

DO PHARMACEUTICAL FIRMS PRICE DISCRIMINATE  
ACROSS RICH AND POOR COUNTRIES?  
EVIDENCE FROM ANTIRETROVIRAL DRUG PRICES\*

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**Abstract**

This paper quantifies the impact of drug monopolies on prices in developing countries using the example of the antiretroviral (*ARV*) drugs used to treat the *HIV* virus. I use a new cross-country price dataset of *ARV* drugs to estimate the relationship between *ARV* prices and per-capita income across countries. I find that *ARV* prices had little or no relationship to developing countries' per-capita incomes in 2000, when there was no generics competition. This relationship strengthened considerably by 2003 following increased generics competition in many developing countries. I consider the implication of these findings for the implementation of the *TRIPS* agreement in developing countries. Finally, the paper motivates and develops a model in which the imperfect information and fairness concerns of wealthy consumers cause a monopolist to consider their reactions when setting prices for poor consumers in a separate segmented market. The paper's two main contributions are to (i) establish the dramatic change in the relationship between per-capita income and *ARV*'s prices between the year 2000, with little generics competition, and the year 2003, with widespread generics competition; (ii) introduce a model to explain the low correlation more generally between patented drug prices and per-capita income in the absence of generics competition.

**Key words:** drug monopolies, pharmaceutical firms' cross-country pricing, antiretrovirals, *TRIPS* agreement.

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# 1 Introduction

"The battle over the price of *AIDS* medications in Africa is focusing new attention on pharmaceutical companies' pricing practices for many drugs in the US"

*Los Angeles Times*, March 25, 2001

What are the welfare costs of enforcing intellectual property rights protection for pharmaceutical patents in the developing world? The 1993 World Trade Organization's *TRIPS* agreement (Agreement on Trade-Related Aspects of Intellectual Property Rights) required enforcement of intellectual property rights, including pharmaceutical patents, in developing countries by the year 2006. Supporters of the original agreement argued that the costs borne by those consumers in developing countries who pay higher drug prices in the short run would be smaller than the benefits they reap from access to better drugs over the long run.<sup>1</sup>

To evaluate the impact of the *TRIPS* agreement, there is a need for empirical work to quantify the welfare costs of pharmaceutical products' markups over marginal cost in developing countries. There have been only a handful of empirical welfare analyses, in published papers or working papers, of the *TRIPS* agreement in the pharmaceutical sector because of the difficulty in gaining access to good cost and price data.<sup>2</sup>

This study analyzes the costs of the *TRIPS* agreement using the example of the antiretroviral (*ARV*) drugs used to treat the *HIV* virus.<sup>3</sup> Antiretroviral drugs are a good case by which to gauge the impact of stricter enforcement of pharmaceutical patents in developing countries. The *HIV* virus is more prevalent in poor than in rich countries. Most antiretroviral drugs remain under patent protection for at least the next five years. Developing countries argue the patent-protected prices for antiretrovirals make them too expensive for their populations to afford. The unit costs to produce the drugs appear low enough for many individuals in developing countries to afford them, however. Production of generic variants of these drugs exists in some countries

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<sup>1</sup>Most developing countries did not enforce patent rights prior to the *TRIPS* agreement. In the US, a firm has a legal monopoly on a drug for twenty years after a patent is filed. This convention was universalized by the *TRIPS* agreement: Every *WTO* member is expected to grant patent protection for a minimum of 20 years to new drugs.

<sup>2</sup>See Chaudhuri, Shubham, Pinelopi K. Goldberg, and Panle Jia. "The Effects of Extending Intellectual Property Rights Protection to Developing Countries: A Case Study of the Indian Pharmaceutical Market." Working Paper, 2003.

<sup>3</sup>*HIV* stands for Human Immunodeficiency Virus.

(Brazil, India). Other countries have had no or very limited access to generic variants of the drugs (South Africa, Uganda). In time, as the *TRIPS* provisions are fully implemented, these variations in patent enforcement will change. But at present it provides a unique opportunity to examine pharmaceutical companies' prices in the presence and absence of patent protection, which will be proxied for by the absence or presence of generic variants of the drugs.

Originator pharmaceutical firms, that is, those who hold patents on *ARVs*, do not release data on their cross-country pricing policies or production costs. In addition, they campaign against efforts by such multilateral agencies as the World Health Organization (WHO) to collect data that would allow cross-country price comparisons.<sup>4</sup> The resulting lack of data has stymied efforts by academic researchers to assess the likely impact of the *TRIPS* agreement on pharmaceutical prices and, thus, welfare.

This paper seeks to remedy this gap by introducing a new cross-country price data set for *ARVs*. The price data come from a collaboration with the *Campaign for Access to Essential Medicines* run by the well-known NGO *Médicins Sans Frontières (MSF)*. The campaign gathers information on drug prices in developing countries for their own procurement needs and to produce policy reports. The paper examines the distribution of antiretrovirals' prices across countries from 2000 to 2003.

The rest of the paper proceeds as follows. The next section reviews the dramatic policy developments since 2001 regarding pharmaceutical patent enforcement in low-income countries. It provides some background to the empirical results in the sections that follow. Section 3 presents summary statistics for the *MSF* data. Section 4 examines how the cross-country distribution of *ARV* prices has changed since 2000. It also compares the cross-country variation of selected *ARVs*' prices and per-capita *GDP*. It finds that *ARV* prices in 2003 covary with per-capita *GDP* much more closely than do *ARV* prices in 2000. Section 5 considers features of the global pharmaceutical market that may have contributed to this flat price distribution in 2000. It discusses the potential impact of tariffs, health expenditure systems, and parallel imports on companies' cross-border pricing strategies. Section 6 presents a stylized model to try to explain why drug prices covary positively with per-capita *GDP* only when generics are widely available. The final section discusses

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<sup>4</sup>See Donald G. McNeil, Jr. "Patent Holders Fight Proposal on Generic AIDS Drugs for Poor." *The New York Times*, May 18, 2000.

policy recommendations that follow from the paper's findings and concludes.

## 2 Policy Developments

When the magnitude of the *AIDS* crisis in Africa, Asia, and Latin America became clear in the late 1990s, a controversy erupted over the prices charged for the antiretroviral drugs (*ARVs*) used to treat the disease.<sup>5</sup> *ARVs* were not widely available or affordable in developing countries. Most *ARV* prices declined from 2000 to 2003 following originator companies' discounts and increased generic competition.

In May of 2000, pharmaceutical companies that owned the patents on various *ARVs* (the originator companies) announced a number of voluntary price reduction programs for residents of poor countries through a new public-private partnership called the Accelerated Access Initiative (*AAI*). The *AAI* was a partnership between five pharmaceutical companies and several United Nations organizations to improve the provision of *AIDS*-related treatment in developing countries.<sup>6</sup> The originator companies also made price offers through bilateral negotiations with individual governments. In practice, unfortunately, it often proved difficult for practitioners in the field to acquire the *AIDS* drugs at the pre-announced prices. Originator companies made their price offers only to countries classified as "Least Developed Countries" (*LDCs*) by the World Bank or in sub-Saharan Africa. Only two of the originator companies, *Merck* and *Roche*, publicized price offers for medium-income countries.

From 2000 on, Indian and Brazilian generics companies' low prices began to put pressure on originator companies to reduce their prices in low- and medium-income countries. For example, competition from generics producers in India and Brazil forced the average branded price of an *AIDS* triple-combination therapy from \$10,439 per year to less than \$1,000 per year in 2000.<sup>7</sup>

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<sup>5</sup>*AIDS* stands for Acquired Immune Deficiency Syndrome.

<sup>6</sup>The pharmaceutical companies are *Boehringer Ingelheim*, *Bristol-Myers Squibb*, *Glaxo Wellcome*, *Merck & Co.*, *Inc.*, and *F. Hoffmann-La Roche*.

<sup>7</sup>Two legal cases between the U.S. and Brazil and South Africa also energized the opposition to the *TRIPS* agreement during this period. In February 1998 multinational pharmaceutical manufacturers filed a suit against the South African government for its "Medicines and Related Substances Control Amendment Act" passed in 1997. The manufacturers argued that the Act violated the *TRIPS* agreement. The Act legalized the importation of patented medicines from other countries, so-called "parallel importation." Both the US and the EU pressured the South African government to change the law. As the case went to court in May 2000 the NGO community began a campaign to protest the suit. In April 2001 the case was unconditionally dropped.

Price competition between *ARV* manufacturers entered a new phase in February 2001 when the Indian generics manufacturer *Cipla* declared it would sell a triple-combination *ARV* treatment for \$350 per patient per year.

In November 2001 at the Fourth *WTO* Ministerial Conference in Doha, Qatar, member states sought to reinterpret the original terms of the *TRIPS* agreement to support governments' rights to protect their citizens' health. The resulting *Doha Declaration* established the principle that member states could privilege public health above the protection of intellectual property rights. It also granted *LDCs* an additional ten years, until 2016 instead of 2006, to implement *TRIPS* fully as *WTO* members. The agreement broadened the grounds on which a country could issue a compulsory license for a drug. Countries could determine internally when a national emergency was at hand: No multilateral authority needed to make this determination as in the past. The agreement also reiterated the general principle that compulsory licenses could be issued without a national emergency.

Member states agreed at Doha that developing countries could issue compulsory licenses to override a patent in the interest of public health but only to produce a drug domestically. Medium-income countries with established pharmaceutical industries could export generics to low-income countries only through 2005. Pharmaceutical manufacturing was not feasible for most low-income countries with high rates of *AIDS*. Doha's failure to provide for the export of generics medicines from such medium-income countries as India, Brazil, or China to *LDCs* left unresolved the problem of drug availability in low-income countries. Drugs produced under a compulsory license in Brazil, for example, could not be exported to Ghana or the Sudan. Most sub-Saharan African countries' small domestic market and limited industrial capacity made domestic pharmaceutical production infeasible.

In August 2003 in Cancun, Mexico *WTO* members agreed that developing countries could import generic variants of drugs under patent to address such public health threats as malaria, *AIDS*, or tuberculosis. This agreement enabled low-income countries to import generics from medium-income countries rather than being forced to set up domestic production to have access

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A second case involved Brazil. The United States brought Brazil before the *WTO* dispute settlement body to protest a law that holders of Brazilian patents manufacture their product domestically. The US claimed this law infringed on US patent holders' rights. The NGO community pressured the U.S. to drop the case, and in June 2001 it did.

to cheaper drugs.

Finally, from 2002 to mid 2003, a number of Latin American countries bargained collectively with originator and generics firms to purchase *ARVs* under the auspices of the Pan American Health Association (*PAHO*). The agreements that resulted reduced *ARV* prices in most of Latin America by the middle of 2003.

### 3 Market and Data

In this section I describe the *MSF* data.

#### 3.1 Data

The price data come from a collaboration with the *Campaign for Access to Essential Medicines* run by the well-known NGO *Médicins Sans Frontières (MSF)*. This campaign gathers information on drug prices in developing countries for their own procurement needs and to produce policy reports. Over the past few years reports by NGO's such as *Health Action International (HAI)* and *MSF* have each collected a single cross-section of antiretroviral drug prices. My data include prices from these studies and additional unpublished price information collected by *MSF*.

The data include the import prices for each product sold over a period of four years, from 2000 to 2003.<sup>8</sup> I define a product as one unit (a single capsule or tablet) of a drug. I define a market as the amount of a drug sold in one country in one year. Table 1 shows the percentage of the price variance for selected drugs that is attributable to drug, year, and country dummies after controlling for the effects of the variables in the remaining columns: 20 percent of the variance in price is over time, 22 percent is across countries, and 15 percent is across drugs.

I supplement the *MSF* data with comparative cross-country information on pharmaceutical tariffs, per-capita gross domestic product (*GDP*) on a purchasing-power-parity basis, and the composition of health expenditure. The tariff data come primarily from Harvey Bale's 2001 study of trade in off-patent medicines. The *GDP* data come from the World Bank's *World Development Indicators* for 2003. The health expenditure data come from the *WHO's World Health Report*

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<sup>8</sup>Most of the prices are CIF, "Cost, Insurance, and Freight." The seller pays the costs and freight to transport the good to the destination port. The buyer is responsible for any additional costs after delivery to the port.

for 2001. The *WHO* data include information on the share of total health expenditure paid out of pocket (without public or private insurance), by the government, and by private insurance plans. They characterize cross-country variation in drug prices due to differences in the structure of health expenditure, and thus, demand.

The data include prices for two types of drugs: antiretrovirals and drugs to treat opportunistic infections associated with the *HIV* virus. Antiretrovirals inhibit the actions of enzymes the *HIV* virus needs to reproduce, thus extending the length and quality of life of infected people. *ARVs* are comprised of two major drug classes, reverse transcriptase inhibitors and protease inhibitors. The first group can be divided into two additional groups: Nucleoside Reverse Transcriptase Inhibitors (*NRTIs*) and Non-Nucleoside Reverse Transcriptase Inhibitors (*NNRTIs*). Therapies that combine drugs from the two classes suppress the *HIV* virus most effectively. Fixed-dose combinations are formulations of more than one of the antiretrovirals and are more common in low-income than in high-income countries.

## 4 The Evolution of *ARVs*' International Price Distribution

This section examines the evolution of *ARVs*' international price distributions from 2000 to 2003.

### 4.1 Nucleoside Reverse Transcriptase Inhibitors (*NRTIs*)

Figure 1 shows prices for the *NRTI* *Abacavir* from 2000 to 2003. *Glaxo Wellcome* (*GW*) holds the patent on the drug which expires in 2009 in the US. *GlaxoSmithKline* (*GSK*), *Abacavir*'s manufacturer, had three price tiers for the drug in 2000: the first tier with the highest prices in Uruguay and Venezuela, the second tier in Argentina and India, and the third tier in the US and Uganda. Prices fell in India and Uganda in 2002 following the entry of the generics manufacturer *Hetero* into the *Abacavir* market and the subsequent offer of the drug at low prices to sub-Saharan African countries by *GSK* through the *AAI*. Prices came down in Argentina, Uruguay, and Venezuela after a large group of Latin American countries negotiated together to purchase *ARVs* from generics manufacturers in mid 2003. The US price remained unchanged over the sample period.

