Africa's Treatment Action Campaign was particularly active in calling for generic and low-priced fluconazole. Pfizer responded with a wide-ranging donation program, offering the drug free of charge in all countries with an HIV prevalence above 1% without a time limit. The program began in South Africa in 2000 and expanded to additional countries in 2003 and again in 2004. Thus far it has reached twenty-one countries.

Since the program began, it has been dogged by criticism.[170] Academic studies looking at donation programs in general have found that "In light of the numerous drawbacks to drug donations, they should neither be relied on nor portrayed as a long-term solution to the ongoing crisis of access to essential medicines."[171] The fluconazole effort specifically has been criticized for red tape, narrow focus, and insufficient geographic reach, particularly the small number of currently included countries. Some critics allege that the donation program has removed the incentive generic companies require to enter the market, and that differential pricing and licensing would have been superior alternatives.

This program, more than any other philanthropic initiative, elicited the most charged responses among reviewers of this report, on all sides. Rating: 3

Political Engagement: Political Contributions

Pfizer was among the first companies to agree to disclose corporate political contributions, in response to ICCR concerns expressed in 2003. They recently informed the Securities and Exchange Commission that its board would review each disclosure before publication.[172] Rating: 4

Political Engagement: Trade Associations

The company does not disclose political contributions made to trade associations for political purposes. Pfizer CEO Dr. Hank McKinnell was the Chair of the Business Roundtable in 2004. During that time, Pfizer became embroiled in a controversy over Social Security privatization, an issue far removed from the company's core business (ICCR had no position - other investors filed resolutions based on their concerns). In response to this report, Pfizer defended Dr. McKinnell's activities by pointing out his engagement in getting the Presidents Emergency Plan for AIDS Relief (PEPFAR) passed.[173]

Our concerns over the lack of transparency about the company's role in trade associations remain. Currently, Dr. McKinnell is vice president of IFPMA.[174] Rating: 1

Pfizer's Bottom Line

Pfizer has immense resources which could bring research-based and market-based solutions to the access to essential medicines crisis. However, the firm has relatively little research investment in the developing world (especially considering its size). Pfizer is heavily dependent on traditional philanthropic approaches to health problems. There is an emphasis on public relations. Given Pfizer's disproportionate influence on the industry we find these issues especially troubling.

F. Hoffman-La Roche Ltd.

Roche (VTX: ROG) is a Basel-headquartered healthcare company involved in the development, manufacture and marketing of novel healthcare solutions. The group has two operative divisions - Pharmaceuticals and Diagnostics. Roche Pharmaceuticals focuses on specialty care therapeutics, and develops drugs for HIV, transplantation, cancer, anemia, and infectious diseases. Roche is the inventor of saquinavir (Invirase) and has the non-American rights to nelfinavir (Viracept), owned by Pfizer. Roche also markets oseltamivir (Tamiflu), invented by Gilead. Oseltamivir is used for influenza and may be important to combating an avian flu pandemic in developing countries.

Roche has also co-developed enfuvirtide (Fuzeon), the first of a new class of HIV drugs (fusion inhibitors) that blocks the virus before it enters host cells. Although it provides a new option to patients not responding to other medical treatments, it carries a high cost - about $20,000 per year.[175, 176] As enfuvirtide is administered as a twice-daily subcutaneous injection, an infrastructure allowing safe disposal of needles needs to be established.[177] Due to the high cost and the challenges of safe administration, enfuvirtide is not even remotely accessible to developing world patients.

Currently, Roche manufactures several ARVs, including nelfinavir in both tablet form and as an oral powder and saquinavir in both 200mg and 500mg tablets.[178, 179] The recently added 500 mg film-coated tablet simplifies dosing regimens, makes the tablet easy to swallow, and does not require refrigeration.[180, 181] Roche is heavily invested in HIV research, with programs looking at several potential targets.[182]

Roche Diagnostics also has important HIV/AIDS products, but for this profile we consider only the pharmaceutical business.

Research: Fixed-Dose Combinations

Roche's saquinavir should be used in combination with low-dose ritonavir as saquinavir/ritonavir 1000mg/100mg twice daily. However, Roche has no collaboration with ritonavir's maker, Abbott Laboratories. In a meeting with people living with AIDS, Roche said that "there are problems with co-formulating Invirase with ritonavir - by the time we did the necessary clinical trials, there will be new drugs. There are also IP and liability problems with co-formulating."[183] Although Roche has stated that it is looking to collaborate with other companies in the development of new drugs that will limit the spread of resistance to treatments for HIV/AIDS, it said in the same meeting as above that it is "not prepared" to allow its drugs to be combined with other drugs in blister packs.[184,185] Rating: 1

F. Hoffman-La Roche Ltd. (VTX: ROG)

COUNTRY: Switzerland	**TOP 10:** No
COMMERCIAL PRODUCTS HIV: saquinavir (Invirase), nelfinavir (Viracept), enfuvirtide (Fuzeon) • Malaria: Mefloquine (Lariam), sulfadoxine/Pyrimethamine (Fansidar) • Influenza: oseltamivir (Tamiflu) • Chagas disease: benzonidazole	**PIPELINE PRODUCTS** HIV: candidate drugs • Malaria: OZ277

Approach	Issue	Score	Industry Mean
Research	Fixed Dose Combination	1	2.9
	Neglected Diseases	3	2.5
Pediatric Needs	Formulations	4	3.1
	Price Cuts	2	3.3
Accessibility	Licensing	2	2.4
	Patent Relaxation	3	1.6
	Differential Pricing	3	3.9
	Registration	5	3.6
Reporting to Shareholders		3	3.2
Philanthropy		4	3.5
Political Engagement	Political Contributions	2	2.3
	Trade Association	1	1.3

BOTTOM LINE: Roche is using a number of different access strategies. It has clear pricing and patent policies. We hope the technology transfer program will be pursued aggressively. We suggest increased emphasis on pediatric needs and increased transparency around political giving.

