

MYTHS AND REALITIES

In the Global Struggle for AIDS Treatment Access

The global movement for affordable medication for millions living with AIDS in poor countries has brought often repeated arguments from research-based pharmaceutical companies and others.

Below are several industry myths side-by-side with the facts.

DRUG COMPANY RESEARCH & DEVELOPMENT

- Drug companies claim that the global movement for access to affordable AIDS treatment is "drying up" R&D in HIV antivirals and scaring off investors. (eg Evans, Robert. "Leaders Say Eased Patent Accord Could Hurt AIDS Research" Boston Globe 20 September 01.) These claims are false. There has been a slowdown in R&D in HIV therapeutics because there has been a slowdown in scientific discoveries.
- Currently 19 antivirals are on the U.S. market, including drug re-formulations and combinations. It has been acknowledged that the market is too crowded for more versions of the same medications. Charles Flexner, a Johns Hopkins University researcher and physician, wrote in July 2001 that the market for antiviral therapy as we know it is most likely saturated. Only four years ago this was not the case, as there were few antivirals approved for use and a clear profit motive for bringing more antivirals to market.
- High drug costs, we are told, recoup money spent on R&D. Instead of devoting profits to R&D for truly innovative HIV drugs, drug companies are funneling disproportionate amounts of their profits into marketing. Industry is more interested in advertising old HIV drugs than in bringing truly innovative drugs to market. This is only one example of many basic flaws in the current market-driven R&D system that supports more innovation in the treatment of male pattern baldness than in drug-resistant HIV, malaria, or tuberculosis.
- When researchers eventually make bona fide breakthroughs in HIV therapeutics, drug companies will fight for the rights to those innovations. Industry will not "hold back" because AIDS activists are campaigning for affordable treatment for poor people who live in countries with non-existent drug markets.
- Pharma's unwillingness to fund aggressive R&D into a new therapeutic HIV target is a more reasonable cause of the slowdown in me-too drugs getting to market than AIDS drugs.

AIDS DRUG PATENTS AND POOR COUNTRIES

- Drug companies insist that patents on AIDS drugs are not a problem for countries in sub-Saharan Africa and other poor regions. Campaigns focusing on making drug patent rules more flexible are irrelevant and threaten innovation, the logic goes.
- No one claims that existing patent monopolies on medications, or those that are about to come into force are the only problems poor people face. But it is deadly to ignore important causes of medication inaccessibility that are within our means to change.
- High drug cost plays a major role in restricting AIDS drug access in poor countries. Patent monopolies on life extending medications like antivirals create artificially high prices in poor and rich countries.
- In Africa, there is clear inter-country variation in the amount of patent protection on HIV drugs. Recent data show that the countries better poised to make antivirals accessible are the very countries with the most patent protection (eg South Africa, Kenya, Zimbabwe). A majority of African countries (31) have patents on at least one AIDS drug. The same company that has sought the most extensive patent protection in Africa—GlaxoSmithKline—also dominates the global antiviral drug market.
- Protease inhibitors—a newer class of AIDS drugs—are not widely patent protected in Africa (with exception including countries listed above), but medicines in the two older drug classes are. Thus African countries have limited ability to construct three drug combinations that are effective, easy to take, and have few side effects—without running into drug company patent monopolies. ddI, for example, is only patent protected in one African country (South Africa), but has cumbersome food restrictions. 3TC is patent protected in 27 African countries, and has no food restrictions.
- The beneficiaries of stiff patent protection that TRIPS assures will be pharmaceutical patent holders in wealthy countries, particularly the United States, who have been the main innovators in the field of medicines. A one-size-fits-all system of 20-year patent protection on medicines will not magically help poor countries become innovators in pharmaceuticals. Instead, monopoly pricing will obstruct drug access, bringing intensified levels of misery and death to poor countries that already spend disproportionate amounts of money purchasing medications.



WHY PATENTS MATTER: THAILAND

In Thailand Pfizer's monopoly on fluconazole made that life-extending drug unaffordable: \$7 per 200mg pill. When Pfizer's exclusivity ran out, competition from generic manufacturers brought the price down to as low as 29 cents per 200mg pill. 25% of Thai people with AIDS will need fluconazole to treat and prevent an otherwise fatal AIDS-related brain infection called Cryptococcal meningitis.

FACING A PATENT EPIDEMIC: 2006

By January 1, 2005 or 2006, poor countries in the WTO will have to comply with 20-year patent protection on pharmaceuticals, a system most common in wealthy, economically developed countries. This is part of WTO Member countries' compliance with the WTO agreement on intellectual property protection (called TRIPS). TRIPS compliance will damage efforts to increase access to affordable drugs for life threatening diseases. Drug company patent holders will be free to set monopoly prices as high as they care to. Developing and Least Developed WTO Members are currently fighting the US and other wealthy countries to gain more flexibility in these rules on patent protection and drugs.

CPTech Review of Patents on Antiretroviral (ARVs) Drugs in Africa

31 countries in Africa have at least 1 ARVs under patent.

27 countries have at least 4 ARVs drugs under patent.

Glaxo's Combivir & 3TC patented in 27 countries.

nevirapine is under patent in 26 countries.

nelfinavir is under patent in 24 countries.

Glaxo's AZT is under patent in 10 countries.

Glaxo's abacavir is under patent in 12 countries.