Figure 4 shows *Abacavir*'s prices in five countries in 2000 and 2003 and compares them to

Drug	Year	Country	
Price (%)	15.2	20.3	22.1

Table 1: Sources of price variation for selected ARVs. Each column shows the percentage of price variance due to country, year, or drug dummy variables controlling for the effects of the variables in the remaining columns. 212 observations. Source: My calculations.

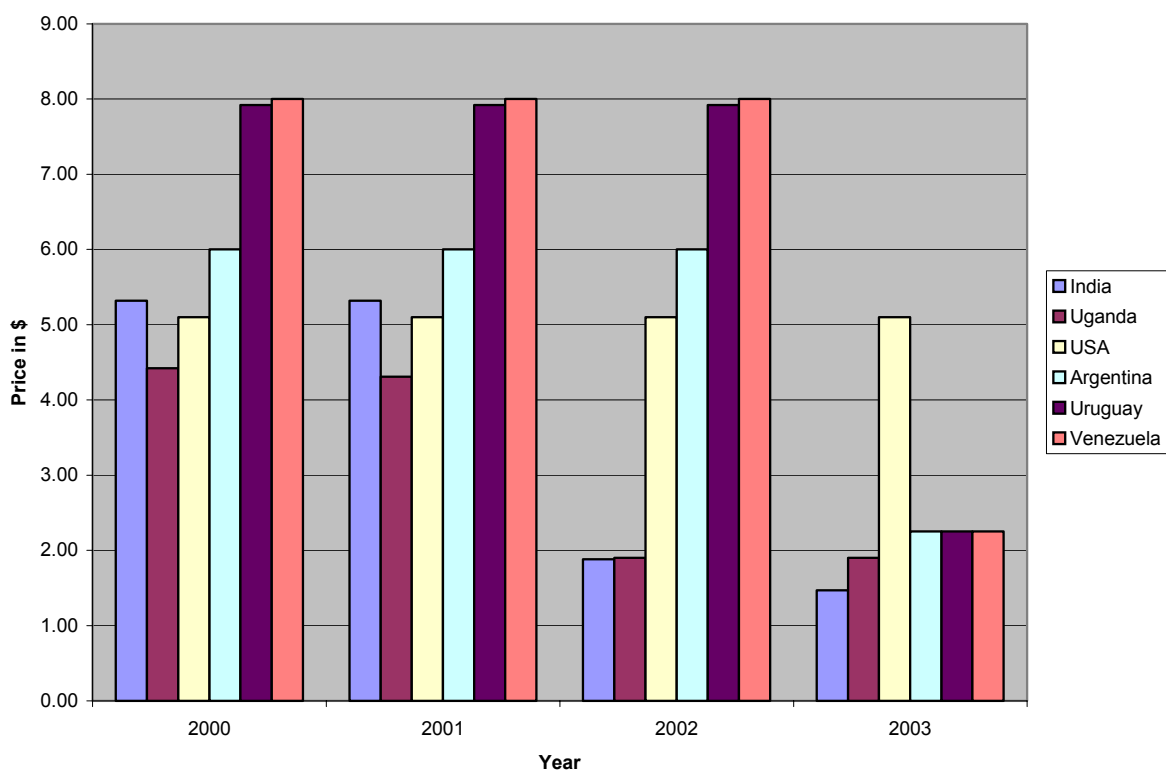


Figure 1: Abacavir 300 mg. tablets

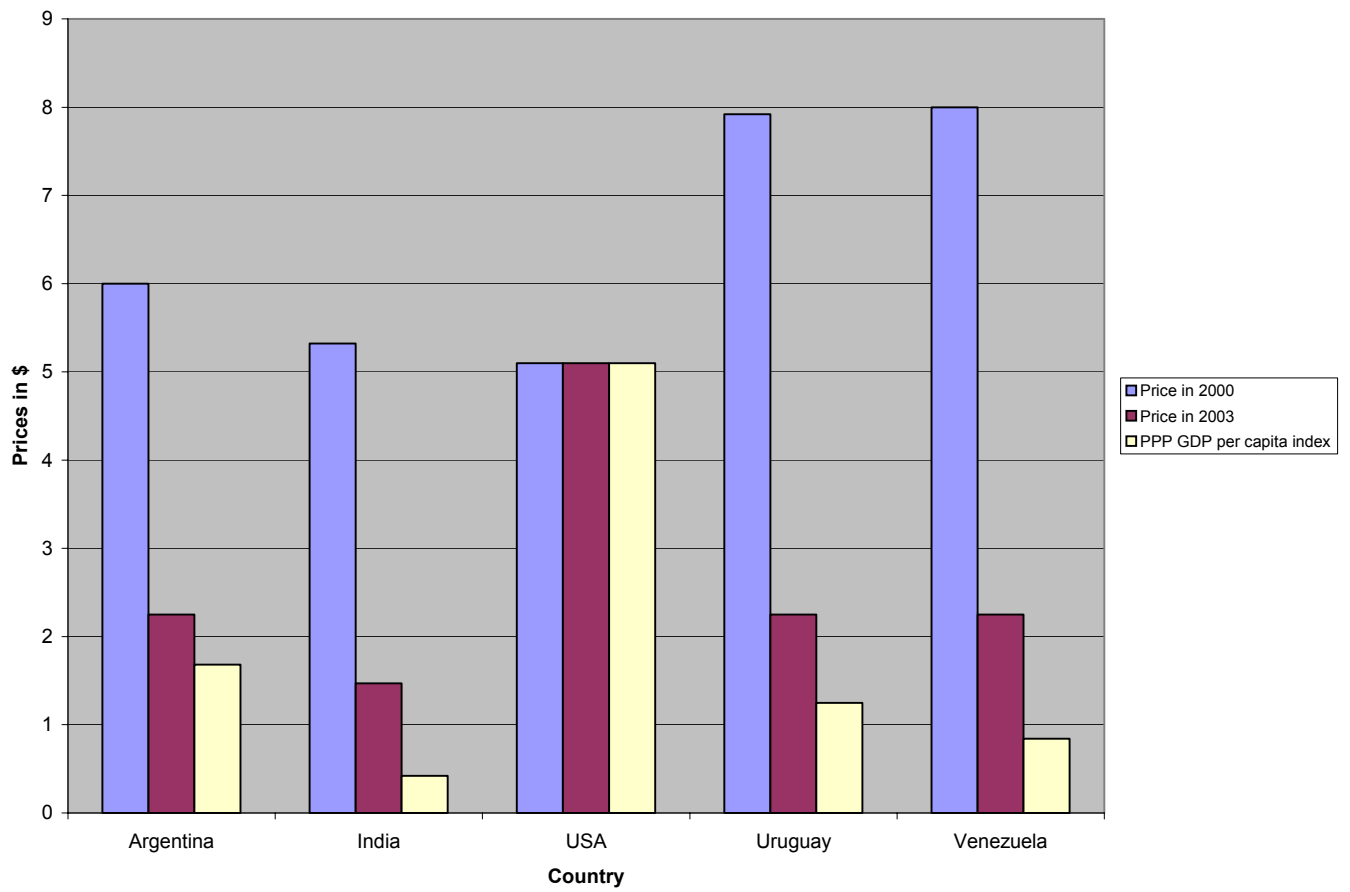


Figure 2: Abacavir's 2000 and 2003 prices and GDP per capita

each country's per-capita *GDP* which is indexed to the US price in 2000. The per-capita *GDP* measure is calculated on a purchasing-power-parity basis which controls for different price levels across countries. In 2000 the drug's prices appeared higher than the per-capita *GDP* index for every country in the sample except the US. By 2003 its prices had fallen and were much closer to the per-capita *GDP* index for the sample's low-income countries than previously.

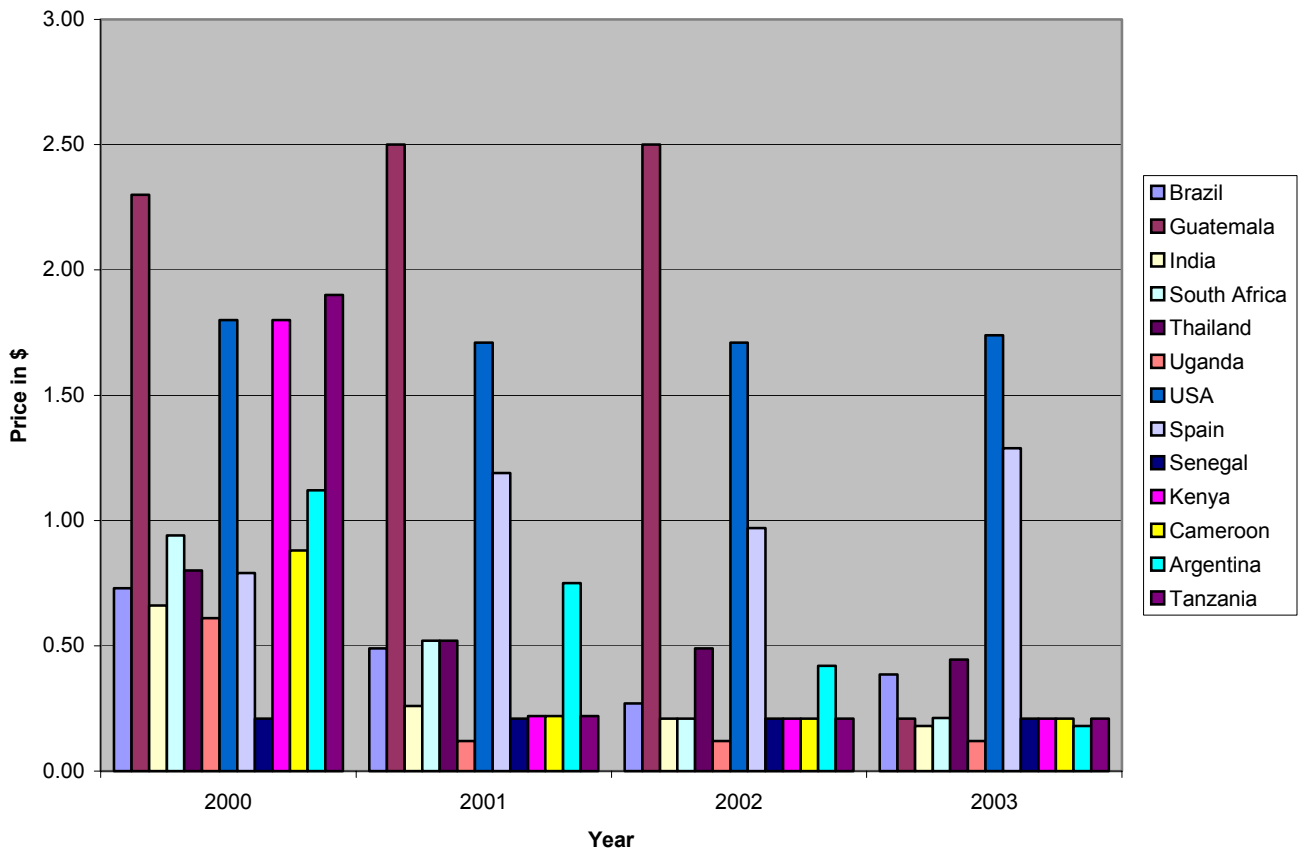


Figure 3: Didanosine 100 mg. packets

Figure 3 shows prices for another *NRTI*, *Didanosine*. *Didanosine*'s patent is held by the firm *Glaxo Wellcome* (*GW*) and the drug is manufactured by *Bristol-Myers-Squibb* (*BMS*). *GW*'s patent rights expire in the US market in late 2006. Figure 3 shows the international distribution

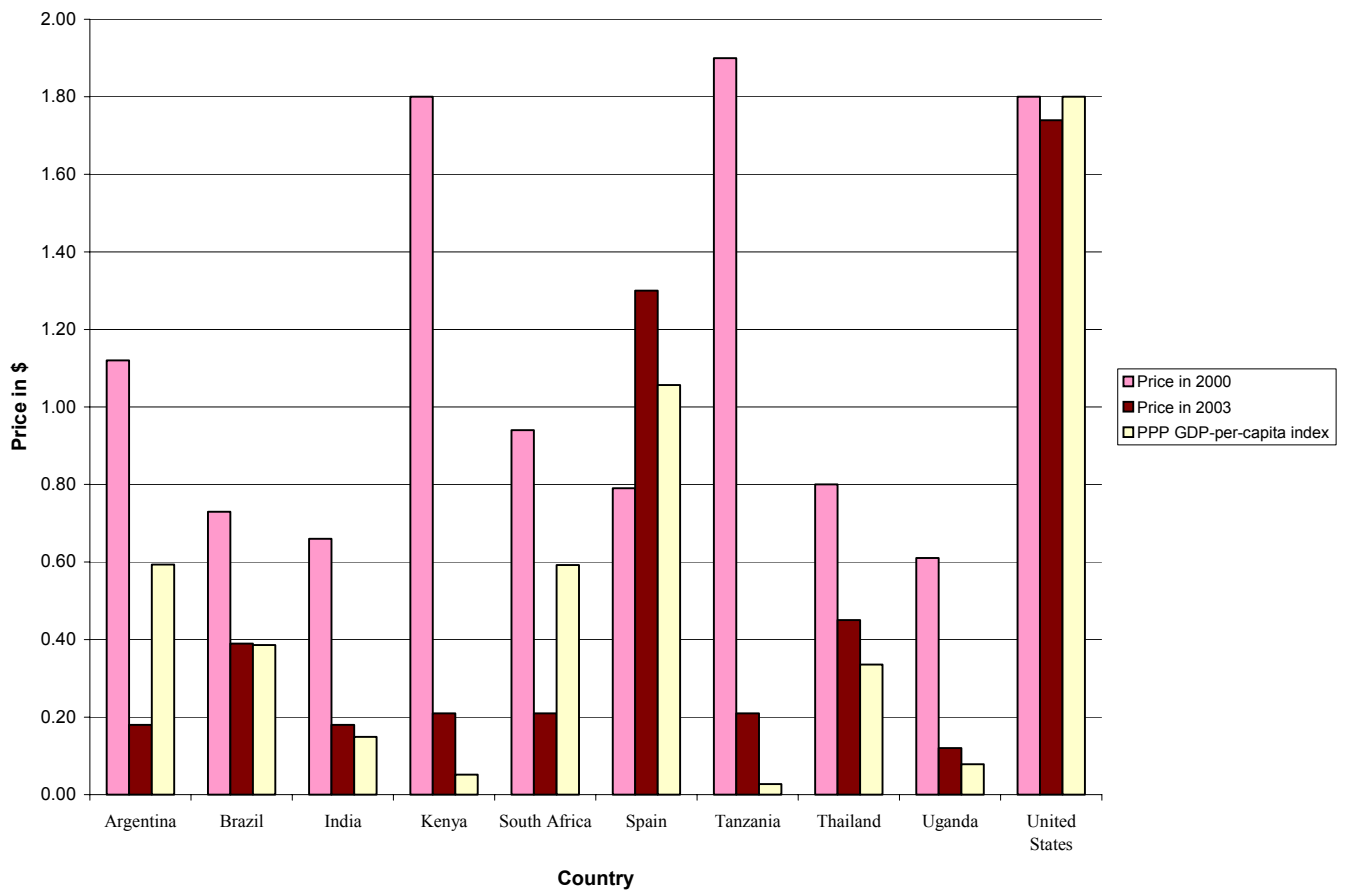


Figure 4: Didanosine's 2003 prices correspond to GDP per capita more closely than its 2000 prices