Research: Neglected Diseases

Roche manufactures oseltamivir - a treatment for influenza - and potentially useful for the treatment of avian flu.

In the Medicines for Malaria Venture (MMV), Roche donated expertise in both industrial drug development and in malaria drug development in support of the molecule known as OZ277, and handed over the role of the pharma partner to a generic company.

Roche developed benzonidazole, an effective drug used to treat Chagas disease. On April 2, 2003, Roche donated the rights and the technology to manufacture benzonidazole to the Brazilian government.[186] Rating: 3

Pediatric Needs: Formulations

Roche manufactures nelfinavir in an oral powder and low-dose tablets.[187] Roche does not manufacture pediatric formulations of saquinavir. We not aware of additional research on scored tablets or other formulations of either drug. Nor is there a timeline for beginning development of these formulations. Rating: 4

Pediatric Needs: Price Cuts

Nelfinavir in oral powder form for Least Developed Countries (LDCs) costs $1,962 per patient per year. For middle-income countries, it is $2,243 annually. This compares to nelfinavir tablets at $978 for least-developed and $2,211 for middle-income countries.[188] This disparity between pediatric and adult formulation prices is much wider than at competitor firms. Rating: 2

Accessibility: Licensing & Technology Transfer

Recently, Roche announced a new Technology Transfer Initiative to provide local manufacturers in LDCs and sub-Saharan Africa with the technical expertise to produce saquinavir, a WHO-recommended second-line protease inhibitor.[189] This is an important step forward, but it is too early to determine the impact of the program. Very few of the countries impacted have current pharmaceutical manufacturing capacity.

The company has donated all rights and the technology to manufacture its medicine Benzonidazole to the Brazilian government for the treatment of Chagas disease.[190]

This past year, Roche has been embroiled in controversy over oseltamivir (Tamiflu), with concerns about price and production capacity for this potential avian-flu-fighting drug. Speaking in reference to Roche, U.N. Secretary-General Kofi Annan said the U.N. should be "making sure that we do not allow intellectual property to get into the way of access of the poor to medication... I wouldn't want to hear the kind of debate we got into when it came to the HIV antiretrovirals."[191] In Washington, Senator Charles Schumer (D-N.Y.) warned, "Roche is putting their own interests ahead of world health. If they don't begin to actually license the patent for Tamiflu to dramatically increase worldwide production, I am going to pursue a legislative remedy."[192]

Roche responded with a statement by William Burns, head of pharmaceuticals, who said intellectual property considerations would not stand in the way of Tamiflu's availability.[193] Several countries, including India, where oseltamivir is not patented announced production plans. One (Taiwan) issued a compulsory license.[194,195,196]

In December 2005, Roche agreed to permit fifteen generic drug labs to produce oseltamivir, upping annual production of the medicine from 27 million to more than 300 million doses per year by the end of 2006. However, the generic firms are production partners only and may not market the drug, with the exception of Indian drug company Hetero and Shanghai Pharmaceuticals.[197] Hetero will manufacture and sell oseltamivir under license in India and other developing and middle-income countries.[198]

Hysteria over bird flu makes licensing of oseltamivir important: it is likely the center of any bird flu epidemic would be in developing countries. These countries would not be able to compete in a bidding war for a limited supply of oseltamivir, driven by rich countries' fears. Rating: 2

Accessibility: Patent Enforcement Relaxation

Roche has a global patent policy which pledges not to file patents on any medicines in LDCs, and has committed not to file patents on HIV medicines in sub-Saharan Africa as well. Yet, many of the countries impacted are not required to have patent protection under WTO rules until 2016.

In 2004, the company announced that it would not enforce its patent protections if generic manufacturers produced Roche HIV/AIDS medicines for LDCs and sub-Saharan Africa. This informed generic suppliers they would not face civil enforcement actions from the patent-holder for production or sale in sub-Saharan Africa. Roche has also pledged no patents for its treatments for malaria - sulfadoxine/pyrimethamine (Fansidar) and mefloquine (Lariam) - in LDCs and sub-Saharan Africa.[199,200,201]

The Roche policy does not impact major pharmaceutical exporting nations, with the notable exception of South Africa. Rating: 3

Accessibility: Differential Pricing

Roche has predictable, transparent pricing for both LDC and middle-income countries, and in 2004 it lowered prices by about one-third.[202] Currently the lowest available prices for nelfinavir in tablet form are $978 for First Category and $2,211 for Second Category. Saquinavir is $989 for First Category; $1,327 for Second Category.[203] Roche annually reviews not-for-profit prices.

In a meeting with people with AIDS, participants expressed concern that prices were still way too high, especially in middle income countries, and that prices were higher than generics. Roche responded that it will not negotiate a no-profit price for regions other than the LDC countries. In the meeting, Roche pointed out that "the fact that our drugs are not affordable in some parts of the world is not Roche's responsibility," and called on other actors such as governments to step in.[204]

Roche was one of the founding partners of the Accelerating Access Initiative (AAI), a UN-brokered program of branded drug manufacturers with the purpose of accelerating access to care and treatment for HIV/AIDS.[205] Some non-government organizations criticize AAI for insufficient price cuts, geographical restrictions, and an emphasis on public relations.[206] Rating: 3

Accessibility: Registration

We are not aware of registration problems involving Roche. Rating: 5

Reporting To Shareholders

Roche's Audit and Corporate Governance Committee is responsible for external stakeholder issues.[207] The company issues a number of reports focusing on HIV/AIDS specifically and developing-world healthcare issues generally.[208] Overall, we felt Roche did a decent job of reporting its activities in regards to research and access activities, but needed better objectives and metrics.

