



SPECIAL ISSUE FEATURING

**Treating Children with HIV:
The Role of Faith-Based Investors**

**Recommendations for Pharmaceutical Company
Responses to the HIV/AIDS, Tuberculosis,
and Malaria Pandemics**

ICCR

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Sudi, age 13, Mombasa, Kenya. The photo on the left was taken shortly before Sudi began antiretroviral treatment, while the photo on the right was taken 5 months later. Sudi is treated by Dr. Shaffiq Essajee in the AIDS Research and Family Care Clinic.

Photo attribution: Photographs courtesy of Stephen Shames, for Keep A Child Alive.

TREATING CHILDREN WITH HIV: The Role of Faith-Based Investors

By **Daniel Rosan**

Program Director, ICCR's Access to Healthcare Working Group

“Children with AIDS are being left to die,” Dr. Shaffiq Essajee told me. Dr. Essajee treats children at the AIDS Research and Family Care Clinic in Kenya; he is funded by the American charity Keep A Child Alive.

He continued, “Apart from Thailand and Brazil, fewer than 15,000 kids worldwide are currently on treatment, and yet HIV-positive children are the most vulnerable group of patients in Africa. Without treatment, mortality approaches 60% in the first 2 years of life, whereas children who get ARVs can lead healthy lives.” That means, in plainer English, that over half of kids with AIDS are dead by age two, unless they get ARVs. ARVs are antiretroviral medicines, life-saving therapies which should be a birthright of every child born with HIV.

HIV and AIDS strike down people in the most vibrant years of their lives, when they are working, raising children, and laying the foundation for the next generation of their – and our – societies. But the cruel calculus of HIV means that women are infected, often by their husbands, and give birth before they are AIDS-sick and aware that they have the virus.

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475 Riverside Drive, Room 1842, New York, New York 10115

212-870-2295

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THE SCOPE OF THE PEDIATRIC AIDS CRISIS

(source: UNAIDS)

EACH DAY:	1,900 children are infected with HIV. 1,350 children with HIV die.
EACH YEAR:	630,000 children become infected with HIV (the vast majority during birth or through breast-feeding). 490,000 children die from HIV. Half of all children with AIDS die before they reach two years old.

The result is a rising wave of children living with HIV. While many become infected through sexual abuse or sexual activity, the vast majority of children with HIV are infected at birth or shortly after.

Often these children lose their HIV-positive parents as well, and become doubly scarred by the virus: both AIDS orphans, and AIDS patients.

During my ICCR-sponsored research trip to Botswana, Kenya, and South Africa almost one year ago, I met the doctors, nurses, lay missionaries, women religious, aunts, and grandmothers who daily care for these children. Many kids owe their lives to faith-based or non-governmental organizations. I remember vividly the pride with which one elderly priest informed me none of his charges died in the past year.¹

Members of the Interfaith Center on Corporate Responsibility are supporting their colleagues in AIDS-impacted regions with a massive effort to encourage new policies at Abbott Laboratories, Bristol-Myers Squibb, GlaxoSmithKline, Merck, Johnson & Johnson, Pfizer, and the biotechnology company Gilead Sciences to increase access to life-saving medicines.

Sister Vicki Bergkamp of the Adorers of the Blood of Christ, and Chair of the HIV/AIDS Caucus at ICCR, explains “ICCR Members see the ravages of HIV and AIDS in their daily work in Africa, India, and China. Our

experience on the ground in these regions has convinced us that leading pharmaceutical companies can – and must – do more to make their life-saving products accessible to the people who desperately need them.”

Abbott, Merck, and their competitors make anti-retroviral drugs (ARVs) which dramatically slow the onset of AIDS in HIV-positive patients, allowing them to lead normal and productive lives, often for many years. Generic competition has dropped the price of these medicines by astounding amounts. For example, a first line treatment regime costing over \$1,000 in 2001 now costs \$400. Generic versions of ARV medicines – which are often combined into a single pill – cost under \$200 per patient per year.²

But children with HIV are largely cut out of this price competition because they have little purchasing power. 2.1 million children live with HIV³, but they cannot finance their own care. Generic drug makers rely on economies of scale to make their thin profit margins. Without a large market, they cannot compete.

For the 1,900 children newly infected with HIV today, big-name American companies are their only hope. Shareholders in those firms have a moral obligation to change management policies to fulfill the promise of life-saving medicines.

“HIV treatment for adults is slowly becoming easier,” explains Dr. Koen Frederix, a pediatrician working in Malawi with the charity Médecins Sans Frontières, “with increasing availability in developing countries of a three-drug cocktail in one tablet. But children who need treatment still have to drink large amounts of foul tasting syrup or swallow large tablets – that’s if they can actually access treatment at all. Children with HIV are generally not interesting to pharmaceutical companies.”