of prices for a single 100 mg packet from 2000 to 2003. *Didanosine* had three tiers of prices in 2000. Prices in Kenya and Tanzania were roughly equal to (or greater than) US prices. The next tier appeared to be medium-income countries such as South Africa and Argentina, and the third tier was middle- or low-income countries such as Thailand, Brazil, India, Uganda, and Spain. Figure 3 shows that *Didanosine*'s 2000 prices in such low-income countries as Kenya and Tanzania were roughly equal to its price in the US. Prices fell to quite low levels in most African countries in 2001. They fell in India as well after generics manufacturers entered the market. The Thai generics manufacturer, *GPO*, entered the market in 2002, and prices fell in Thailand in that year. Prices remained high through 2002 in those Latin American countries without access to generics such as Guatemala. Brazil's prices fell in a manner similar to the decline in India's prices as a result of production of the drug by a domestic generics firm, *Far Manguinhos*, which was supported by the Brazilian government. The *PAHO* negotiations led to dramatic price reductions in many Latin American countries in 2003. The decline was most dramatic for Guatemala, going from \$2.50 for a 100 mg capsule of *Abacavir* in 2000 to 20 cents for the same dose in 2003.

Figure 4 shows that *Didanosine*'s prices in such low-income countries as Kenya, Uganda, and Tanzania far exceeded their respective per-capita *GDP* indexes in 2000. *Didanosine* did not appear to be priced according to low-income countries' ability to pay for it. Such medium-income countries as Brazil and India also had *Didanosine* prices in 2000 that exceeded their respective per-capita *GDP* indexes, but not by as much as in the sub-Saharan countries. High-income countries such as Spain had prices roughly on par with their per-capita *GDP* indexes in 2000.

*Lamivudine*, another *NRTI*, exhibited a price pattern similar to that of the other *NRTI*'s from 2000 to 2003. *Lamivudine* is manufactured by *GlaxoSmithKline* (*GSK*) under the trade name *Epivir* and remains under patent in the US until 2009. Figure 5 shows the international distribution of prices for a single 100 mg capsule from 2000 to 2003. Prices in South Africa, Tanzania, and Uganda in 2000 were roughly equal to those in Spain. By 2001 the prices in Africa and in those Latin American countries with access to generics fell dramatically. The price of a 100 mg capsule fell from about \$1.50 in Tanzania and Uganda to about 30 cents for the same dose in 2001. In 2002 *GSK* began to offer the drug to sub-Saharan and *LDC* countries for 21 cents for a 100 mg capsule. Prices in countries with access to generics continued to decline in 2001 and 2002. Generics firms began manufacturing the drug in Brazil, Colombia, India, and Thailand in 2002.

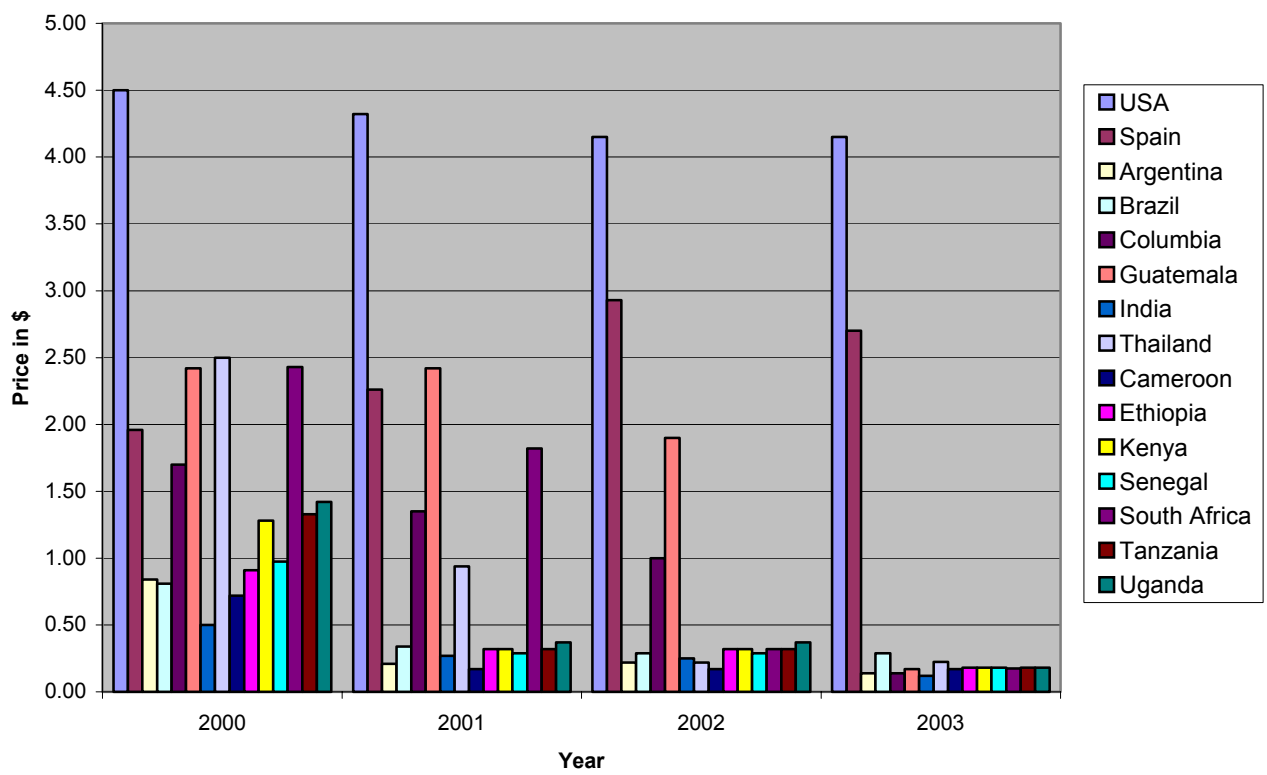


Figure 5: Lamivudine 100 mg. capsules

Prices fell in Caribbean countries in 2002 following their joint negotiation with drug companies to purchase *ARVs*. Other *PAHO* agreements led to price reductions in most of Central and South America by the middle of 2003. Meanwhile the US price fell by about 40 cents per dose over the sample period and the Spanish price rose by roughly the same amount.

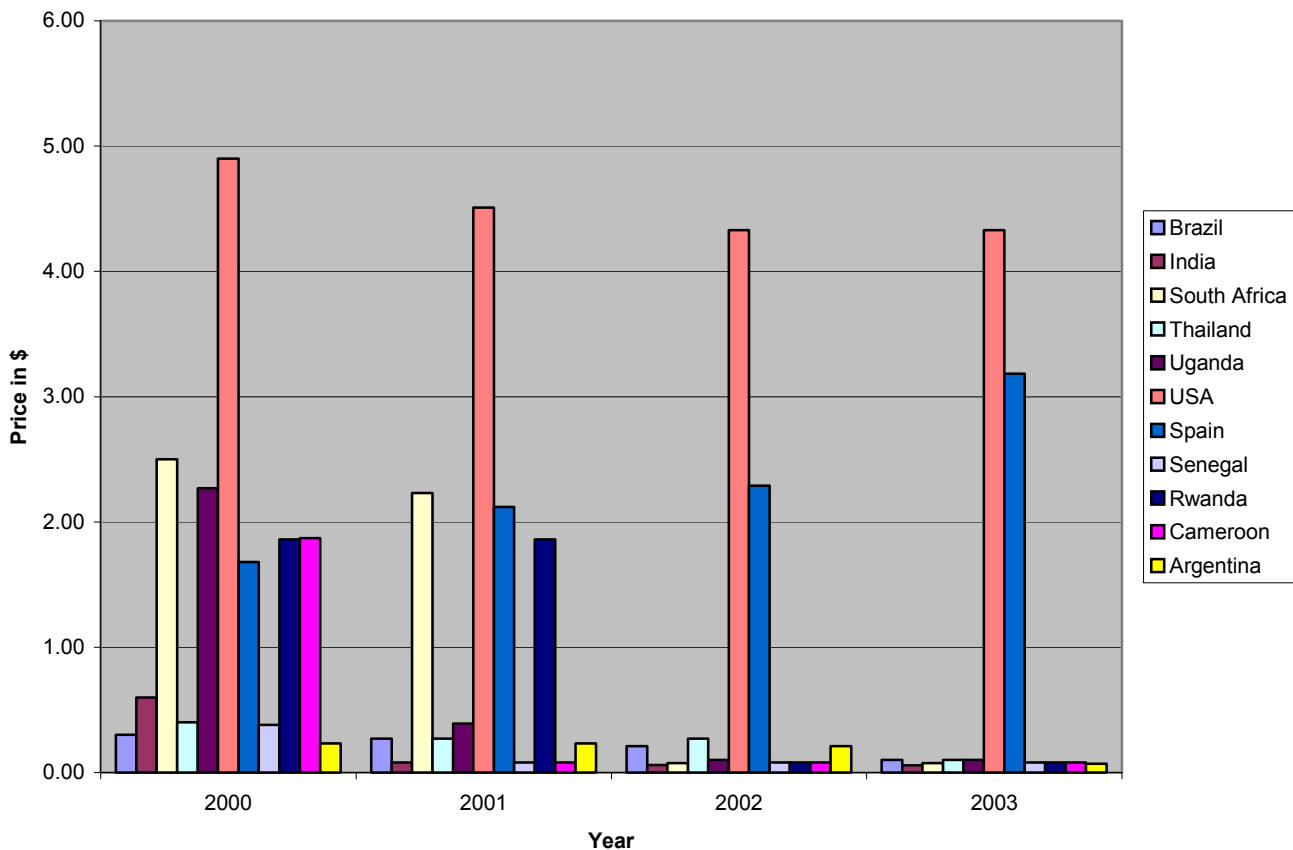


Figure 6: Stavudine 40 mg capsules

*Stavudine* is an *NRTI* manufactured by *Bristol-Myers Squibb (BMS)*. Yale University holds the US patent on the drug which expires in 2008. Figure 6 shows the international distribution of prices for a single 40 mg capsule from 2000 to 2003. *BMS* made the drug available to *LDCs* and Sub-Saharan countries at 7 cents a dose starting in 2001. Figure 6 shows that the price of a

40 mg capsule fell from about \$2.00 a dose in Cameroon in 2000 to about 7 cents a dose in 2001. A similar reduction occurred in Senegal in 2002. India's prices fell steadily from 2000 to 2003 which likely resulted from generic competition from its domestic pharmaceutical industry. Two Indian generics firms manufactured the drug in 2001. By 2002 five generics firms had entered the market, four Indian firms and one Thai firm. Meanwhile prices fell in the US from close to \$5.00 a capsule in 2000 to \$4.25 in 2003, and rose in Spain from less than \$2.00 a capsule in 2000 to about \$3.10 in 2003.

*Zidovudine* is another *NRTI* manufactured by *GlaxoSmithKline (GSK)*. *Glaxo Wellcome* holds the patent which expires in the US market in 2005. Figure 7 shows the international distribution of prices for a single 100 mg capsule from 2000 to 2003. In 2000, *Zidovudine* exhibited a typical *ARVs* cross-country price distribution. Figure 7 shows that the US price at \$1.60 for a 100 mg capsule exceeded all other countries' prices. Four African countries, Cameroon, Ethiopia, Kenya, and Tanzania had the next highest prices in 2000. Two Indian generics firms manufactured *Zidovudine* in 2001: By 2003 two additional generics firms, a Thai manufacturer and a Spanish manufacturer, had entered the market. By 2001 prices had fallen in Cameroon, Ethiopia, Kenya, and Tanzania to about 20 cents per capsule and continue to decline to reach 10 cents a capsule in 2003.

Figure 8 compares *Zidovudine's* prices in 2000 and 2003 to a per-capita *GDP* measure which is indexed to the US price in 2000. Prices appeared roughly equal to the per-capita *GDP* index for South Africa, Thailand, India, and Brazil. Low-income countries such as Cameroon, Ethiopia, Kenya, Tanzania, and Uganda faced prices far greater than their respective per-capita *GDP* indexes and roughly equal to Spain's price. From 2001 through 2003, prices fell dramatically for most low-income countries, a bit for the US, and rose significantly for Spain, thus narrowing the gap between its price and its per-capita *GDP* index.

## 4.2 Non-Nucleoside Reverse Transcriptase Inhibitors (*NNRTIs*)

*Efavirenz* is a Non-Nucleoside Reverse Transcriptase Inhibitor (*NNRTI*) produced by *Merck* that is under patent in the US until 2015. Figure 9 shows the international distribution of prices for a single 200 mg capsule from 2000 to 2003. Although Indian manufacturers produced a generic variant of the drug, its availability in other countries was very limited over the sample period.

