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Myths and Realities on Prices of AIDS Drugs

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Introduction:

The introduction of antiretroviral drugs (ARVs) as part of HIV/AIDS clinical care has relegated AIDS from a debilitating terminal illness to a manageable chronic condition. As there is still no cure for HIV/AIDS, ARVs are the best treatment option currently available. ARV therapy is only effective if there is a healthcare infrastructure - doctors, nurses, clinics, supplies, and storage and distribution systems. This infrastructure is often lacking in developing countries, where the majority of AIDS victims live.

Media and health activists have focused on the price of drugs as opposed to the larger healthcare infrastructure obstacles to treating AIDS patients. Yet, the price of both patented and copy ARV drugs is a relatively small part of total treatment costs, estimated at approximately 20 percent.[1] This paper addresses just the pricing issue. It does not discuss the safety and efficacy of the drugs currently promoted by WHO, NGOs and U.S. media. There is no evidence that these drugs, which are incorrectly called "generics," have undergone human bioequivalence testing verified by rigorous drug regulatory agencies. They are thus properly termed "investigative new drugs" or "copy" drugs.

Though the debate on ARV pricing is hardly new, it has recently come to the forefront with increased urgency. With the Bush administration's pledge of $15 billion over the next five years to combat AIDS in 14 African countries and the Caribbean, Indian drug companies, the WHO and many NGOs have stepped up their claim that the U.S. Government should purchase these copy ARV drugs because they are less expensive than patented ARV drugs.

National media has supported these views as well. A recent *Washington Post* article asserted that "brand-name drugs in most cases are about three times the price of generics," [2] while the *Associated Press* reported that "pills, produced by generics manufacturers, are considerably cheaper than the patented equivalents." [3] *The New Republic* stated in a recent editorial that generic drugs made by the Indian drug company Cipla could "be one-third the price of brand-name drugs manufactured in the United States." [4]

The prevailing belief is that these copy drugs are much cheaper than patented brand-name drugs. The majority of recent editorials have admonished the Bush administration for not purchasing them. *The Boston Globe* advised the United States Government to "relent in its opposition to the generics," since they "cost far less than brand-name drugs."[5] The *Washington Post* chastised the administration as well for its reluctance to use "unpatented 'generic' medicines made by foreigners."[6]

By focusing on just the price of drugs, the media and health activists perpetuate the misunderstanding that this is the largest barrier to effectively treating AIDS patients. Insisting that innovator or patented "brand-name"

drugs are significantly more expensive is, however, fundamentally misleading.

The purpose of this paper is to separate myths from realities in the global debate over ARV pricing. The majority of patented ARV drugs, either administered separately as single drugs in a "cocktail" or combined into one tablet as a fixed dose combination (FDC), are less expensive than copy drugs. Indeed, there is only one patented drug which is significantly more expensive.

Myths and Realities:

Myth 1: Single-dose ARV patented drugs are more expensive than their copy drug counterparts.

Reality: According to the latest pricing guide by Medecins Sans Frontieres (MSF), for the poorest eligible countries, the average price (per person per year) of the thirteen ARV drugs compared[7] was $404 for patented drugs and $449 for copy drugs. The average patented price includes the cost of transportation, while the average copy drug price excludes it. When calculated with a 10 percent increase for transportation, the average price for a copy drug comes to $494. This average cost of transportation can be higher, however, depending on the distance of the purchasing country from the manufacturing country, whether drugs are shipped via air or sea freight, if the shipment is needed on an emergency basis, and the size of the order.

Table 1

Single Dose ARV Drugs	Total Average Price (US $pp/py)	Average Price Plus Transportation
Patented	$404	$404
Copy	$449	$494

Modified from: *Untangling the Web of Price Reductions: A Price Guide for the Purchase of ARVs for Developing Countries,* April 2004.[8]

The average prices in the above the MSF guide were comparable to another pricing guide published by WHO, UNICEF, UNAIDS, and MSF.[9] In this guide the average patented drug price was $413 including transportation, while the copy drug was $538 excluding transportation. Including transportation, the average price of the copy drug increased to $597.