Treating children is not easy. The cost is high, diagnosis is challenging, and ensuring adherence (taking pills consistently and correctly, which is important to prevent viral mutations) is complicated. The stigma attached to HIV casts a shadow over the whole process.

Dr. Essajee explains, “While there are many issues that contribute to this tragic situation, one of the key problems is the lack of access to drugs. Pediatric formulations are many times the cost of adult meds - whether

THE COST OF TREATING KIDS

(source: Médecins Sans Frontières)

Pediatric First Line:	Three oral syrups of d4T, 3TC, & NVP
Pediatric Annual Cost:	\$284 per year
Adult First Line:	One tablet containing d4T/3TC/NVP
Adult Annual Cost:	\$244 per year
Pediatric Second Line:	Three oral syrups of ZDV, ddl, & NFV
Pediatric Annual Cost:	\$3150 per year
Adult Second Line:	Three tablets of ZDV, ddl, & NFV
Adult Annual Cost:	\$1096 per year

generic or branded - and the supply chain - especially from US manufacturers is woefully inadequate to support the numbers of kids who need treatment.”

But treatment is possible, given the resources. In Sao Paulo – which has the largest number of pediatric AIDS cases in Brazil – median survival time is over seven years, a hopeful contrast to the half of children with AIDS who die before age two.⁴

Adherence challenges can also be met. In Thailand, forty-four children at Prachomklao Hospital in Petchburi achieved a 95% adherence rate. Doctors found “continuous support for adherence was the main challenge for treatment success.”⁵ Only five children died, all of tuberculosis, and none due to poor adherence.

Adding to these treatment burdens is the high cost of treating children. In Thailand, pediatric cases cost the health care provider 18,600 Baht (\$475) per child, with families absorbing 6,231 Baht (\$160).⁶ In Brazil, two sites providing care to HIV-positive children spent 62% and 78%, respectively, of their cost total on ARV drugs, despite an aggressive program by the Brazilian government to negotiate lower prices from Western drug companies.⁷

When leading medical providers were asked to identify the greatest barrier to treating children, the consensus was clear: money. Dr. Aziz O. Abdallah, the Director of HIV Care Services at Liverpool VCT and Care Center in Kenya, sent a terse email from Nairobi: “The unavailability of affordable pediatric ARV formulations.” He recommended drug companies simply “reduce the cost” of the drugs his patients need.⁸

Recently, ICCR members developed a menu of policy options for the Boards of Directors of major pharmaceutical companies. Sister Doris Gormley, a corporate responsibility consultant to the Society of Jesus, explained why: “While many companies have taken some positive action in the past, it is clear to us that no pharmaceutical company is taking advantage of the range of policy options available to them to increase access to medicines. Shareholders want to see strategic leadership from the Board of Directors to this crisis, not just ad hoc responses.”

This menu covers both adult and pediatric AIDS-drug access issues. But for children, we focused on three core areas: **Reduce, Research, and Register.**

First, drug companies should commit to holding pediatric prices at adult levels.

Second, they should direct research energies to developing pediatric formulations which work in the real world settings of resource poor countries. That means chewable tablets, fixed-dose combination syrups, smaller pills, and more research in dosing. As children grow, dosing is a constant problem for caregivers.

Finally, all ARV drugs in all formulations should be registered in all countries. Too often, companies do not navigate the bureaucratic hurdles in the local equivalents of our Food and Drug Administration. Ideally, of course, those bureaucratic hurdles would be slight. But patients must be not be punished for the inefficiencies of their governments. They need companies to aggressively bring all formulations to market.

With this advocacy, faith-based investors are completing the circle begun by the faith community in Africa and Asia, who have embraced children with AIDS as the most vulnerable of patients. I am pleased to report that ICCR shareholders are leading the way. The question now is, will management follow?