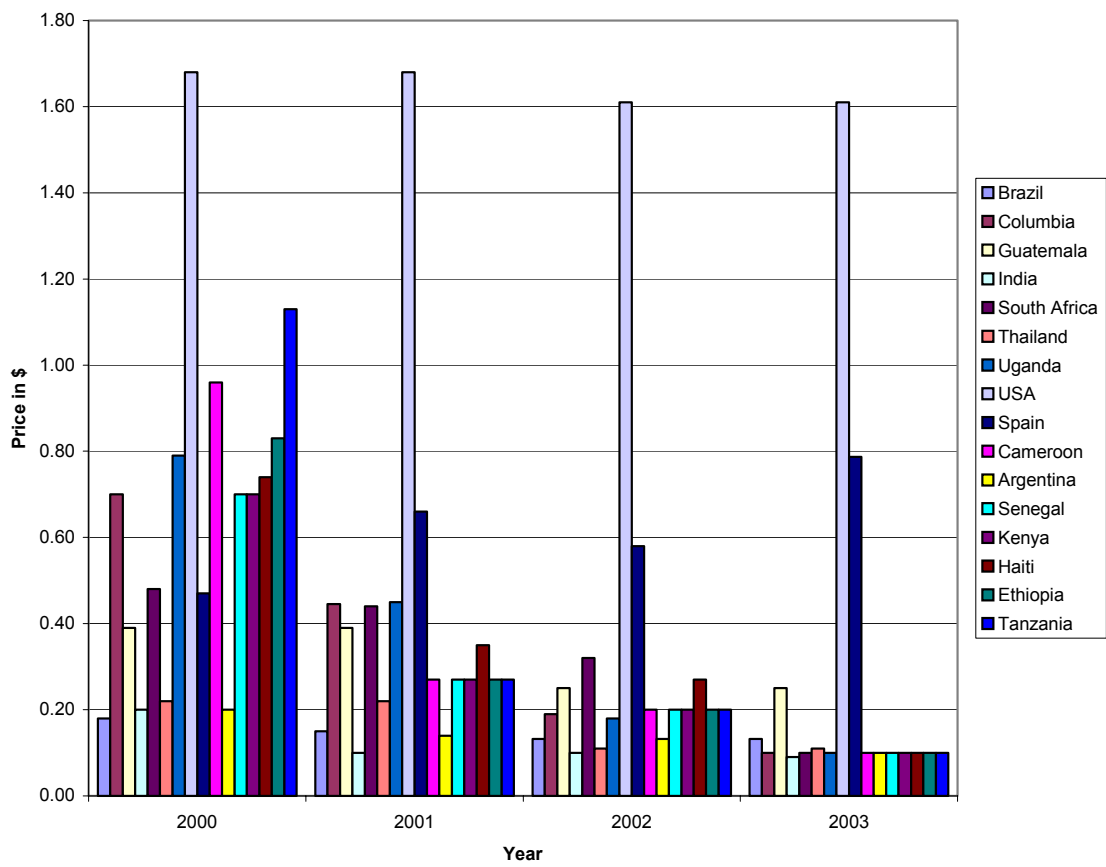


Figure 7: Zidovudine 100 mg. capsules

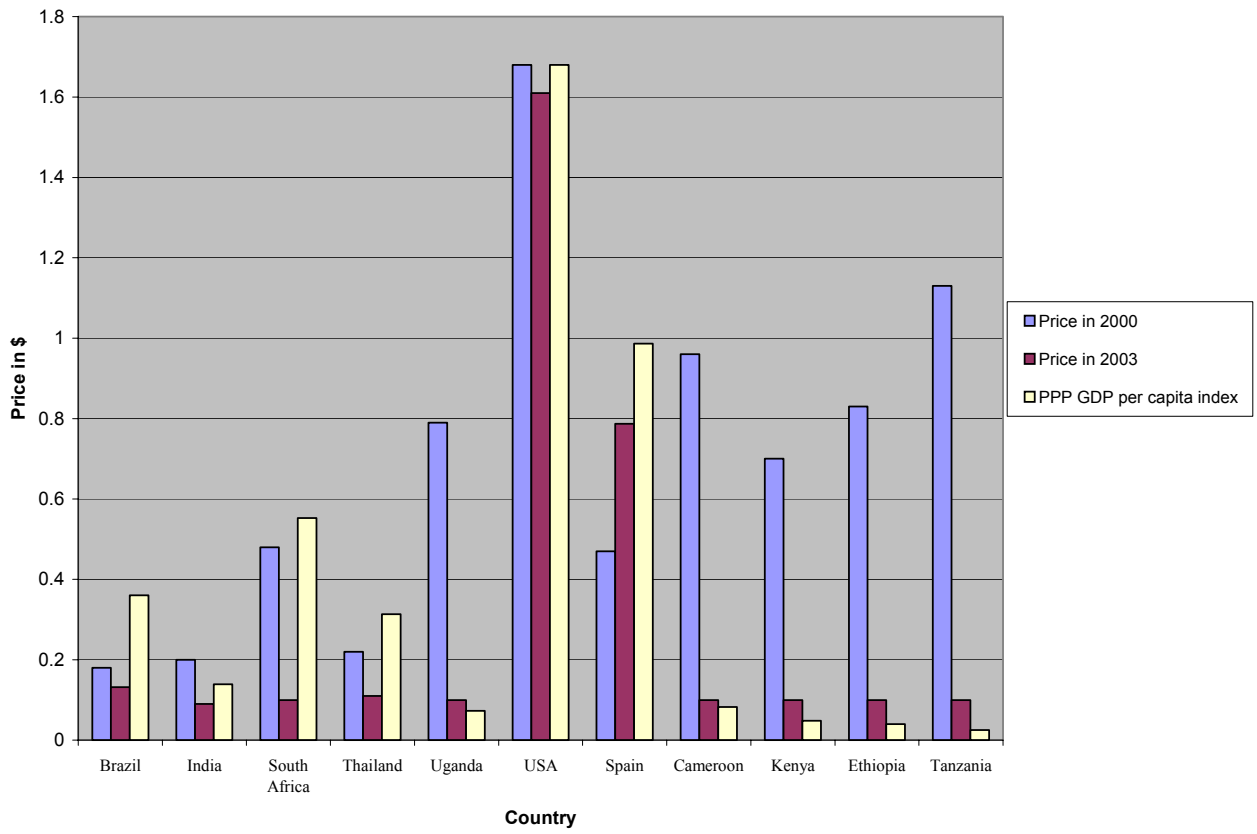


Figure 8: Zidovudine's 2000 and 2003 prices and GDP per capita

*Merck* began to provide *Efavirenz* at \$1.37 for low income countries and \$2.52 for medium-income countries with an HIV prevalence of less than one percent of the population. *Merck* also developed a 600 mg formulation of the drug which it made available only in developing countries. Figure 9 shows that starting in 2001 *Efavirenz*'s prices declined in the African countries in the sample. Prices fell in Latin American and Asian countries as well from 2001 through 2003 by which time only the US and Spanish prices retained their original prices of 2000.

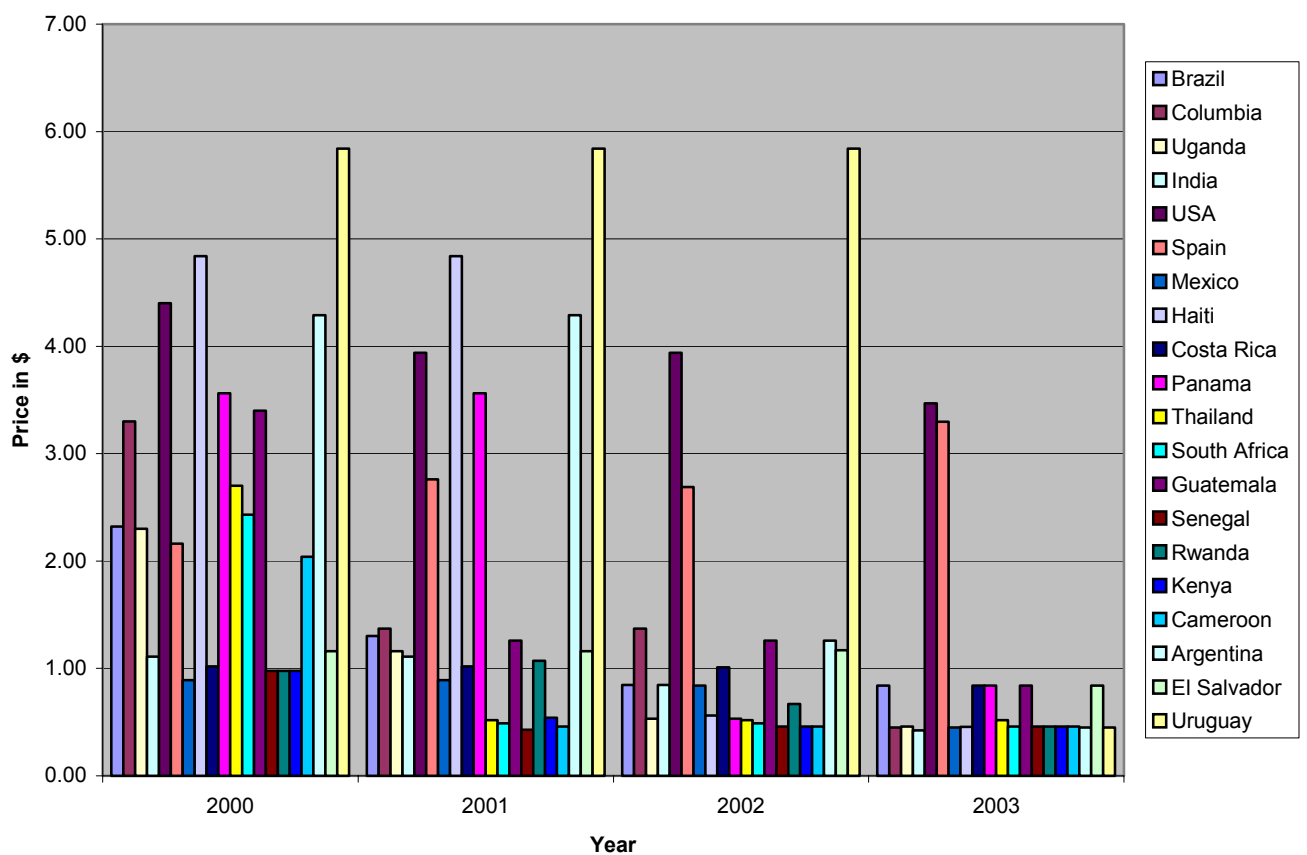


Figure 9: Efavirenz 200 mg capsules

Another commonly used *NNRTI* is *Nevirapine*. *Boehringer-Ingelheim (BI)* holds the patent on *Nevirapine* through late 2011 in the US and also manufactures the drug for the global market.

*Nevirapine*'s cross-country price distribution changed dramatically from 2000 to 2003 and is shown in Figure 10. In 2000 *BI* had a fairly flat pricing regime across countries. Those countries with some domestic generics production such as Brazil and India faced prices significantly lower from the world price. The price of Uganda was close to that of the US, both near \$4.50 per capsule. The rest of the world saw prices between \$3.50 and \$4.00 per capsule. Prices fell in those African and Latin American countries with access to generics starting in 2001. Latin America as a whole was the last region to experience price reductions, illustrated most dramatically with the fall in the drug's price in Colombia and Uruguay from more than \$4.00 per capsule in 2000 to roughly 20 cents per capsule in 2003.