In its 2005 Annual Business Report, Roche lists as one of its 2006 objectives "[to establish] the Roche Business Case for Sustainability," with a goal of identifying "drivers of business case, and monitoring and measuring against appropriate key performance indicators." In 2006, Roche aims to "document the business case" and "define a set of relevant key performance indicators."[209] In response to this report, Roche informed us that it plans to report on its progress and findings in its 2006 Annual Report and on its website.[210] Rating: 3

Philanthropy

Roche is involved in a number of community projects around the world, including a public-private partnership in Cambodia, and a four-country treatment program in Cote D'Ivoire, Kenya, Senegal and Uganda. In October 2005, Roche became a founding member of International Committee of the Red Cross (ICRC) Corporate Support Group, which creates a long-term partnership with ICRC to support humanitarian missions.

The company has designated senior managers responsible for community issues. This level of philanthropy is in line with peer companies. The assignment of senior management is particularly important. Rating: 4

Political Engagement: Political Contributions

The company has a policy of not disclosing corporate giving to political parties or candidates. The code of ethics discusses political giving but Roche does not disclose oversight procedures. There is no board-level review.

In Roche's business report, it says that it "only makes political donations in clearly defined exceptional cases and in line with prevailing legal and ethical standards" and that "... donations are made only to political organizations that support conditions that favour innovation and not to individuals." It says that political donations account for 2% of all donations and sponsorship expenditure."[211] Rating: 2

Political Engagement: Trade Associations

Roche is a member of several trade associations but does not report on dues paid which are used for political purposes. Rating: 1

Roche's Bottom Line

Roche is using a number of different access strategies. It has clear pricing and patent policies. We hope the technology transfer program wil be pursued aggressively. We suggest increased emphasis on pediatric needs and increased transparency around political giving.

sanofi-aventis

Sanofi-aventis (NYSE: SNY) is Europe's largest pharmaceutical company. It has 100,000 employees in over a hundred countries. The company engages in the research, development, manufacture and marketing of pharmaceutical products for sale in the prescription market worldwide but is also one of the world's top two manufacturers of vaccines.

Research: Fixed-Dose Combinations

Sanofi-aventis has no antiretrovirals for HIV.

Fixed-dose combinations can also reduce pill burden, increase patient compliance and reduce the emergence of drug-resistant strains for other infectious diseases besides HIV. Rating: N/A

Research: Neglected Diseases

Sanofi-aventis is involved in research and development on malaria, polio and leishmaniasis, and tuberculosis.[212]

Sanofi-aventis has a strong Impact Malaria program, created in 2001, which has four major axes:

- To develop new antimalarial drugs;
- To develop new combinations and formulations of existing drugs;
- To inform and educate about malaria, including reaching out to remote healthcare facilities; and
- To distribute antimalarial drugs at "no profit-no loss" cost.[213]

The WHO has urgently warned pharmaceutical companies that monotherapeutic treatment of malaria with artemisinin - the most promising new malaria drug - could create an "incurable strain of the disease." Following WHO demands that pharmaceutical companies stop selling the antimalarial drug artemisinin in monotherapeutic form, sanofi-aventis has been phasing out its monotherapy artemisinin products and now sells two artemisinin cocktails.[214] Sanofi-aventis offers co-packaged antimalarial drugs artesunate+amodiaquine (Arsucam) and artesunate+sulfadoxine with pyrimethamine (Arsudar).[215]

With Drugs for Neglected Diseases Initiative (DNDi), sanofi-aventis will produce the anti-malaria amodiaquine+artemisinin combination drug.[216] This formulation is cheaper and simpler than previous formulations, reducing the pill burden from twenty-four to six pills over three days.[217] Sanofi-aventis gained access to an innovative method for combining two separate malaria drugs developed by one of DNDi's research partners as part of the agreement. In exchange, the group will make the drug available in the developing world at less that $1 per treatment.

Sanofi-aventis produces two treatments for leishmaniasis: pentamidine mesylate (Pentamidine) and meglumine antimoniate (Glucantime). It also signed a five-year $25 million partnership with WHO to combat sleeping sickness, including drugs, disease monitoring and control with mobile teams, and continued R&D. It currently produces pentamidine mesylate (Pentamidine), melarsoprol (Arsobal), and difluoromethylornithine (Eflornithine).[218]

The vaccines unit is attempting to combine diphtheria, tetanus, pertussis, polio, and Haemophilus influenzae type b and hepatitis B into a single injection.[219] It is also developing a vaccine for dengue fever, and an antimeningococcal vaccine will be available in 2006.[220] The unit is involved in public-private partnerships to develop an HIV vaccine (with several clinical trials ongoing), and is running clinical trials for a dengue fever vaccine.

sanofi-aventis (NYSE: SNY)

COUNTRY: France	**TOP 10:** ✓
COMMERCIAL PRODUCTS • Malaria: artesunate+amodiaquine (Arsucam), artesunate+sulfadoxine with pyrimethamine (Arsudar) • TB: rifampicin (Priftin), rifampicin+isoniazid+ethambutol+pyrimethamine (Rifafour) • Leishmaniasis: pentamidine mesylate (Pentamidine), meglumine antimoniate (Glucantime) • Sleeping sickness: pentamidine mesylate (Pentamidine), melarsoprol (Arsobal), difluoromethylornithine (Eflornithine)	**PIPELINE PRODUCTS** Malaria: amodiaquine+artemisinin • Dengue fever: candidate vaccine • Neglected diseases: candidate diphtheria+tetanus+pertussis+polio+Haemophilus influenzae type b+hepatitis B vaccine

Approach	Issue	Score	Industry Mean
Research	Fixed Dose Combination	N/A	2.9
	Neglected Diseases	5	2.5
Pediatric Needs	Formulations	N/A	3.1
	Price Cuts	N/A	3.3
Accessibility	Licensing	N/A	2.4
	Patent Relaxation	N/A	1.6
	Differential Pricing	4	3.9
	Registration	N/A	3.6
Reporting to Shareholders		4	3.2
Philanthropy		4	3.5
Political Engagement	Political Contributions	3	2.3
	Trade Association	1	1.3

BOTTOM LINE: Sanofi-aventis has a number of drugs for neglected diseases and is conducting further research into neglected diseases via a number of partnerships. This level of neglected disease involvement is commendable. We support the use of core business competencies to address the health crisis in emerging markets and recommend that sanofi-aventis consider additional strategies, beyond differential pricing, to ensure that its products reach patients.