NOTES

- 1 Daniel Rosan. “AIDS Is Like A Competitor: Report of the 2004 HIV/AIDS Fact-Finding Trip to Botswana, Kenya, and South Africa.” 22 September 2004. Propriety for ICCR Members only.
- 2 Medecins Sans Frontieres. “Untangling the web of price reductions” 6th edition. 19 April 2004. The example given is of a ZDV/3TC + EFV regime and a d4T/3TC/NVP regime, respectively.
- 3 Demographic statistics drawn from UNAIDS, “2004 Report on the Global AIDS Epidemic.” July 2004.
- 4 L.H. Matida. “Impact of early diagnosis and free access to HAART for perinatally acquired AIDS, Sao Paulo, Brazil.” Abstract presented at XV International AIDS Conference, Bangkok, Thailand. 11 July 2004.
- 5 W. Petdachai. “Antiretroviral therapy for children in Thailand.” Abstract presented at XV International AIDS Conference, Bangkok, Thailand. 11 July 2004.
- 6 A. Rodsom. “Economic cost of pediatric AIDS in Nan province, Thailand.” Abstract presented at XV International AIDS Conference, Bangkok, Thailand. 11 July 2004.
- 7 H.H.S. Marques. “Costs of care to children with HIV/AIDS in a teaching hospital in Sao Paulo, Brazil.” Abstract presented at XV International AIDS Conference, Bangkok, Thailand. 11 July 2004.
- 8 Email exchange with the author, 9 January 2005.

Recommendations for Pharmaceutical Company Responses to the HIV/AIDS, Tuberculosis, and Malaria Pandemics

By ICCR's Access to Healthcare Working Group

The Interfaith Center on Corporate Responsibility 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 rights enumerated in the *Principles For Global Corporate Responsibility*, specifically that “every person has the right of access to health care.”¹

Today, 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., and Pfizer.

We believe that a failure to adequately respond to the HIV-TB-Malaria pandemic creates a wide variety of risks to shareholders. We are indebted to the investor organization the Pharmaceutical Shareowners Group (PSG)² for articulating those risks in a recent report. They include:

- Risks to the social contract on which drug companies depend to finance innovation;
- Threats to the development of emerging markets;
- Risks in rich-country regulatory environments;
- Adverse impacts on staff morale and recruitment prospects; and
- A potential inability to successfully secure new markets.

In our dialogues with pharmaceutical companies, ICCR members are often asked for guidance in responding to the pandemics. In addition, other stakeholders – including investors such as the PSG, non-governmental organizations,³ associations of people living with AIDS, and multilateral institutions – have articulated best practices for the industry. There is clear consensus that a range of approaches is required. Acting flexibly ensures firms will be better prepared to respond to changing expectations and regulatory environments.

In this document we build on that foundation and identify best practices in the areas of research, pediatric needs, accessibility, reporting to shareholders, philanthropy, and political engagement. Consistent with both our experience in the field and our fiduciary duty, we recommend research-based pharmaceutical companies carefully consider and implement, as appropriate, the following responses to the HIV-TB-Malaria pandemics:

RESEARCH:

Fixed-Dose Combinations

Fixed-dose combinations (FDCs), which are available generically, combine multiple medicines into a single pill, greatly reducing the complexity of supplying, tracking, and most importantly, actually taking anti-retroviral drugs. They can reduce the pill burden for patients to as few as one pill per day.

Thus far, drug companies have created fixed-dose products, such as COMBIVIR (lamivudine-zidovudine) or KALETRA (lopinavir-ritonavir), only for pairs of products which they distribute. In contrast, patients often need combinations of the drugs produced by different companies.

Firms should collaborate with each other to develop FDCs, as Bristol-Myers Squibb and Gilead Sciences are doing.⁴ While such development takes place, firms should rapidly roll-out 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. One co-packaged product by the generic manufacturer Aspen has already been granted FDA approval.⁵

Neglected Diseases

The stunning truth that no new tuberculosis drug has been developed in the past twenty years means there is a severe public health threat posed by neglected diseases – diseases of poverty, on which no market-driven research and development takes place. Pharmaceutical firms can respond by giving non-profit partnerships such as the Drugs For Neglected Diseases Initiative (DNDi) or the International Microbicide Project which are focusing their research exclusively on diseases of poverty, unfettered access to their molecular libraries and scientists.⁶

In addition, several multilateral aid agencies and international philanthropies have discussed “prizes” or “pull mechanisms” which would reward research and development into diseases, such as pediatric AIDS, which do not have viable rich-country markets. Companies which have already invested in these areas will have some advantage in securing these prizes.

PEDIATRIC NEEDS:

Price Cuts

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.⁷ 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.

Pediatric Formulations

Clinicians treating children with HIV/AIDS have an urgent need for improved formulations. These include child-friendly delivery systems such as chewable tablets, better syrups, and smaller pills. While syrups or solutions are clearly needed for very young children, providers in the field are desperately calling for better solid formulations for children.⁸

Clinicians also require formulations which simplify treatment and improve adherence, such as fixed-dose combinations. Co-packaging and packaging organized around dispensing practices would be useful in the interim. Firms should devote all necessary resources to developing products that meet these needs. When developing new product lines, pediatric needs should be included in the development process.