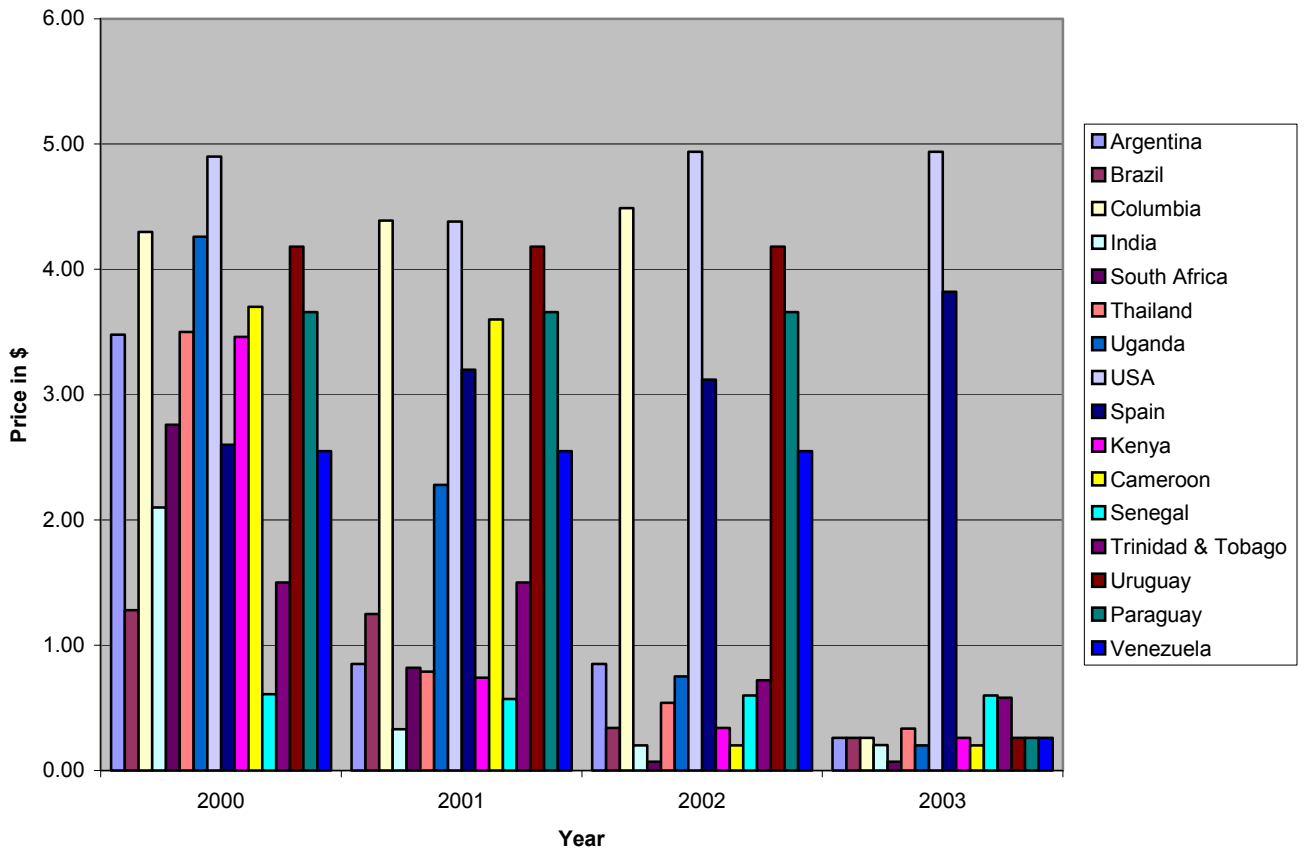


Figure 10: Nevirapine 200 mg capsules

### 4.3 Protease Inhibitors (PIs)

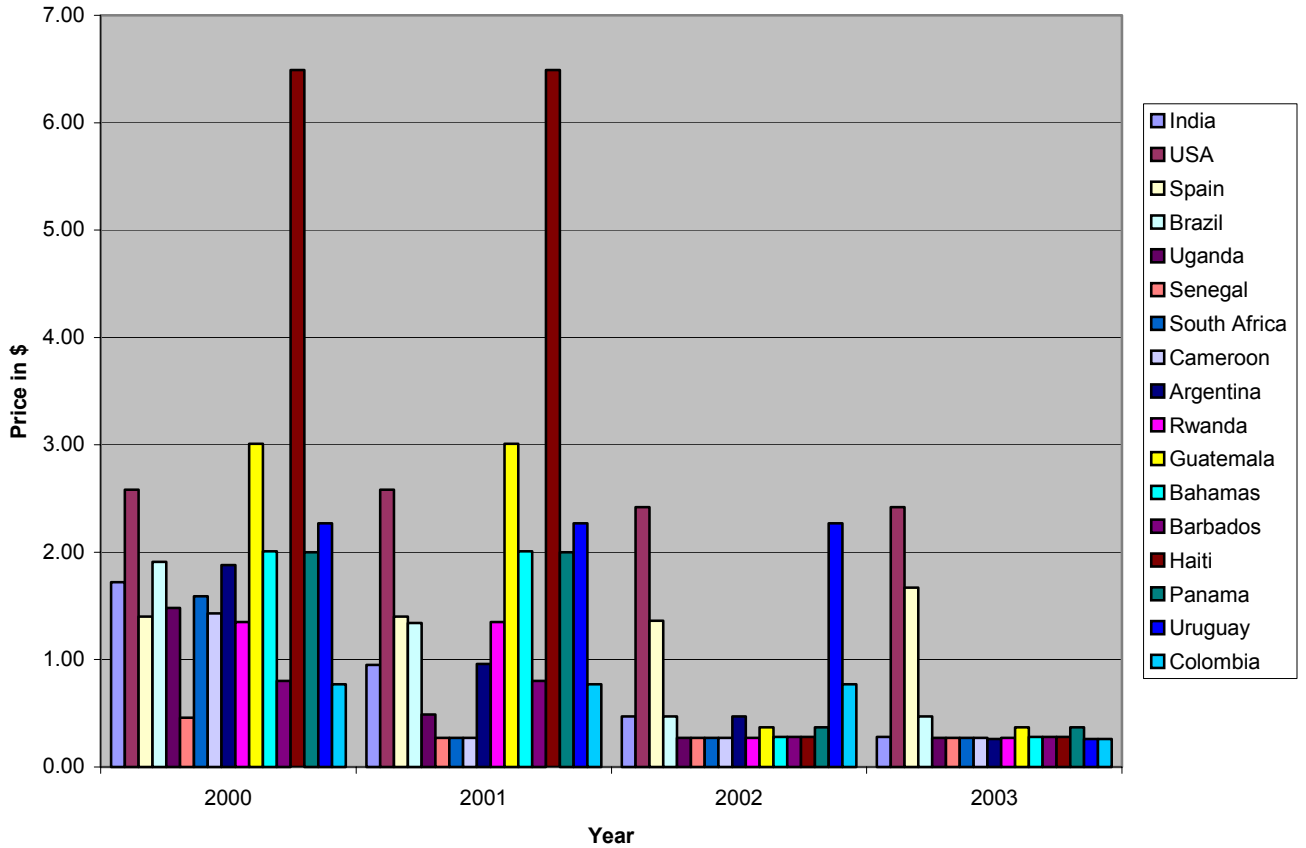


Figure 11: Indinavir 400 mg capsules

*Merck* holds the patent on *Indinavir*, a protease inhibitor, and also manufactures it. Its patent expires in 2013 in the US market. Figure 11 shows the international distribution of prices for a single 400 mg capsule from 2000 to 2003. In 2000 *Merck* appeared to have a one-tier pricing system for the drug. Two Indian generics firms began to manufacture the drug in 2001. Some African countries such as Senegal and Cameroon saw price reductions to 40 cents per a capsule in 2001 and to 27 cents per capsule in 2002. These offers were soon matched by other generics manufacturers. Prices fell in Brazil in 2002 and in most of Latin America in 2002 and 2003.

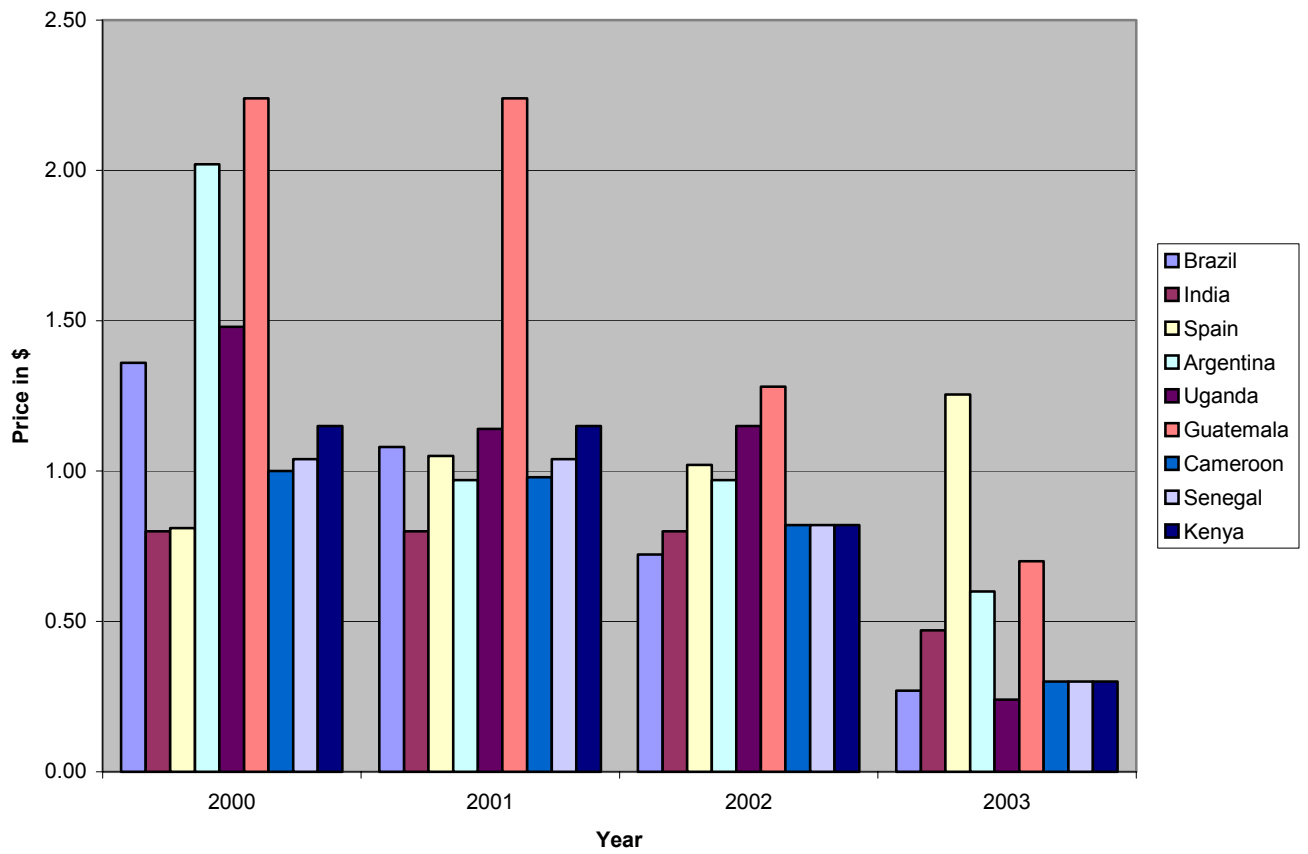


Figure 12: Nelfinavir 250 mg tablets

*Nelfinavir* is another protease inhibitor and is manufactured by *Roche*. It is under patent in the US market until 2013. Figure 12 shows the international distribution of prices for a single 250 mg capsule from 2000 to 2003. Only one Indian firm manufactured a generic variant of the drug in 2001. In 2002, *Nelfinavir* was offered at 87 cents per tablet by *Roche* and at 41 cents per tablet by the Indian generics firm *Hetero*.

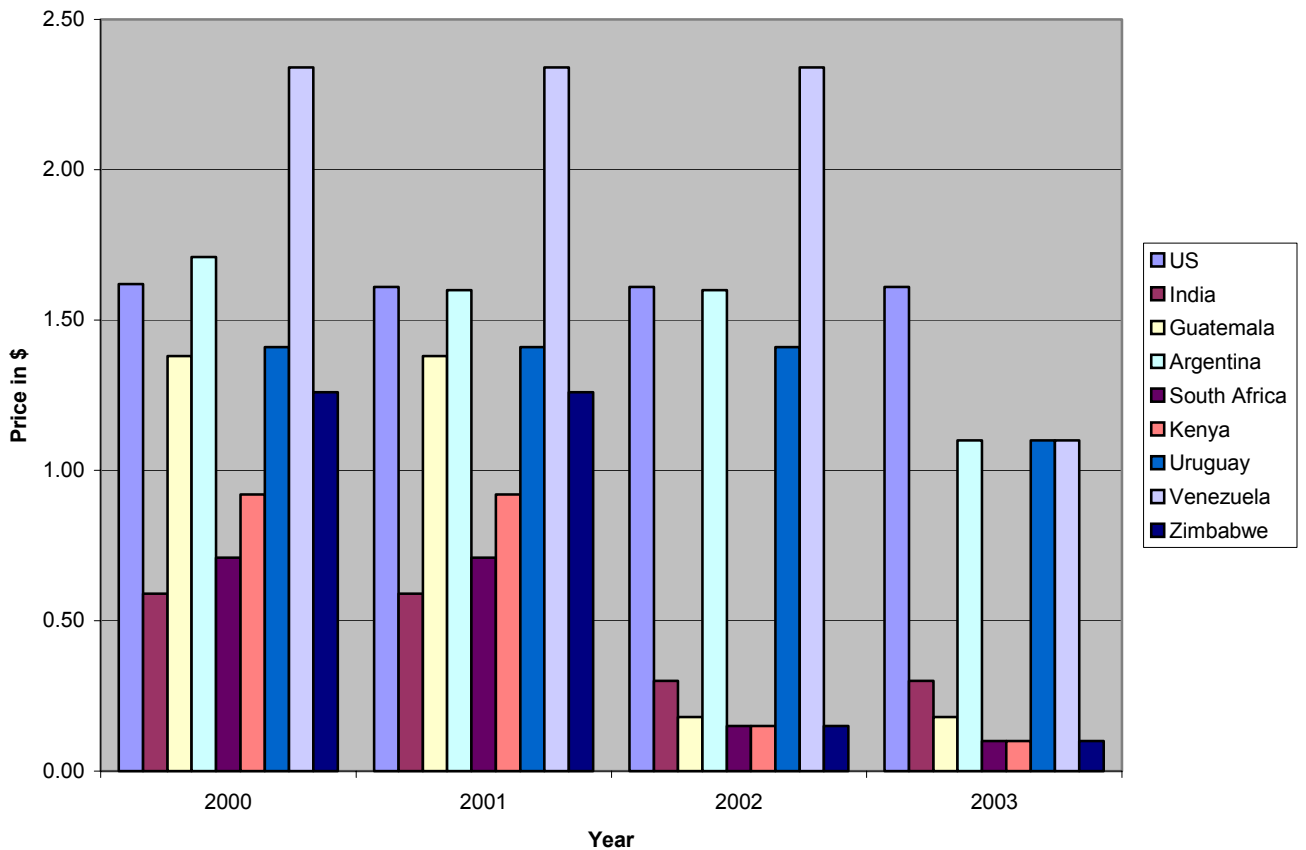


Figure 13: Ritonavir 100 mg. capsules

*Ritonavir* is another protease inhibitor. *Abbott* holds the patent on *Ritonavir* in the US market through 2013 and also manufactures it. Figure 13 shows the international distribution of prices for a single 100 mg capsule from 2000 to 2003. *Ritonavir* had two price tiers in 2000 with only

India below the \$1.50 price of a capsule in the US and in most other countries. Over the sample period *Abbott* consistently offered the drug to low-income countries at prices below those offered by generics manufacturers. *Abbott* offered the drug for 77 cents per capsule in 2001 when the lowest generics price offer was six times that price. Latin American countries were not included in these offers: their prices fell to roughly \$1.10 per capsule in 2003 much less than the dramatic price reductions for some of the other *ARVs* in 2003.