Finally, sanofi-aventis has two products on the market for tuberculosis. It is a key supplier of rifampicin (Priftin), which is not clinically appropriate for patients with HIV-TB co-infection.[221] In South Africa, it also markets a combination of four anti-TB drugs in a single tablet: rifampicin+isoniazid+ethambutol +pyrimethamine (Rifafour). According to sanofis-aventis, this product could be distributed in other countries following WHO approval.[222] Rating: 5

Pediatric Needs: Formulations

Currently, sanofi-aventis has no antiretrovirals for the treatment of HIV.

However, the company has moved to create pediatric versions of malaria products.[223] Sanofi-aventis and DNDi will create a pediatric tablet formulation of their amodiaquine+artemisinin combination drug.[224] Rating: N/A

Pediatric Needs: Price Cuts

Currently, sanofi-aventis has no antiretrovirals for the treatment of HIV.

Sanofi-aventis is expecting the at-cost price of the new amodiaquine+artemisinin FDC to be below $1 for adults and 50 cents for children.[225] Rating: N/A

Accessibility: Licensing & Technology Transfer

Currently, sanofi-aventis has no antiretrovirals for the treatment of HIV and has made no statements on voluntary licensing.

Licensing for generic production may be a useful tool for additional patented essential medicines beyond anti-retroviral drugs. Rating: N/A

Accessibility: Patent Enforcement Relaxation

Currently, sanofi-aventis has no antiretrovirals for the treatment of HIV and has no statements discussing patent relaxation for specific products.

Companies selling patented essential medicines in emerging markets should consider patent relaxation as a method of increasing generic production of their products. Rating: N/A

Accessibility: Differential Pricing

For the public sector, sanofi-aventis has committed to supply antimalarial medicines at cost. In Cameroon, Gabon and Madagascar, the private sector is included as part of the access-card to antimalarials (CAP) program; the program is set to be extended to sub-Saharan Africa as well.[226]

According to its agreement with DNDi, sanofi-aventis has committed to selling the new artesunate+amodiaquine FDC at cost to affected countries. Sanofi-aventis expects this cost to be below $1 for adults and 50 cents for children.[227]

In conjunction with UNICEF, GAVI (Global Alliance for Vaccine and Immunization) and the Vaccine Fund, Sanofi Pasteur practices a tiered pricing policy on a large number of vaccines: oral polio vaccine, measles, Diphtheria-Tetanus-Polio, antimeningococcal vaccine, Measles-Mumps-Rubella, yellow fever and Diphtheria-Tetanus-Polio - Haemophilus influenzae B.[228] Rating: 4

Accessibility: Registration

Currently, sanofi-aventis has no antiretrovirals for the treatment of HIV, and we are not aware of criticisms for lack of drug registration.

Its co-blistered artesunate+amodiaquine (Arsucam) antimalarial drug is registered in over fifteen African countries.[229]

According to its agreement with DNDi, sanofi-aventis is responsible for filing the dossier for the registration of the artesunate+amodiaquine FDC with the regulatory authorities in the countries concerned and for filing for WHO pre-qualification.[230] Rating: N/A

Reporting To Shareholders

The company assigns a Vice President to Access to Medicines, who reports directly to the CEO.

Sanofi-aventis publishes a Sustainable Development Report covering both access programs and R&D for developing world diseases and places access to medicines in the developing world at the heart of the group's strategic concerns.[231] The company takes a relatively business-like approach to the developing world by discussing market opportunities and market presence in addition to the traditional philanthropic language used in other reports.

Nonetheless, we found a lack of impact measurements and quantitative metrics in the reporting. Rating: 4

Philanthropy

The company has a three-pronged approach to philanthropy: economic development micro-finance; access to healthcare; and patient support.

The healthcare access programs, particularly the Impact Malaria program, are well integrated with the core functions of the business (see above). The Malaria program focuses on capacity building and training of staff. Similar programs on sleeping sickness, polio eradication, and tuberculosis are tied to the company's products for these diseases.[232,233]

The company supports tuberculosis treatment literacy in South Africa. This is important because non-compliance with TB treatment can create drug resistant strains. Sanofi-aventis has provided $15 million to the program, which expects to have 100,000 people trained by 2008.[234] Rating: 4

Political Engagement: Political Contributions

The company's code of ethics prohibits donations to political parties. Its system for implementing its ethical code does not provide for reporting, including details of any breaches and enforcements. Rating: 3

Political Engagement: Trade Associations

Sanofi-aventis is a member of the European Federation of Pharmaceutical Industries and Associations (EFPIA) and PhRMA and does not disclose dues paid which are for political purposes. Rating: 1

Sanofi-aventis's Bottom Line

Sanofi-aventis has a number of drugs for neglected diseases and is conducting further research into neglected diseases via a number of partnerships. This level of neglected disease involvement is commendable. We support the use of core business competencies to address the health crisis in emerging markets and recommend that sanofi-aventis consider additional strategies, beyond differential pricing, to ensure that its products reach patients.

Schering-Plough

Schering-Plough (NYSE: SGP) is a relatively small company, with only 30,500 employees and $8.3 billion in net sales. Led since 2003 by Fred Hassan (former CEO of Pharmacia), the company is in the midst of a highly public turn-around. SP is refocusing on specialty products and oncology. The company also has a strong hepatitis C franchise. We include them here because of a research focus on HIV. SP has a CCR5 receptor antagonist called vicriviroc in phase II trials. Vicriviroc has only been tested in relatively small populations of patients (it is an oral once-a-day pill) but it may come to market as second-line therapy.