Table 2

Single Dose ARV Drugs	Patented Drug Price (US $pp/py)	Average Copy Drug Price (US $pp/py)	Average Copy Drug Price + 10% for Transportation	Copy Drug Price Range (US $pp/py)
Nelfinavir	$942	$1,519	$1,671	$1132-$1789
Ritonavir	$83	$311	$342	$204-$394
Saquinavir	$956	$1,022	$1,124	$1022
Abacavir	$887	$979	$1,077	$803-$1314
Lamivudine	$69	$96	$106	$55-$171
Zidovudine	$212	$201	$221	$140-$292
Indinavir	$400	$402	$442	$321-$467
Efavirenz 600 mg	$347	$412	$453	$347-$462
Efavirenz 200 mg	$500	$414	$455	$329-$462
Didanosine	$310	$263	$289	$146-$415
Stavudine 40 mg	$55	$47	$52	$26-$77
Stavudine 30mg	$48	$40	$44	$21-$60
Nevirapine	$438	$129	$142	$112-$256

Source: *Untangling the Web of Price Reductions: A Price Guide for the Purchase of ARVs for Developing Countries,* April, 2004.[11]

Table 2 shows the actual prices of each of the thirteen drugs from the MSF guide. The first eight patented drugs are cheaper than the average copy drug price, including transportation. Of the remaining five drugs, only one patented drug, nevirapine, is significantly higher-priced than the patented. The German manufacturer, however, offers this drug free of charge to developing countries for use in their mother-to-child transmission prevention programs.[10]

In addition to transportation, the price of copy drugs does not include replacement of damaged goods during transport or in-country medical monitoring for adverse drug reactions. Such items are included in the above price for virtually all patented drugs.

Table 2 does not show the considerable add-on costs to the prices of all drugs. There are import taxes, tariffs, customs and value added taxes (VAT) that vary from country to country, and are applied to both patented and copy drugs. For instance, in Malawi there is a 15 percent duty plus 20 percent surtax on AIDS drugs. In the Congo, there is a 30 percent duty plus a 13 percent turnover tax.

On top of these costs there are in-country mark ups by local distributors. In Dubai, for instance, when drugs clear customs at the airport, the distributor tacks a 70 percent mark-up before releasing them to wholesale and retail outlets. Then, additional mark-ups and taxes are included. In South Africa, pharmacists apply a VAT of 15 percent before releasing a prescription to a customer.

All of these duties, tariffs, custom charges, distributor mark-ups, and VATs increase drug prices well beyond their advertised prices. When considering the dire health emergency HIV/AIDS poses in the developing world, it is highly questionable why developing countries' governments are imposing taxes on these life-saving medicines.

Myth 2: Fixed dose combination drugs (FDCs) made by Indian and Thai companies are cheaper than their patented counterparts.

Reality: According to the same pricing guide by MSF, the average price of the three FDCs compared is $659 for patented drugs and $1,178 for copy drugs. Adding transportation, the average price for copy drugs comes to $1,296, compared to $659 for transported patented drugs.

Table 3

Fixed Dose Combination Drugs	Total Average Price (US $pp/py)	Average Price Plus Transportation
Patented	$659	$659
Copy	$1,178	$1,296

Modified from: *Untangling the Web of Price Reductions: A Price Guide for the Purchase of ARVs for Developing Countries,* April, 2004.[12]

The above average prices can be compared to the other guide done by WHO, UNICEF, UNAIDS, and MSF.[13] This showed an average patented FDC price of $690 including transportation, compared to the copy FDC price of $1,923 excluding transportation. Adding transportation, the price of the average copy FDC increases to $2,135.

Table 4 below shows the actual prices of FDCs from the MSF guide. There are only three FDC ARVs made by both innovator and non-innovator companies. All three patented FDCs are cheaper than the average price of the copy FDCs made by Indian and Thai companies.

Table 4

Fixed Dose Combination (Double and Triple Doses)	Patented Drug Price (US $pp/py)	Average Copy Drug Price (US $pp/py)	Average Copy Drug Price + 10% for Transportation	Copy Drug Price Range (US $pp/py)
LPV/r Lopinavir + Ritonavir	$500	$1,971	$2,168	$1,971
ABC + 3TC + ZDV Abacavir + Lamivudine + Zidovudine	$1,241	$1,304	$1,434	$1,029-$1,579
ZDV + 3TC Zidovudine + Lamivudine (**Combivir**)	$237	$258	$284	$197-$426
3TC + d4T + NVP Lamivudine + Stavudine + Nevirapine 30 mg (**Triomune** and **Triviro**)	No Existing Patented Drug	$253	$278	$153-$341
3TC + d4T + NVP Lamivudine + Stavudine + Nevirapine 40 mg (**Triomune** and **Triviro**)	No Existing Patented Drug	$270	$297	$168-$375
3TC + d4T Lamivudine + Stavudine 30 mg	No Existing Patented Drug	$113	$124	$73-$131
3TC + d4T Lamivudine + Stavudine 40 mg	No Existing Patented Drug	$124	$136	$80-$146
ZDV + 3TC + NVP Zidovudine + Lamivudine + Nevirapine	No Existing Patented Drug	$353	$388	$277-$416

Source: *Untangling the Web of Price Reductions: A Price Guide for the Purchase of ARVs for Developing Countries,* April 2004. [14]

Table 4 shows that prices of some FDCs cannot even be compared with brand name drugs since there is no existing patented drug. This is the case with Triomune and Triviro, (fourth row), the triple dose FDC developed by the Indian drug companies Cipla and Ranbaxy respectively. These drugs are the ones most frequently cited as the cheapest and best way to treat HIV/AIDS patients. However, they have not been approved by any developed country's drug regulatory agency for safety and efficacy. Nor has evidence been provided by these companies or WHO to show that human bioequivalence tests were done and independently verified.