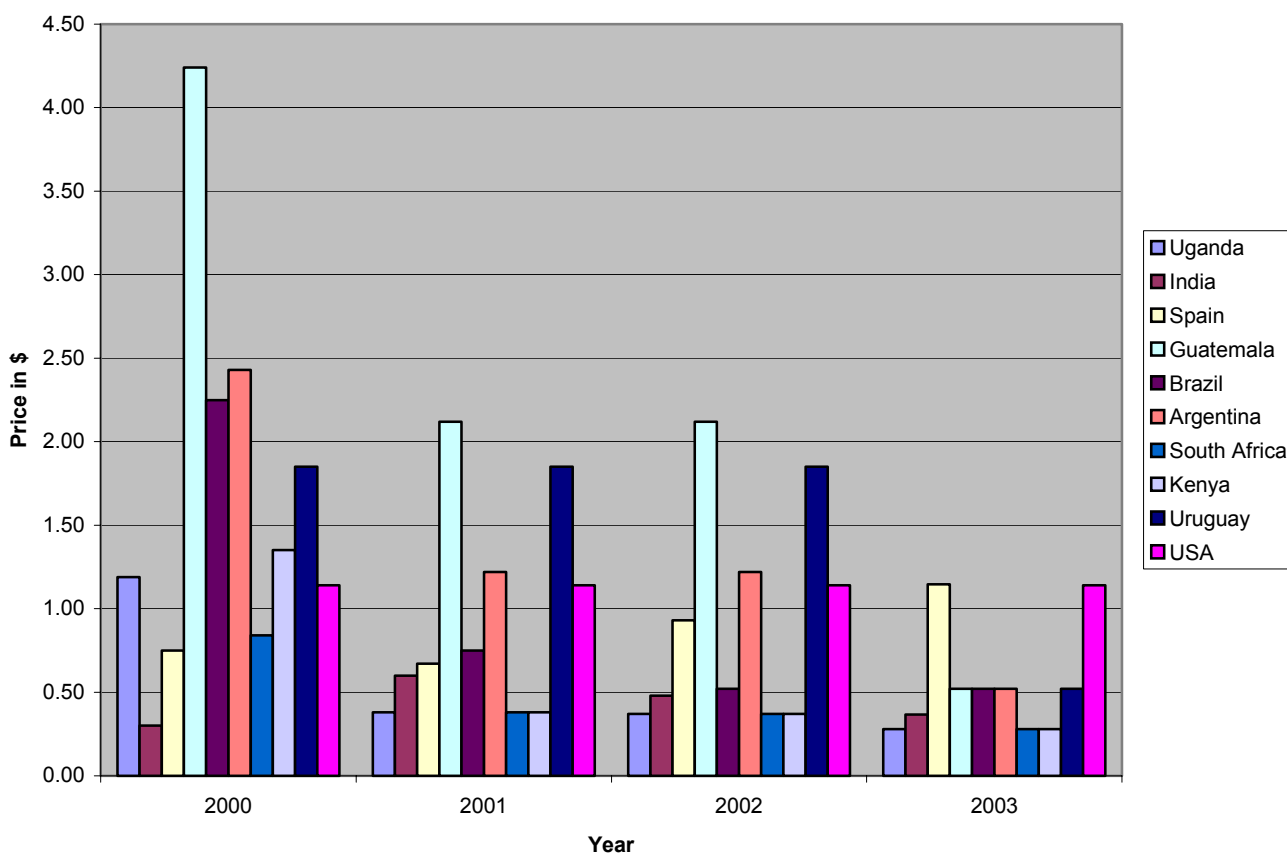


Figure 14: Saquinavir 200 mg. gel tablets

*Saquinavir* is a protease inhibitor under patent in the US market until 2010. Its patent is held by Hoffman-La Roche. Figure 14 shows the international distribution of prices for a single

200 mg tablet from 2000 to 2003. *Saquinavir*'s 2000 price in Kenya, \$1.40, was higher than its US price, \$1.20. *Roche* offered the drug through the *AAI* for 43 cents per tablet starting in 2001. The Ugandan price fell from \$1.20 in 2000 to 50 cents in that year. Meanwhile the Spanish price rose from 70 cents per tablet in 2000 to over \$1 a tablet in 2003. Prices in Latin American countries like Guatemala and Argentina fell in 2003 to levels slightly above those in Africa. US prices remained unchanged over the sample period. As of 2003, there is no generic production of the drug.

#### 4.4 Fixed-Dose Combinations (*FDCs*)

*Combivir* is a fixed-dose combination manufactured by *GlaxoSmithKline (GSK)*. Figure 15 shows the international distribution of prices for a single dose from 2000 to 2003. Indian generics firms began manufacturing the drug in 2001. Prices fell around the world with the advent of generic production from 2000 into 2002. Prices stabilized at roughly 50 cents per capsule in 2003 as illustrated in Figure 15.

Figure 16 compares the prices of *Combivir* in 2000 and 2003 to a per-capita *GDP* measure which is indexed to the US price in 2000. Argentina's price in 2000 was far below its per-capita *GDP* index while Brazil, India, and South Africa's 2000 prices were roughly on par with each country's per-capita *GDP* index. *Combivir*'s 2000 prices in the African countries of Kenya, Rwanda, and Uganda were greater than each country's respective per-capita *GDP* index. In contrast, *Combivir*'s 2003 prices were roughly equal to the per-capita *GDP* index numbers for the African countries and far below the index numbers for the Latin American countries and for India.

#### 4.5 Other Drugs

*Amphotericin B* is a powder produced and marketed by *Bristol-Myers Squibb*. It is off-patent but its production process is difficult. As a result, *BMS* does not face competition from any generics manufacturers. *Amphotericin B* is used to treat some of the opportunistic infections associated with *AIDS*, including meningitis. Figure 17 shows the international distribution of prices for a single 50 mg injection from 1999 to 2001. Figure 17 also illustrates the static pricing pattern one normally observes for pharmaceuticals when they are not the subject of public controversy.

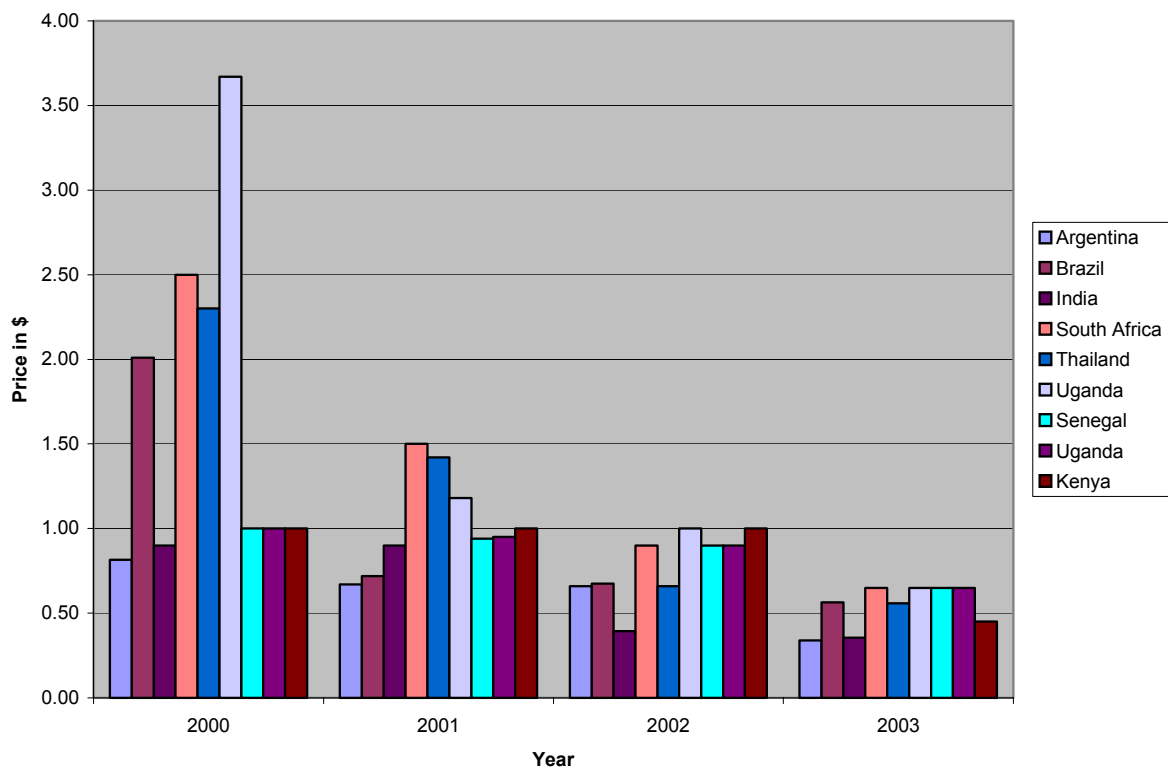


Figure 15: Combivir: Zidovudine 300 mg & Lamivudine 150 mg

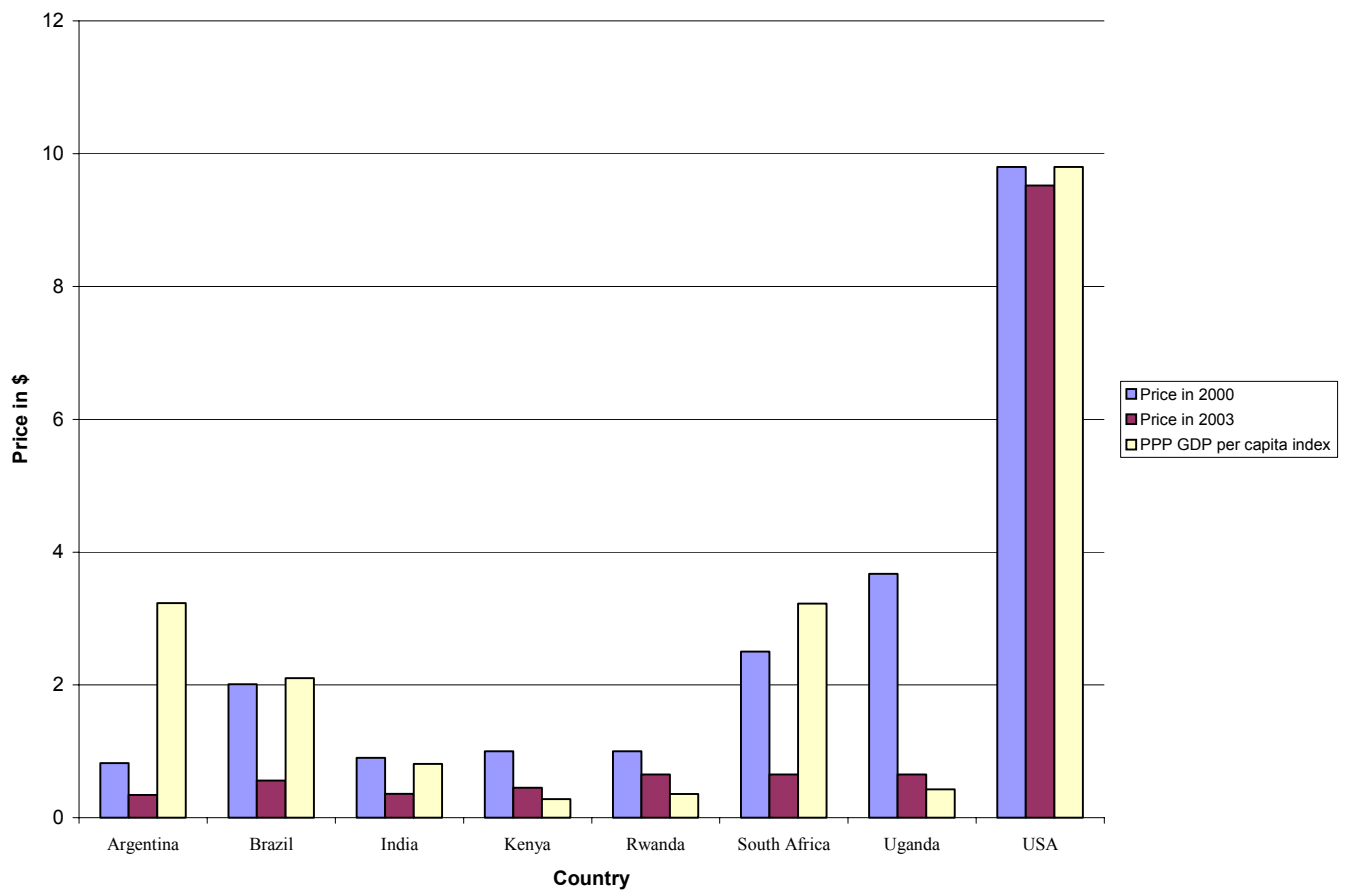


Figure 16: Combivir's prices in 2000 and 2003 and GDP per capita

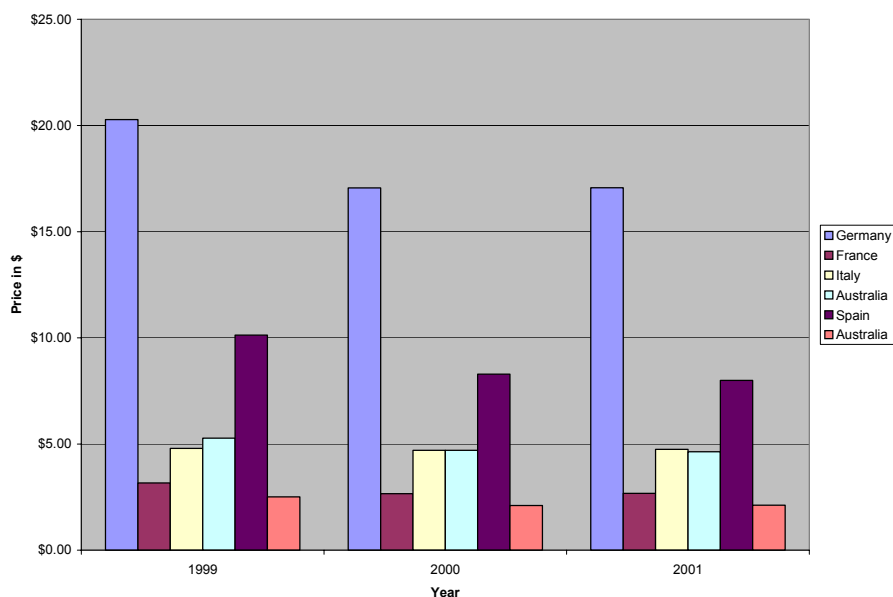


Figure 17: Amphotericin B 50 mg. fluid injection

Figure 18 shows a similarly stable price distribution from 2000 to 2001 for *Menomune*, a vaccine for meningitis which is under patent in the US market until 2014. Figure 19 compares the prices of *Menomune* in 2000 and 2001 to *GDP* per capita on a PPP basis which is indexed to the US price in 2000. Figure 19 shows that most European countries had *Menomune* prices that were significantly below their per-capita *GDP* index, including France, Germany, the UK, Ireland, Greece, Hungary, and the Czech Republic. Medium-income countries such as Saudi Arabia and Turkey had prices roughly equal to their respective per-capita *GDP* indexes. The holder of *Menomune*'s patent faced little public pressure to change its prices in low-income countries over the sample period, so the price distribution remained fairly stable. The graph does illustrate how much higher markups tend to be in the US than in Europe, hence the importance of the US consumer to multinational pharmaceutical firms' profits.