Research: Fixed-Dose Combinations

Vicriviroc development is at an early stage and appropriate combinations have not been established. Rating: N/A

Research: Neglected Diseases

SP has very little research into neglected diseases of any kind, with the exception of HIV. Its product pipeline disclosures include no information on neglected diseases.[235,236] Rating: 1

Pediatric Needs: Formulations

Vicriviroc development has not advanced sufficiently to begin testing in children. Rating: N/A

Pediatric Needs: Price Cuts

SP does not currently have antiretroviral therapies on the market.

Pediatric formulations of essential medicines should be sold at costs in line with adult formulations on a per-patient per-treatment course basis. Rating: N/A

Accessibility: Licensing & Technology Transfer

SP does not currently have antiretroviral therapies on the market. The company has made no public statements about exploring licensing options. However, Fred Hassan was the CEO of Pharmacia when that company out-licensed an ARV and advocated strongly for other companies to do the same. [237] Rating: N/A

Accessibility: Patent Enforcement Relaxation

SP does not currently have antiretroviral therapies on the market. The firm has made no statements regarding patent rights in developing countries.

Schering-Plough (NYSE: SGP)

COUNTRY: United States	**TOP 10:** No
COMMERCIAL PRODUCTS	**PIPELINE PRODUCTS** HIV: Vicriviroc

Approach	Issue	Score	Industry Mean
Research	Fixed Dose Combination	N/A	2.9
	Neglected Diseases	1	2.5
Pediatric Needs	Formulations	N/A	3.1
	Price Cuts	N/A	3.3
Accessibility	Licensing	N/A	2.4
	Patent Relaxation	N/A	1.6
	Differential Pricing	N/A	3.9
	Registration	N/A	3.6
Reporting to Shareholders		1	3.2
Philanthropy		N/A	3.5
Political Engagement	Political Contributions	4	2.3
	Trade Association	1	1.3

BOTTOM LINE: It is exciting to see a company never before working on HIV/AIDS working on a new product in this area. However, if the company is going to leverage vicriviroc effectively, SP will need to take advantage of the wide range of accessibility tools we've highlighted. It would also benefit from substantially increasing the quality of its reporting.

Companies selling patented essential medicines in emerging markets should consider patent relaxation as a method of increasing generic production of their products. Rating: N/A

Accessibility: Differential Pricing

SP does not currently have antiretroviral therapies on the market and has not released any information on its potential pricing policies.

Differential pricing policies should be predictable and transparent for any essential medicines sold in emerging markets. Rating: N/A

Accessibility: Registration

SP does not currently have antiretroviral therapies on the market.

Other essential medicines should also be pre-qualified by the WHO, and registered and available in all relevant emerging markets. Rating: N/A

Reporting To Shareholders

SP reporting on access to essential medicines issues is thin. We believe that all companies have to account for the risks and opportunities of the medicines crisis, regardless of its product mix. For a company attempting to bring an HIV product to the market, this is even more true. Yet SP has almost nothing on its website or in its annual report concerning Global South health issues. (The company produces a separate environmental report but not a corporate citizenship report equivalent to others considered in this study). Rating: 1

Philanthropy

SP does not appear to have substantial philanthropic activities in developing countries. Rating: N/A

Political Engagement: Political Contributions

The company discloses its corporate political donations and those donations are overseen by an independent committee of the board. Rating: 4

Political Engagement: Trade Associations

The company does not disclose trade association dues used for political purposes. Rating: 1

Schering-Plough's Bottom Line

It is exciting to see a company never before working on HIV/AIDS working on a new product in this area. However, if the company is going to leverage vicriviroc effectively, SP will need to take advantage of the wide range of accessibility tools we've highlighted. It would also benefit from substantially increasing the quality of its reporting.

Wyeth

Wyeth (NYSE: WYE), a top ten pharmaceutical company, focuses on small molecules, vaccines, and biotechnology research. The company has large mental health and women's health portfolios. Wyeth has been particularly active in developing an HIV vaccine and recently enlisted Emilio Emini, formerly of the International AIDS Vaccine Initiative, to head its vaccine research division.[238]

Research: Fixed-Dose Combinations

Wyeth does not have antiretroviral therapies on the market.

Fixed-dose combinations can also reduce pill burden, increase patient compliance and reduce the emergence of drug-resistant strains for other infectious diseases besides HIV. Rating: N/A

Research: Neglected Diseases

Wyeth has a long vaccine tradition and is today running trials for a children's pneumococcal conjugate vaccine in several African locations (Wyeth works closely with the Global Alliance for Vaccines and Immunization).[239, 240] Its current public-private partnership with the Centers for Disease Control investigating HIV vaccine candidates follows in this tradition. However, Wyeth's biotechnology and small-molecule research is not applicable to neglected diseases. There are no substantial resources devoted to public health needs in developing countries. Rating: 1

Pediatric Needs: Formulations

Wyeth does not have antiretroviral therapies on the market.

All essential medicines clinically appropriate for children should be available in a range of pediatric formulations. Rating: N/A

Pediatric Needs: Price Cuts

Wyeth does not have antiretroviral therapies on the market.

Wyeth (NYSE: WYE)

COUNTRY: United States	**TOP 10:** ✓
COMMERCIAL PRODUCTS	**PIPELINE PRODUCTS** HIV: candidate vaccine

Approach	Issue	Score	Industry Mean
Research	Fixed Dose Combination	N/A	2.9
	Neglected Diseases	1	2.5
Pediatric Needs	Formulations	N/A	3.1
	Price Cuts	N/A	3.3
Accessibility	Licensing	N/A	2.4
	Patent Relaxation	N/A	1.6
	Differential Pricing	N/A	3.9
	Registration	N/A	3.6
Reporting to Shareholders		1	3.2
Philanthropy		1	3.5
Political Engagement	Political Contributions	1	2.3
	Trade Association	1	1.3

BOTTOM LINE: The longstanding vaccine business should give Wyeth an effective way to integrate the risks and opportunities presented by the public health crisis in emerging markets into its core business strategy. It does not appear to be doing so. While vaccine research remains a bright spot, Wyeth's remaining public health initiatives in the Global South appear only charitable and modest.