ACCESSIBILITY:

Licensing

Non-exclusive, voluntary licenses are vital tools in the expansion of access to essential medicines.

These licenses save time, money, and energy when compared to government-issued compulsory licenses, which are often difficult to acquire and litigious. Recent changes in international trade policies make voluntary licensing – on reasonable terms and conditions – even more important.

India’s recent regulatory changes on the granting of product patents, and the increasing use in bilateral trade agreements of data exclusivity – changes encouraged by the pharmaceutical industry – have reduced the ability of generic producers to enter the market in the absence of compulsory or voluntary licenses.

Licenses have clear public health benefits: they reduce the cost of medicines via market competition, they reduce the chance a given market would face a drug shortage, and they encourage the production of fixed-dose combinations.

Indeed, given these advantages, it is no surprise that there are several examples of successful voluntary licenses. Yet to date, few American anti-retroviral producers has issued them. GlaxoSmithKline, Lilly, and, briefly, Pharmacia have shown leadership in this area.

As a result of an agreement with South Africa’s Treatment Action Campaign, GlaxoSmithKline has licensed RETROVIR (zidovudine) and EPIVIR (lamivudine) to one Kenyan and four South African generic producers.⁹ Merck, responding to similar concerns by South African activists, has issued one license for STOCRIN (efavirenz), and more such licenses are needed.¹⁰

Similarly, Lilly has taken the extraordinary step of transferring manufacturing technology needed to produce SEROMYCIN (cycloserine) and CAPA-STAT (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.¹¹

In 2003, Pharmacia created an innovative program which granted licenses to an NGO to pass on to generic producers. The drug in question was RESCRIPTOR (delavirdine). The International Dispensary Association facilitated the license, only for use in nations with less than \$1,200 per capita GDP. Pfizer's acquisition of Pharmacia ended the program before it was fully implemented. Nonetheless, the model of cooperation remains.¹²

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.

Patent Relaxation

In 2001, Bristol Myers Squibb announced that it would not enforce its patent protections if generic manufacturers produced BMS HIV/AIDS medicines for least developed countries. In 2004, Roche followed suite with a similar announcement. Both firms have essentially informed generic suppliers they would not face civil enforcement actions from the patent-holder for production or sale in sub-Saharan Africa. This elementary step should be taken by other patent holders of essential medicines.¹³

Differential Pricing

Every maker of anti-retroviral AIDS drugs has committed to charging lower prices in markets with a reduced ability to pay. Such differential pricing policies must be strengthened in two ways.

First, they should be expanded geographically. Many countries restrict their policies to sub-Saharan Africa when the HIV pandemic is rapidly expanding globally. Middle-income nations are also regularly excluded from differential pricing schemes or treated on an ad-hoc basis. It is clear, however, that poor patients in Haiti or Thailand have the same right to medicine as those in Mozambique.

Second, differential prices should be regularly reviewed for their impact on drug access. Prices which are significantly higher than generic prices should trigger a review and reduction. And, health care providers and people living with HIV should be regularly consulted when determining prices.

Finally, we note differential pricing does not address concerns about the sustainability of drug supply or the production of fixed-dose combinations.

Registration

Drug registration in poor countries can be difficult because of a lack of capacity and the presence of corruption. Nonetheless, pharmaceutical companies have often failed to register all the available dosages and formulations of their products with national drug regulatory agencies. This makes price discounts offered to least developed nations illusions – because drugs cannot be prescribed in nations where they are not registered with the appropriate authorities.

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.

REPORTING TO SHAREHOLDERS:

In addition to these policy steps, pharmaceutical companies must demonstrate leadership at the highest levels, with regular Board involvement on developing HIV/AIDS – TB – Malaria policies.

Our concern as stockowners of pharmaceutical firms extends beyond the negative public relations impact of the AIDS pandemic. 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.

Often, corporate reporting on HIV/AIDS focuses solely on philanthropy. We suggest instead 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.¹⁴

PHILANTHROPY:

ICCR members appreciate the philanthropic response pharmaceutical companies have made to the HIV/AIDS pandemic. Philanthropy has a place in a broader corporate response. But philanthropy itself is not sufficient – and we do not believe that philanthropic responses to the pandemics (gifts of money or products) are sustainable.

Nonetheless, philanthropy has been embraced by the industry. Merck, for example, has committed \$50 million in cash and donations of STOCRIN (efavirenz) over five years to Botswana, one of the world's hardest hit countries.¹⁵ Where such programs have been established, companies have an obligation to fund them for as long as is necessary to ensure self-sufficiency, and a particular obligation to ensure patients started on anti-retroviral drugs have access to those drugs for the rest of their lives.