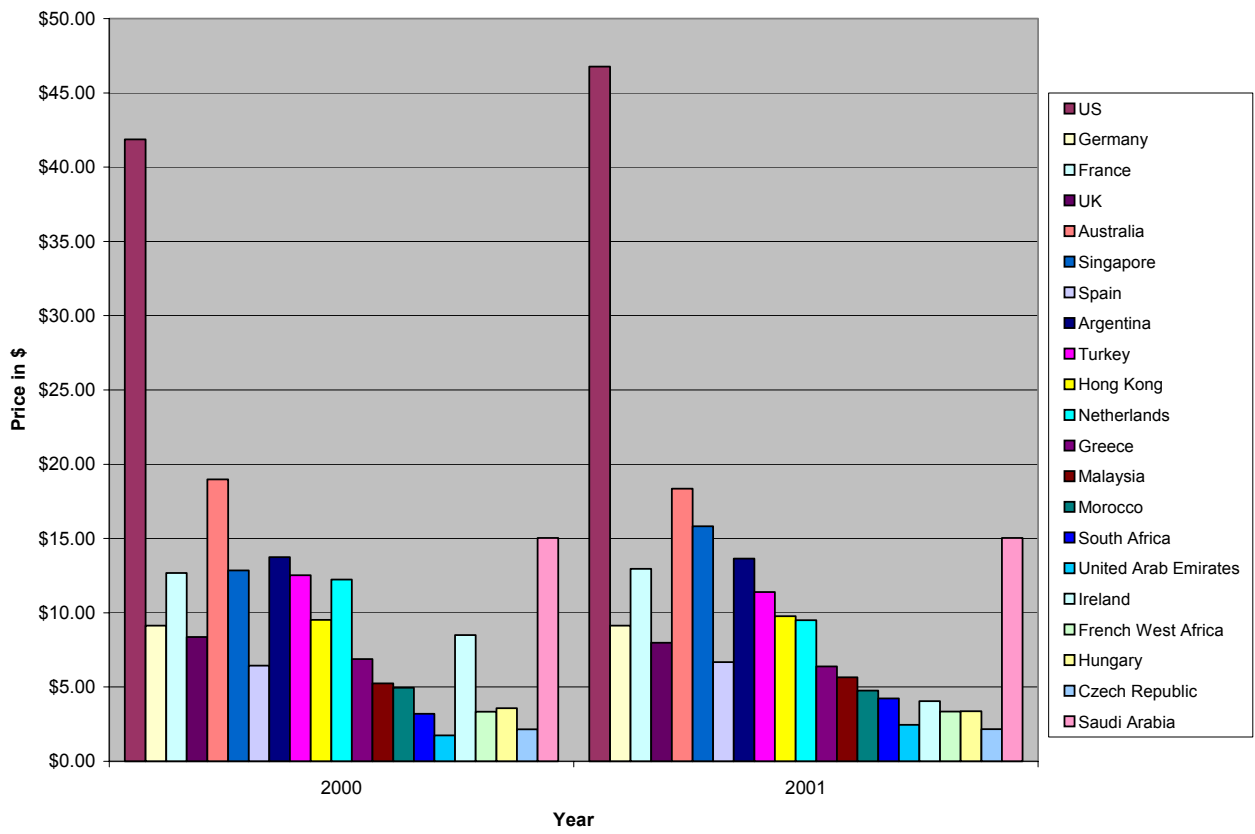


Figure 18: Menomune Vaccine

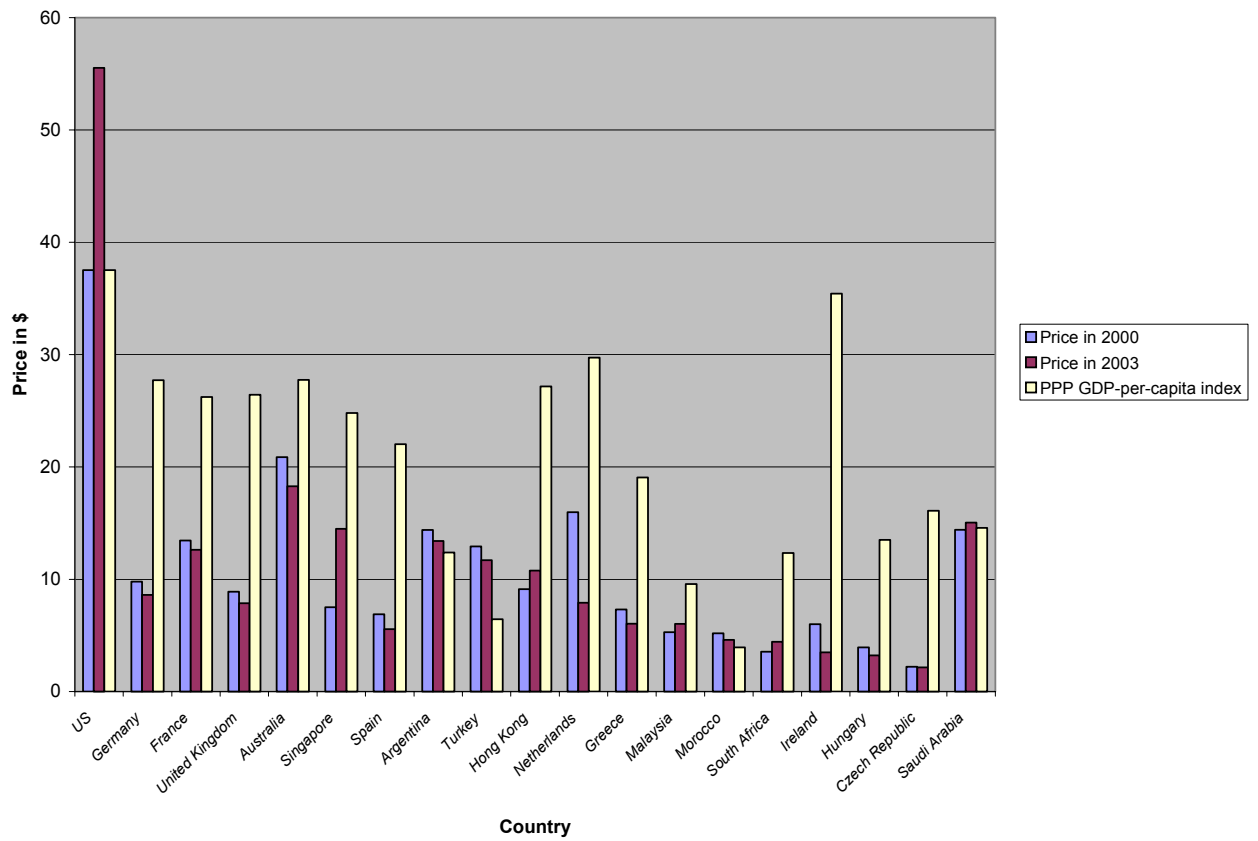


Figure 19: Menomune's 2000 and 2003 prices and GDP per capita

## 5 Per-Capita *GDP* and Prices

Figure 20 highlights a counterintuitive finding from the *MSF* data: Individual drug's prices are routinely as high or higher in poor countries such as Uganda or Tanzania as in wealthy countries such as the US or EU under a *TRIPS*-like patent regime, that is, when generic substitutes for patented drugs are not widely available in poor countries.

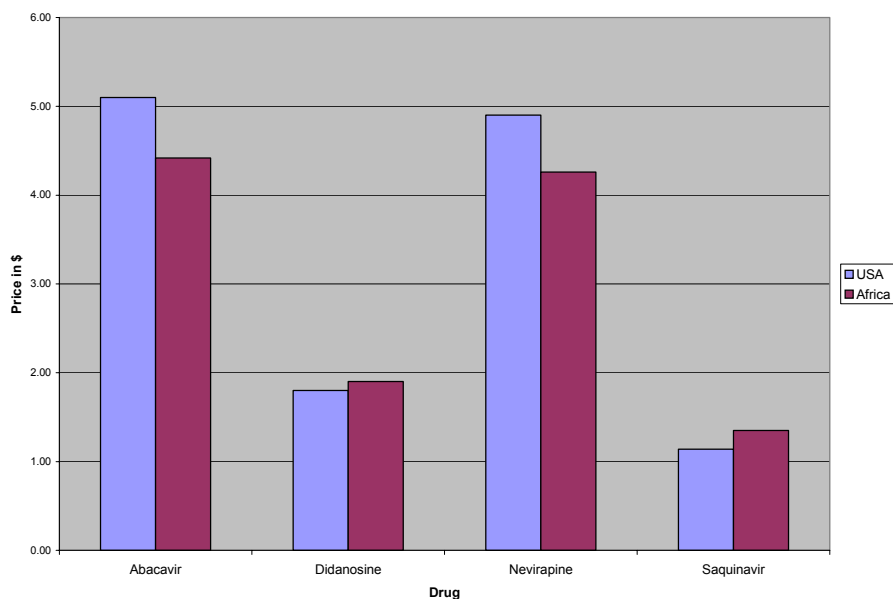


Figure 20: Selected drug prices for the US and Kenya, Tanzania, or Uganda in 2000

Table 2 shows the correlations between selected drugs' 2000 and 2003 prices and per-capita *GDP* calculated on a purchasing-power-parity basis (PPP *GDP*). The correlation is positive and low for most of the drugs' year 2000 prices: .19 for *Didanosine*, .29 for *Efavirenz*, .29 for *Stavudine*, and .41 for *Zidovudine*. The correlation is negative for one drug, *Abacavir*, at -.49. In 2003, in contrast, the correlation is high and above .9 for every *ARV* in the sample: for example, it is .92 for *Didanosine*, .94 for *Efavirenz*, .94 for *Stavudine*, and .95 for *Zidovudine*. The exception to this pattern is *Menomune*, the meningitis vaccine, which did not undergo the intense public scrutiny of prices of the *ARVs*.

Table 3 reports the coefficients from simple regressions of selected drugs' prices on PPP *GDP*

	Drug	Price in 2000	Price in 2003
PPP GDP per capita	Abacavir	-.49	.99
	Combivir	.87	.92
	Didanosine	.19	.92
	Efavirenz	.29	.94
	Lamivudine	.44	.92
	Menomune	.49	.45
	Stavudine	.29	.94
	Zidovudine	.41	.95

Table 2: *Correlations between PPP GDP per capita and selected drugs' prices*

	Drug	Price in 2000	Price in 2003
PPP GDP per capita	Abacavir	-.37 (.97)	.74 (10.35)*
	Combivir	.83 (4.36)*	.92 (5.69)*
	Didanosine	.17 (.54)	.92 (6.58)*
	Efavirenz	.73 (2.23)*	.99 (6.51)*
	Lamivudine	.62 (1.85)	1.18 (8.62)*
	Menomune	.42 (2.38)*	.55 (2.08)*
	Stavudine	.58 (.84)	1.37 (7.88)*
	Zidovudine	.36 (1.33)	.95 (8.95)*

Table 3: *Results from regressions of drug prices on PPP GDP per capita.* Robust t-statistics in parentheses under the coefficients. Those starred are significant at the 5-percent level.

per capita. PPP *GDP* per capita can be distinguished statistically from zero for only three of the eight drugs considered: *Combivir*, *Efavirenz*, and *Menomune*. For the year-2003 prices, in contrast, its coefficient is large and statistically significant from zero for all eight drugs.

Two puzzles emerge from section 4's discussion of the price data and from section 5's regression results. First, why do the year-2000 prices have such a weak relationship to *GDP* per capita? Second, why does the relationship strengthen by the year 2003?

## 6 Why Don't Prices Covary with Per-Capita *GDP*?

This section explores several possible explanations for why prices may not vary positively with per-capita income across countries. It examines three characteristics of national pharmaceutical markets that may also affect prices: the health expenditure system, the presence of trade barriers such as tariffs, and the likelihood of parallel imports.

### 6.1 Health Expenditure

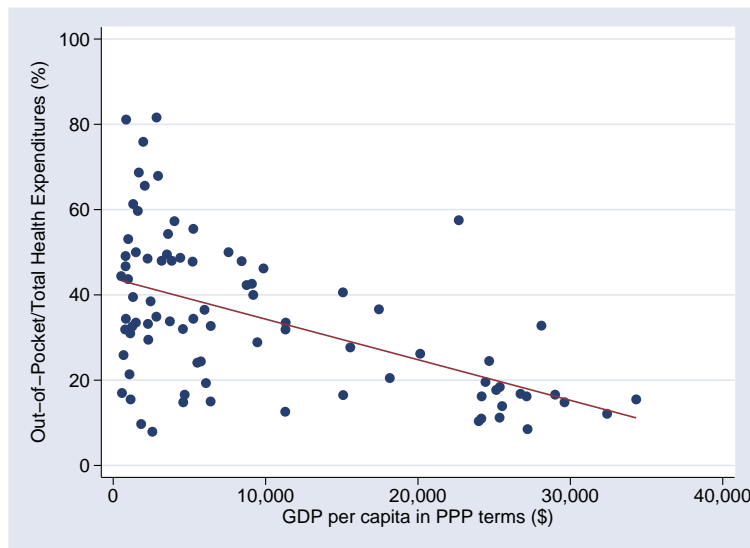


Figure 21: Out-of-pocket expenditure as a share of total health expenditure falls as per-capita *GDP* rises

A country's health expenditure system should affect domestic drug prices through its impact on the structure of demand. Such systems differ in important ways between rich and poor countries. As Figure 21 illustrates, as the average per-capita income of a country rises, the share of its total health-care expenditures paid for out of pocket (that is, without public or private insurance) falls. Consumers negotiate drug prices individually in most low-income countries, while in most high-income countries public or private insurance firms negotiate drug prices on consumers' behalf. That is, firms or governments use their monopsony power from representing a large pool of consumers to bargain for lower prices. One would thus expect prices to rise when a large share of the population pays for pharmaceuticals out of pocket.

	Price in 2000	Price in 2003
PPP GDP per capita (in 1000's)	.07 (2.79)*	.10 (8.13)*
Health Expenditure Out of Pocket (%)	.005 (.43)	.01 (2.93)*
Constant	1.27 (2.43)*	-.54 (-2.72)*
Observations	82	82
$R^2$	.15	.68

Table 4: *Drug prices increase with PPP GDP per capita and the share of out-of-pocket expenditure in total health expenditure.* Robust t-statistics in parentheses under the coefficients. Those starred are significant at the 5-percent level.