Pediatric formulations of essential medicines should be sold at costs in line with adult formulations on a per-patient per-treatment course basis. Rating: N/A

Accessibility: Licensing & Technology Transfer

Wyeth does not have antiretroviral therapies on the market.

Licensing for generic production may be a useful tool for additional patented essential medicines beyond anti-retroviral drugs. Rating: N/A

Accessibility: Patent Enforcement Relaxation

Wyeth does not have antiretroviral therapies on the market.

Companies selling patented essential medicines in emerging markets should consider patent relaxation as a method of increasing generic production of their products. Rating: N/A

Accessibility: Differential Pricing

Wyeth does not have antiretroviral therapies on the market. The company "will consider flexible pricing terms" for developing country markets and has done so in the past with birth control pills. Rating: N/A

Accessibility: Registration

Wyeth does not have antiretroviral therapies on the market.

Other essential medicines should also be pre-qualified by the WHO, and registered and available in all relevant emerging markets. Rating: N/A

Reporting To Shareholders

Wyeth reporting on access to essential medicines issues is weak. We believe that all companies have to account for the risks and opportunities of the medicines crisis, regardless of its product mix. For a company highly focused on HIV vaccine research, this is even more true. Yet Wyeth has almost nothing on its website or in its various reports concerning Global South health issues.

We found only two exceptions. A 2003 philanthropy report contains little information about Wyeth programs beyond donations and no information on the fiduciary impact or reasoning for these programs.[241] And, Wyeth does have a policy statement on health care in developing countries.[242]

The policy statement would be a sound beginning to systematic, forward-looking, and quantitative reporting. By itself, however, it does not fulfill shareholder needs. Rating: 1

Philanthropy

Wyeth philanthropy includes a substantial amount of product donations coordinated by large NGOs such as Americares. Unlike peer companies, Wyeth does not make long-term, large-scale financial commitments (i.e. $100 million over five years). We are nonetheless concerned that Wyeth puts Global South health care issues in the philanthropic box only. Rating: 1

Political Engagement: Political Contributions

Wyeth does not disclose corporate political contributions and those contributions are not overseen by the board. Rating: 1

Political Engagement: Trade Associations

Wyeth does not disclose dues paid to trade associations used for political purposes. Rating: 1

Wyeth's Bottom Line

The longstanding vaccine business should give Wyeth an effective way to integrate the risks and opportunities presented by the public health crisis in emerging markets into its core business strategy. It does not appear to be doing so. While vaccine research remains a bright spot, Wyeth's remaining public health initiatives in the Global South appear only charitable and modest.

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Discussion

Our analysis demonstrates that pharmaceutical companies are not in compliance with the current best practices in responding to HIV/AIDS and neglected diseases. But the difference between current practices and best practices range widely, and some strategies are more widely used than others.

This leads to a number of potential impacts for public health and for institutional investors exposed to the pharmaceutical sector.

Emerging Patterns

Looking at the industry, we see differential pricing (mean: 3.9) and philanthropy (mean: 3.5) are the two most widely used strategies. Yet both are a full point or more away from the best practice recommendation. The industry is even further behind in other areas, such as voluntary licensing, meeting pediatric needs, neglected diseases research, and transparent political engagement.

Some patterns emerged in our evaluation. First, higher scores in reporting to shareholders do not appear to correlate with higher scores in other areas. This surprised us: one would expect that companies with better performance would want to report on it, or alternatively, that companies whose shareholders demand reporting would need to perform better. One possible reason for the lack of correlation is the lack of standard reporting formats and metrics. This makes reporting both difficult to evaluate and less reflective of actual company activity, both positive and negative.

Scores for reporting also do not correlate with whether or not companies have AIDS drugs on the market. Again, given the increased public attention specifically on those companies, this is a somewhat surprising result.

KEY FINDINGS		
For Investors	*Strategies Vary*	Individual responses vary substantially by company: the industry cannot be judged monolithically.
	Reporting Is Sub-Standard	Most companies are not reporting on material useful to either shareholders.
	Substantial Risks Remain	Depending on product mix and policies, some companies continue to face substantial downside risks.
	Improve Public Health, Reduce Company Risk	The soundest way to reduce risk is to address, as much as possible, the underlying public health crisis.
For Public Health	*Neglected Disease R&D*	Some companies are distinguishing themselves, but the majority are taking little action.
	Pediatric AIDS	Children with AIDS continue to have unmet medical needs.
	Second-Line AIDS Drugs	Second-line drugs are less likely to be affordable or available generically.
	AIDS Drug Access Beyond Africa	Company policies are overwhelmingly focused on Africa. Companies may not be prepared to address the spread of AIDS to other regions.

Second, European firms clearly score higher (mean: 4.0) on neglected disease research than American firms (mean: 1.7). All three high scores were for European firms (GSK, Novartis, and sanofi-aventis, respectively). American companies were truly dismal. Seven companies scored a 1; six were American companies. Neglected disease research also varied positively with whether or not a company was a player in the HIV market: companies without anti-AIDS products (mean: 2.8) scored a bit higher than AIDS drug makers (mean: 2.2). One could speculate that some companies without AIDS drugs in their portfolios turn to other mechanisms to demonstrate their commitment to access to medicines, and use research as one outlet.

Third, American companies clearly score higher (mean: 2.7) on political contribution transparency and accountability than their European counterparts (mean: 1.5). All high scorers were U.S.-based firms: Johnson & Johnson, Lilly, Merck, Pfizer, and Schering-Plough (each scored a 4). We speculate that money in politics is a more salient political issue in the United States. The U.S. social investment community's interest in this issue may also play a role. All companies do equally poorly (score: 1) on the need for transparency in trade association spending on political activity, with the lone exception of Gilead Sciences (score: 5), which is not a member of the key trade associations.