POLITICAL ENGAGEMENT:

Political Contributions

In a highly regulated industry such as pharmaceuticals, companies must have a transparent and accountable voice in the political process. This extends to political contributions. 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 contributions; and a clear rationale ensuring that corporate managers are acting in the interests of shareholders and patients.¹⁶

Trade Associations

Most pharmaceutical firms choose to participate in trade associations such as the Pharmaceutical Research Manufacturers Associations (PhRMA). If they do so, dues to – and the expenses of – such organizations should be disclosed. 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. In short, companies must demonstrate that their public policy positions and lobbying efforts are aligned with their strategic response to pandemic diseases.

NOTES

- 1 Taken from the "Principles For Global Corporate Responsibility" 3rd edition, released in April 2003 by the Global Principles Steering Committee. More information is available at www.benchmarks.org. The Steering Committee includes: Bench Marks Foundation of Southern Africa; Censat Agua Viva; Christian Centre For Socially Responsible Investment; Ecumenical Council for Corporate Responsibility; Hong Kong Christian Industrial Committee; Interfaith Center on Corporate Responsibility; and KAIROS: Canadian Ecumenical Justice Initiatives.
- 2 PSG elaborates on these risks in the September 2004 report "The Public Health Crisis in Emerging Markets" available at www.pharmashareownersgroup.org. PSG members include: Central Finance Board of the Methodist Church; Co-operative Insurance Society; Credit Agricole Asset Management; Ethos Investment Foundation; Henderson Global Investors; Insight Investment; ISIS Asset Management; Jupiter Asset Management; Legal & General Investment Management; Morley Fund Management; PGGM Investments; SAM Sustainable Asset Management; Schroder Investment Management (UK); and Universities Superannuation Scheme (USS).
- 3 See, for example, Oxfam's 2001 paper "Formula For Fairness: Company Briefing Paper, Pfizer."
- 4 "Bristol-Myers Squibb, Gilead Sciences And Merck & Co., Inc. Announce Plans To Develop Fixed-Dose Combination Of Three HIV Medicines." 16 May 2004. http://www.bms.com/news/press/data/fg_press_release_4772.html
- 5 "FDA approves generic AZT/3TC/NVP Fixed Dose Combination." HIV I-base. <http://www.i-base.info/htb/v6/htb6-2/FDA.html>.
- 6 "IPM will Take Over the Development of Tibotec Pharmaceuticals Limited's Promising Microbicide to Help in the Prevention of the Sexual Transmission of HIV." 29 March 2004. http://www.jnj.com/news/jnj_news/20040329_094940.htm
- 7 Doctors Without Borders/MSF Briefing Note: Children and AIDS: Neglected Patients. 2 November 2004.
- 8 UNICEF/WHO Technical Consultation summary "Improving Access to Appropriate Pediatric ARV Formulations," November 3, 2004, Geneva.
- 9 See GlaxoSmithKline's 2004 corporate citizenship report at http://www.gsk.com/corporate_responsibility/cr_report_2004/am_dc_voluntary_licensing.htm.
- 10 "Merck & Co., Inc. Grants License for HIV/AIDS Drug Efavirenz to South African Company, Thembalami Pharmaceuticals, in Effort to Accelerate Access to Life-Saving Treatment." 13 July 2004. <http://www.csrwire.com/article.cgi/2882.html>
- 11 See the Lilly MDR-TB Partnership website at <http://www.lillymdr-tb.com>.
- 12 "Pharmacia Tries New Approach on AIDS Drug." AP, 24 January 2003. ICCR responded to the ending of that initiative here: http://www.iccr.org/news/press_releases/pr_pfizeraidspoor.htm.
- 13 See the Roche global patent policy at: http://www.roche.com/home/sustainability/sus_med/sus_med_pat.htm. See also, re: Bristol-Myers, "Maker Yielding Patent in Africa for AIDS Drug," New York Times, 15 March 2001.
- 14 These recommendations are expanded upon in the PSG report "The Public Health Crisis in Emerging Markets" available at www.pharmashareownersgroup.org.
- 15 More information on the African Comprehensive HIV/AIDS Partnership is at www.achap.org.
- 16 See "Johnson & Johnson and Schering-Plough to Publicly Disclose All Political Contributions," 7 April 2005. http://www.iccr.org/news/press_releases/pr_jnj0040705.htm



Interfaith Center on Corporate Responsibility

475 Riverside Drive, Room 1842

New York, NY 10115

Phone: 212-870-2295

Fax: 212-870-2023

E-mail: info@iccr.org

Visit us on the web at www.iccr.org