Glaxo's amprenavir is under patent in 12 countries.

ddC, ddI, d4T, delviridine ritonavir, Kaletra are off patent outside of South Africa

efavirenz, indinavir and saquinavir: lightly patented outside of South Africa.

ritonavir: the only anti-HIV drug not patented in South Africa.

**PhRMA's survey, August 1, 2001*

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INFRASTRUCTURE

- No one disputes that healthcare infrastructure is lacking in many parts of the developing world. Infrastructure problems should not be minimized, and a broad commitment from world governments to seek solutions is desperately needed.
- As it stands today, vast numbers of people with AIDS are dying in (or within reach of) hospitals and clinics that can dispense prescriptions but lack the medications necessary to save their lives. Infrastructure issues are thus no reason to delay the delivery of treatment, any more than the lack of infrastructure in areas of the US and Western Europe should cause drugs to be withheld in Washington or Paris. Médecins Sans Frontières, Oxfam, and Harvard's Partners in Health--organizations with unquestionable expertise in the field--have repeatedly stated that affordable antiretroviral treatments could save lives immediately.

PILL BURDEN & FOOD REQUIREMENTS

- "Experts" have been quoted in the press saying that antiretroviral treatment involves "30 to 40 pills a day" when, in fact, none of the first-line treatment combinations recommended in the official US treatment guidelines involve taking this many pills (the minimum is 5; none are more than 15 pills a day). An efficacious combination can typically involve three pills, taken all together twice daily. Recently, both GlaxoSmithKline and Cipla have taken steps to reduce this burden to just one pill twice daily.
- References to onerous dosing schedules and food and liquid requirements almost exclusively apply to just one protease inhibitor drug, Crixivan. This drug is approved to be taken every 8 hours, on an empty stomach with several glasses of water. In fact, Crixivan is now commonly combined with a low dose of another drug, Norvir, in order to allow twice-daily dosing and circumvent food requirements. Two other antiretroviral drugs, Videx and the rarely used Hivid, must be taken on an empty stomach. No antiretroviral drug has to be taken with milk.

ADHERENCE & RESISTANCE

- The evidence contradicts the assumption that treatment adherence is unachievable in a developing world setting. Examples come from antiretroviral treatment programs in Côte d'Ivoire, Brazil and Haiti. A recent plan proposed by Harvard supports studying adherence strategies while delivering antiretroviral treatment in developing countries. This would improve upon the situation in the West, where adherence support programs remain mostly improvised even five years after combination antiretrovirals became available.
- There is no evidence that a "drug resistant supervirus" could develop. Although comparisons with TB are frequently made, TB's genome is made of DNA, making drug-resistance mutations slow to occur but potentially long lived. HIV's genome consists of RNA, meaning mutations can happen rapidly but are much less stable over time. Available evidence (including a recent New England Journal of Medicine study by Steve Deeks et al) demonstrates that multi-drug resistant HIV reproduces less well than non-resistant or "wild-type" virus. The drug AZT has been available in the US since 1987, but epidemiological evidence shows that less than 10% of new infections involve AZT-resistant HIV. This is despite the fact that for at least eight years AZT was prescribed as a single therapy, and resistance almost inevitably developed. There would thus seem little justification for arguing that the luxury of developing drug resistance should be reserved for people in developed nations.
- Discussion regarding drug resistance rarely acknowledges the ever-expanding genetic diversity of the HIV as it spreads around the world, particularly the world where no treatment exists. A recent study in the Democratic Republic of the Congo was unable to assign 10% of HIV samples to any known clade or subtype of the virus, meaning they contained multiple uncharacterized mutations. Alterations in the behavior of a virus, including altered virulence, are a known risk under these circumstances. Treating HIV and preventing new infections are the best ways of reducing this risk. Treatment options will greatly expand the credibility and capacity of such programs within their communities.

PREVENTION

- Treatment and prevention go hand in hand. The availability of treatment motivates individuals to be tested, whereas stigmatization and certain death discourage people from being informed about HIV status.
- Even in the US, CDC researchers documented a significant increase in the number of people getting tested for HIV over the period 1994 to 1997, the time effective treatments became available and widely publicized during the International AIDS Conference in Vancouver in 1996.
- Treatment will augment, not replace, the prevention efforts already in place. In many areas, programs currently exist that provide prevention education and palliative care for those with AIDS and
- Treatment prevents the creation of more orphans. As the world population of children orphaned by AIDS moves into the tens of millions, it is imperative that treatment become rapidly available to infected parents and adult caretakers to stem this massively growing tragedy.

Every day 8000 people die from AIDS around the world. Gross inequity in access to life-extending medications makes HIV a death sentence in poor countries, while in wealthy countries it is a treatable condition.

Every day 37,000 people die from preventable diseases such as HIV/AIDS, malaria, and tuberculosis.* Most of these deaths are in the developing world where many life-saving drugs are unaffordable because they are patented under rules set by the World Trade Organization (WTO).

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PEOPLE LIVING WITH HIV & DRUG MONOPOLIES

- 40% PLWHIV in Sub-Saharan Africa live in countries where 7 or more ARVs are protected by patent
- 48% live in countries with 6 or more ARVs are under patent
- 55% live in countries with 4 or more ARVs are under patent
- 74% live in countries that have already issued at least two patents on ARV drugs, indicating the existence of a patent regime.

For more information:
Health GAP
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Email: info@healthgap.org
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