Key Findings For Investors:

Strategies Vary

Companies are using a range of approaches to respond to the public health crisis in emerging markets. We found a wide disparity among companies in approaches and in the success of these approaches. For example, Gilead is spearheading fixed-dose-combination development, scoring a 5, well above the industry mean (2.9). But Gilead has been hesitant to issue voluntary licenses (score: 2). GlaxoSmithKline has licensed enthusiastically, scoring a 4, but GSK has not engaged in fixed dose combination development (score: 2). Each company is showing leadership in one area, and failing to maximize its opportunities in another.

Different companies make different decisions on access to medicines policy, and have different risks and opportunities based on their particular product mixes and skills. While many companies participate in industry-wide efforts such as the Accelerating Access Initiative, investors would be best served by evaluating responses to the crisis on a company-by-company basis.

Reporting Is Sub-Standard

Almost without exception, we found that company reporting on the public health crisis is poor from an investment value perspective. It appears that the majority of companies are driving their reporting from their public relations or marketing functions. Most reporting does not contain useful information to make public health judgments. Similarly, it does not assist investors in judging the degree of senior management attention or strategic planning informing policy and programmatic responses. Investors are advised to seek more robust pharmaceutical industry reporting.

Company reporting on the public health crisis is poor from an investment value perspective.

Substantial Risks Remain

We began our inquiry by looking at industry-wide risks posed by the public health crisis, particularly around the extension of global intellectual property norms. Little that we found has reassured us that companies are responding adequately to address that systemic, industry-wide risk.

However, individual companies are also exposed to company-specific regulatory and headline risks. This is particularly true for companies responding inadequately to pediatric AIDS issues, as children with AIDS is a potent topic for the public.

Individual companies are exposed to company-specific regulatory and headline risks.

Improve Public Health, Reduce Company Risks
Ultimately, the soundest risk reduction strategy for any pharmaceutical company is a response which privileges public health, so that the underlying cause of the crisis – infectious diseases in developing countries – is addressed. As we discussed earlier, it is not possible for pharmaceutical companies to wholly bring this about. However, companies have a wide range of options available to them. By and large, they are failing to take advantage of those options.

The soundest risk reduction strategy for any pharmaceutical company is a response which privileges public health.

Key Findings For Health Care Providers:

Neglected Disease R&D
The number of public – private partnerships and intensive neglected disease research programs, such as Novartis' initiative, is quite a bit larger today than it was several years ago. The entry of philanthropic private players such as the Bill and Melinda Gates Foundation has changed the landscape for neglected disease research for the better.

But the range of company responses on this topic is quite wide, with seven 1 scores and three 5 scores. This is an area in which some companies, like GlaxoSmithKline, are distinguishing themselves and others, such as Wyeth or Eli Lilly, are staying static. R&D is risky business, and increasing the number of players would increase the chances of success. Neglected disease R&D may offer companies the greatest opportunity to make a substantial public health impact. Only a small number of companies appear to recognize this.

Pediatric AIDS
There is an urgent need for pharmaceutical companies to increase resources devoted to making and distributing – at a price health care providers can afford – pediatric AIDS medicines. The average score for pediatric formulations was 3.1 and the average score for price cuts was 3.3, demonstrating that the gap between best practices and current company practices is wide.

Second-Line AIDS Drugs
Based on our analysis of the differential pricing and licensing and technology transfer categories, we are confident that first-line AIDS drugs are reasonably affordable and that generic availability is adequate (although we saw room for improvement, particularly with Merck and Gilead products). However, second-line AIDS drugs continue to be much more expensive, and less likely to be licensed or available generically. This will rapidly become the next phase of treatment advocacy by health care providers and people living with AIDS.

With strategic thinking and a willingness to take advantage of a range of access options, makers of second-line drugs such as Bristol-Myers Squibb and Abbott can respond quickly and avoid the mistakes of the past. However, we saw only scattered evidence that firms are moving in that direction.

With strategic thinking, makers of second-line drugs could respond quickly and avoid the mistakes of the past.

AIDS Drug Access Beyond Africa

The consistent failure of differential pricing policies and other access programs run by companies surveyed is their lack of applicability beyond Africa. The AIDS pandemic is expanding rapidly in the Caribbean basin, Central America, southeast Asia, central Asia, some provinces of India, and some provinces of China. Our analysis of current company policies is that firms are ill-prepared for this shift, and have crafted policy responses geared towards Africa only. Essentially, firms have one patent, licensing, and pricing strategy for sub-Saharan Africa and treat the rest of the developing world on an ad hoc basis.

However, governments of states such as India, Brazil, Thailand, and Guatemala (where there are politically active constituencies of people living with AIDS) are not likely to accept sub-standard access policies. Companies obviously need different sets of policies for countries with different regulatory and public health infrastructures. The standard practice is to create policies ad hoc. Instead, firms should be crafting access policies which are transparent and predictable globally.

Firms are ill-prepared for the shift of the AIDS pandemic to the Caribbean basin, Central America, central Asia and Russia, and parts of south Asia.

Further Research

This report raised some questions for us that we were unable to answer: What are the risks and opportunities for makers of diagnostic products? How can we more effectively measure the public health impact of specific programs, such as public-private partnerships? Does the pharmaceutical industry need a common framework (similar to the Global Reporting Initiative's framework on environmental and social reporting) for reporting on access to medicines issues? How does one measure issues such as political lobbying or other topics which we did not wrestle with here?

In Conclusion

Pharmaceutical companies have an immense impact on the lives of billions of people at risk or victim to pandemic diseases and other public health threats. No industry, and certainly no company, will be able to address these health issues in isolation. Governments have a strong role to play. Both developed and developing country governments must be held accountable when they fail to respond to public health needs. Governments should recognize that responding to AIDS effectively is a key element in maintaining a favorable investment climate for many markets. Civil society and faith-based organizations must also act responsibly and vigorously.