Myth 3: The triple-dose FDCs such as Triomune and Triviro, are available for $140 according to an agreement made between Indian companies and the Clinton Foundation.[15] (See these drugs in Table 4, fourth row)

Reality: Cipla and Ranbaxy, the companies that produce Triomune and Triviro, have not yet consented to such an agreement. In an April 2004 *New York Times* piece, Ranbaxy did not confirm its participation.[16] According to the same article, Cipla's chairman, Dr. Yusuf K. Hamied, said that the pricing agreement had not been put into writing. The pricing guide by MSF backs up the statements of these two Indian drug companies. Cipla's price for the drug is $234, while Ranbaxy's is $285. Adding transportation, the prices are $257 and $314 respectively. The most affordable price for the drug from the Indian drug company, Hetero, is $168 including transportation. However, the WHO has not placed this drug on its prequalification list and there is no evidence that it is being sold at this price anywhere.

In reality, for those FDCs prequalified by WHO, the price can be greater than $234 and $257 (with transportation). Table 5 compares actual prices paid for this FDC by seven different countries in another study by MSF.[17] In six of the countries, either Triomune or Triviro was procured. In Thailand, a similar FDC made by GPO, a Thai company, was procured. The drug made by GPO, however, has not been prequalified by WHO, nor has WHO recommended it for use outside of Thailand. Of the seven countries listed, the cheapest price was $277 while the most expensive was $426. The range in prices can be attributed to a number of factors including different packaging, differential pricing through different suppliers, different volumes and different terms of payment.

Table 5

Country	Price listed
Cameroon	$277
Malawi	$288
Kenya	$292
Cambodia	$350
Thailand	$352
Mozambique	$389
Honduras	$426

Source: *Surmounting Challenges: Procurement of Antiretroviral Medicines in Low and Middle-Income Countries: The Experience of Medecins Sans Frontieres,* November 2003.[18]

When transportation is added, the prices of the drugs are significantly higher – between two and three times the price most commonly quoted by newspapers and activist groups for this drug.

Myth 4: It is acceptable to take risks with cheap drugs not approved by developed countries since more people can receive treatment at a lower price.

Reality: This approach fails to consider the cost benefits of AIDS treatment using copy drugs vs. patented products. In comparative studies on the effectiveness of AIDS drugs, patients on nevirapine (one of the ingredients of the WHO-recommended pill) experience treatment failure earlier than those on Efavirenz.[19] There are significantly more toxic and sometimes fatal side effects using nevirapine as well. When AIDS patients fail treatment, their only recourse is a more expensive second line treatment. In the MSF study, second line treatment averaged almost three thousand dollars.[20] Thus, taking risks with untested drugs will very likely prove to be more expensive in the long run.

Conclusion:

The pricing surveys published by MSF clearly show that copy ARVs made by foreign manufacturers are by no means cheaper than patented ARVs. The majority of patented drugs are less expensive.

Moreover, there is no basis for comparing the WHO-recommended FDC with a patented FDC drug since there is no patented drug with the same ingredients. Finally, the $140 price, advertised by health activists and repeated by the U.S media, has not been confirmed by the Indian companies. Studies show that these manufacturers actually sell this same drug for two to three times this price to poor countries.

More importantly, however, the singular focus on ARV drug prices, as seen in the U.S. national media and NGOs, shifts attention from the real obstacles in treating AIDS globally - high import taxes as well as the lack of doctors and nurses, clinics, supplies, storage, distribution systems, and honest governments in so many of the countries most afflicted by this disease.

In late March and early April of 2004, the Indian government's Ministry of Health conducted negotiations with local manufacturers of FDCs, seeking lower prices for AIDS-infected nationals. The ministry was unsuccessful in its efforts. Pharmaceutical company representatives, including those offering cheaper prices to WHO and the Clinton Foundation, explained to government negotiators that prices are scarcely

the main barrier to procuring effective HIV/AIDS treatment: "It is not the money that makes a difference - the infrastructure to make the drugs available needs to be in place, the medical fraternity needs to be trained on the issue and systems need to be in place to monitor the administration of the medicines to keep a check on patients developing drug resistance."[21]

It is these medical infrastructure problems that need the attention of the media and health activists. Only then can we continue to help the world's 40 million people infected with this deadly virus.

Endnotes:

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