Pharmaceutical company stakeholders and investors increasingly recognize that pharmaceutical companies must do better. Our analysis shows a number of areas in which pharmaceutical companies can improve their responses to AIDS and other pandemic diseases. For both investors and public health, the benefits of action clearly outweigh the risks. Now it is up to pharmaceutical companies to do their part in keeping the promise.

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Research	Fixed Dose Combination	2	N/A	1	5	5	2	N/A	N/A	4	N/A	N/A	1	N/A	N/A	N/A	2.9
	Neglected Diseases	1	3	1	1	1	5	4	1	3	5	3	3	5	1	1	2.5
Pediatric Needs	Formulations	3	N/A	2	4	3	3	N/A	N/A	4	N/A	2	4	N/A	N/A	N/A	3.1
	Price Cuts	5	N/A	5	3	1	4	N/A	N/A	3	N/A	N/A	2	N/A	N/A	N/A	3.3
Accessibility	Licensing	1	N/A	3	2	2	4	2	5	2	N/A	1	2	N/A	N/A	N/A	2.4
	Patent Relaxation	1	N/A	1	3	1	1	1	N/A	1	3	1	3	N/A	N/A	N/A	1.6
	Differential Pricing	3	N/A	4	4	4	4	N/A	N/A	5	4	N/A	3	4	N/A	N/A	3.9
	Registration	2	N/A	4	5	2	5	N/A	N/A	2	N/A	N/A	5	N/A	N/A	N/A	3.6
Reporting to Shareholders		3	4	2	3	3	5	4	4	4	4	3	3	4	1	1	3.2
Philanthropy		4	2	3	4	N/A	4	4	4	5	4	3	4	4	N/A	1	3.5
Political Engagement	Political Contributions	2	1	1	2	1	1	4	4	4	1	4	2	3	4	1	2.3
	Trade Association	1	1	1	1	5	1	1	1	1	1	1	1	1	1	1	1.3

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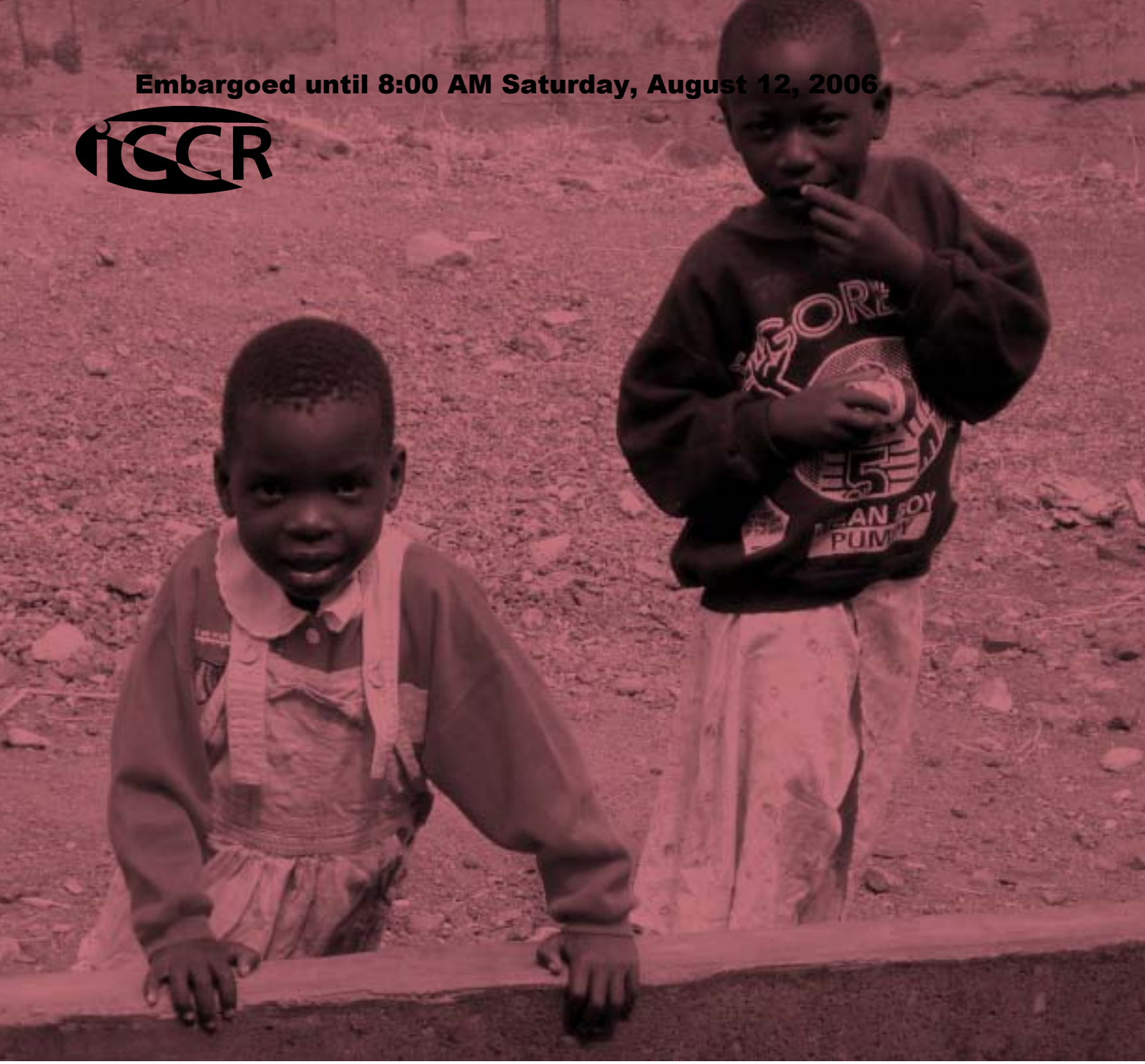

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