Table 4 shows the coefficients from simple regressions of selected drugs' prices on PPP *GDP* per capita and on the share of total health expenditure paid for out of pocket. The table reports that PPP *GDP* per capita is significant in 2000 while the share of health expenditure paid out of pocket for drugs is not. In 2003, in contrast, the share of health expenditure paid out of pocket is positive and significant. In both regressions, prices rise with per-capita income, as one would expect. As the share of total health expenditure paid out of pocket (*OOPS*) rises, prices also rise. One can interpret the *OOPS* variable as an inverse measure of consumers' market power. As *OOPS* rises as a share of total health expenditure, public and private insurance's share falls, and so does consumers' bargaining power. One can interpret the coefficients in table 4 as follows: for each \$1000 increase in per-capita *GDP*, the average *ARV*'s price rises by 10 cents, and for each

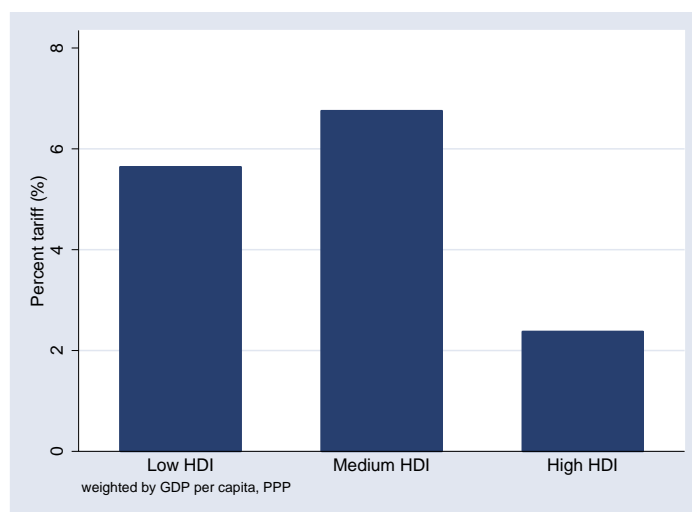


Figure 22: Average tariffs on medicines by HDI level

percent increase in *OOPS*, the average *ARV*'s price rises by 1 cent.

## 6.2 Trade Barriers

Trade barriers create additional cross-country variation in drug prices. Tariffs on pharmaceutical imports rise as per-capita income falls in cross-country comparisons. This pattern is illustrated in Figures 22 through 24. Low-income countries rely heavily on border taxes to raise government revenue and are thus more likely to tax drugs at the border than are high-income countries. Figure 22 shows the average tariff level across low, medium, and high human-development-index (HDI) countries.<sup>9</sup> Low- and medium-HDI countries tax pharmaceutical imports at roughly three times the rate in high HDI countries. Figure 23 is a scatterplot that illustrates the inverse relationship between each country's ad valorem pharmaceutical tariff and *GDP* per capita. Figure 24 names the countries at selected data points from Figure 23. Wealthy countries such as the US, the EU, Japan, and Norway all have high per-capita income and zero drug tariffs. Some African countries also have zero drug tariffs, such as Uganda and South Africa. Many of the countries with very low per-capita income (and in most cases, high incidence of *AIDS*) such as Nigeria, Ethiopia,

<sup>9</sup>The HDI index is calculated by the United Nations.

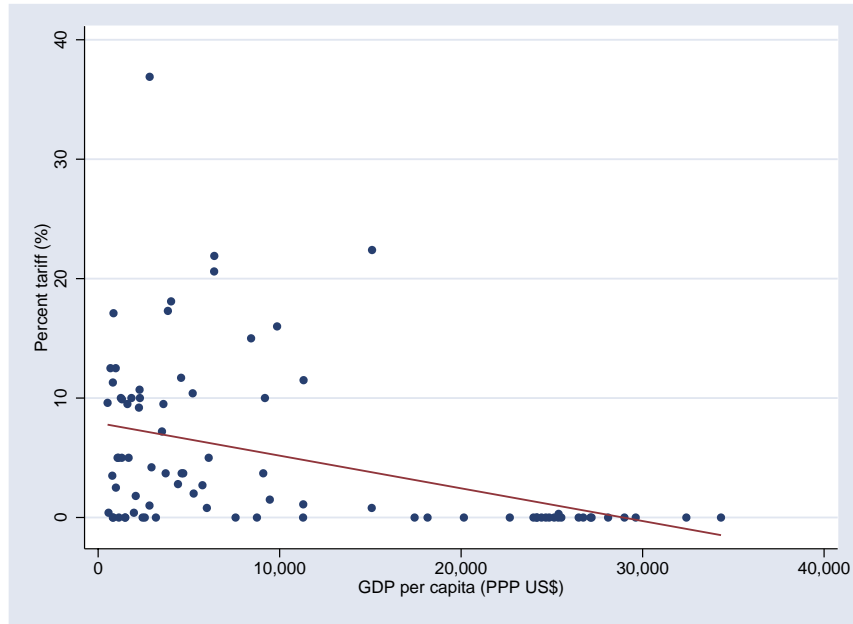


Figure 23: Tariffs on medicine and GDP per capita on a PPP basis

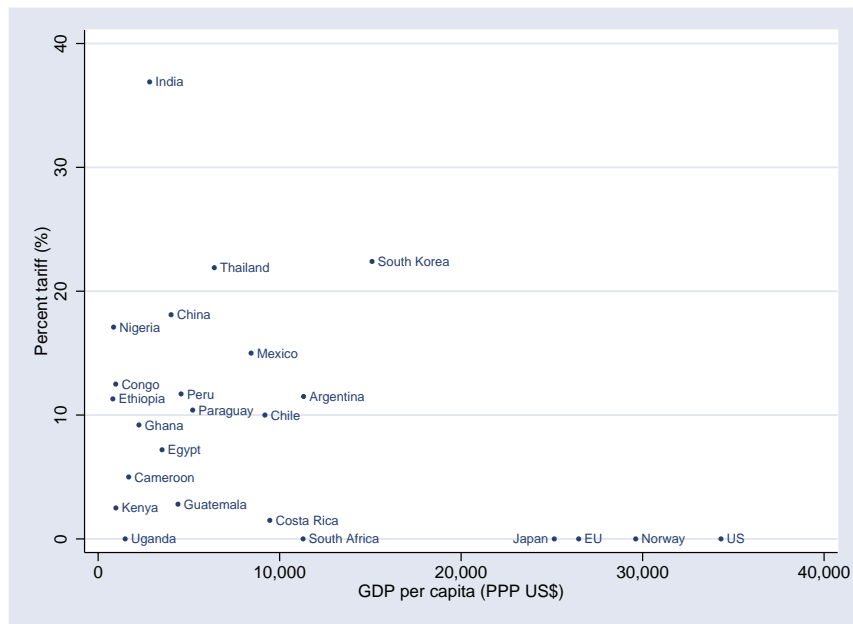


Figure 24: Selected tariffs on medicines and GDP per capita on a PPP basis

	Price in 2000	Price in 2003
PPP GDP per capita (in \$1000's)	.07 (2.88)*	.10 (8.19)*
Pharmaceutical tariffs (%)	-.003 (-.17)	-.001 (.19)
Constant	1.52 (5.89)*	-.05 (-.54)
Observations	82	82
$R^2$	.14	.66

Table 5: *Drug prices do not vary significantly with tariffs.* T-statistics in parentheses under the coefficients. Those starred are significant at the 5-percent level.

and Ghana have pharmaceutical tariffs of 10 percent or more. Medium-income countries with high tariffs such as India, Thailand, and China intend to protect their domestic pharmaceutical manufacturing base from foreign competitors.

Table 5 shows the coefficients from simple regressions of selected drugs' prices on each country's PPP *GDP* per capita and ad-valorem pharmaceutical tariffs. The tariff variable is not significant in either regression. The coefficient on per-capita *GDP* does not change from the previous regressions and remains significant. Tariffs do not appear to play an important role in the *MSF* data's cross-country price variation.

### 6.3 Parallel Imports

The likelihood of parallel importation, that is, that a drug will be diverted to (or from) consumers in a nearby country should also affect a drug's price. A country's drug prices, thus, should vary with the geographic proximity of countries with much higher or lower per-capita income. A low-income country will face prices appropriate to its citizens ability to pay only if its products cannot be re-exported to a nearby high-income country.

Thus far, the most egregious case of parallel importation of *ARVs* occurred in 2002 when, as reported by *The New York Times*, "Schemes in which deeply discounted *HIV* and *AIDS* drugs meant for poor and dying patients in Africa were resold in Europe (Netherlands, Germany,

Belgium, and France) at huge profits... Around one-fifth of *GlaxoSmithKline's* marked-down *AIDS* medication destined for impoverished patients in five African countries wound up instead in the hands of profiteers, the company said."<sup>10</sup> Glaxo estimated it lost roughly \$16 million dollars in sales – roughly one percent of the annual global revenue for each of the drugs involved. This example indicates that originator companies' potential profit losses from parallel importation of *ARVs* are not negligible.

## 7 Model

The previous sections identify an interesting stylized fact in cross-country *ARV* prices from 2000 to 2003. Under a *TRIPS*-like patent regime, that is, when generic alternatives to patented drugs are not widely available in poor countries, drug prices are routinely as high or higher in poor countries such as Uganda or Tanzania as in wealthy countries such as the US or the EU. This section introduces a model to try to explain this stylized fact as originator companies' profit-maximizing response to the incentives they face in the global pharmaceutical market.

The model examines how consumers' imperfect information about firms' production costs in the pharmaceutical industry affects firm behavior. Manufacturers have market power derived from consumers' uncertainty about their production costs. Consumers get utility from the perception that they are being treated fairly and they have an understanding of what is a fair markup over marginal cost. A high markup that violates this sense of fairness will cause them to be willing to bear the fixed costs to set up a national system of price controls to punish the manufacturer by reducing its profits.

### 7.1 Demand

Suppose we observe demand for a product in two countries: a rich country, country 1, and a poor country, country 2. Let a product be one unit of a drug. Let a market be the total demand for the product in one time period and in one country. Each country's demand is characterized by a representative individual. The indirect utility for the representative consumer in country 2 (hereafter, consumer 2) in consuming the product takes a quasi-linear form:

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<sup>10</sup>Gregory Crouch. "Europeans Investigate Resale of *AIDS* Drugs." *The New York Times*, October 29, 2002.

$$u_{2t} = \begin{cases} x_{2t}\beta - \alpha_2 p_{2t} + \varepsilon_{2t} & \text{if purchase the product} \\ 0 & \text{otherwise} \end{cases} \quad (1)$$

where  $\varepsilon_{2t}$  is a mean-zero stochastic term. A consumer's utility from consuming the product is a function of the product's characteristics  $x$  and the product's prices  $p$ . The indirect utility for the representative consumer in country 1 (hereafter, consumer 1), in consuming the product takes the following quasi-linear form:

$$u_{1t} = \begin{cases} x_{1t}\beta - \alpha_1 [\xi(p_{1t}^*) + (1 - \xi)(p_{1t})] + \varepsilon_{1t} & \text{if purchase the product} \\ 0 & \text{otherwise} \end{cases} \quad (2)$$

where  $p_{1t}^*$  is country 1's price after the imposition of price controls and  $\xi(p_{1t} - p_{2t})$  is a nonlinear indicator function that depends on the difference between the product's prices in country 1 and in country 2:

$$\xi(p_{1t} - p_{2t}) = \begin{cases} 1 & \text{when } p_{1t} - p_{2t} > \kappa, \xi'(p_{1t}) > 0, \xi'(p_{2t}) < 0, \\ 0 & \text{otherwise} \end{cases} \quad (3)$$

When the value of  $\xi$  exceeds some threshold value  $\kappa$ , consumer 1 chooses to bear a fixed cost  $\tau$  to set up a national system of price controls. Consumers 1 and 2 do not have the option to cross the border to purchase the product in the other consumer's country. By assumption, the demand elasticity of consumer 1 is always lower in absolute value than that of consumer 2:  $\left| \frac{\partial x_{1t}(\cdot)}{\partial p_{1t}} \right| < \left| \frac{\partial x_{2t}(\cdot)}{\partial p_{2t}} \right|$  because consumer 2 has a lower income than consumer 1. While consumers with lower incomes do not always have higher demand elasticities (in absolute value) this is often the case.<sup>11</sup>

## 7.2 Supply

Let there be a monopolist that produces the market's only drug. The monopolist chooses its price in each of the two countries to maximize its profits:

$$\Pi_t = (p_{1t} - mc_t) x_{1t}(p_{1t}, p_{2t}, p_{1t}^*) + (p_{2t} - mc_t) x_{2t}(p_{2t}) \quad (4)$$

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<sup>11</sup>See Tirole (1988).

where  $p_{jt}$  is the price of the product in country  $j$  at time  $t$ ,  $x_{jt}$  is the quantity demanded of the drug in country  $j$  at time  $t$ , and  $mc_t$  is the marginal cost to produce the drug which does not vary across countries. Assuming the firm sets prices to maximize profits, the price  $p_{jt}$  must satisfy the first-order conditions:

$$0 = x_{1t} + (p_{1t} - mc_t) \frac{\partial x_{1t}}{\partial p_{1t}} \quad (5)$$

$$0 = x_{2t} + (p_{1t} - mc_t) \frac{\partial x_{1t}}{\partial p_{2t}} + (p_{2t} - mc_t) \frac{\partial x_{2t}}{\partial p_{2t}} \quad (6)$$

This gives us a set of two equations, one for each product where  $\frac{\partial x_{kt}}{\partial p_{jt}}$ ,  $j, k=1, 2$ , is the change in demand for the  $k$ th country's product given a change in the  $j$ th country's price for the product. The first-order conditions can be rewritten to give expressions for the determinants of the product's price in each country:

$$p_{1t} = mc_t - \frac{x_{1t}}{\left(\frac{\partial x_{1t}}{\partial p_{1t}}\right)} \quad (7)$$

$$p_{2t} = mc_t \left(1 + \frac{\frac{\partial x_{1t}}{\partial p_{2t}}}{\frac{\partial x_{2t}}{\partial p_{2t}}}\right) - \frac{x_{2t}}{\frac{\partial x_{2t}}{\partial p_{2t}}} - p_{1t} \left(\frac{\frac{\partial x_{1t}}{\partial p_{2t}}}{\frac{\partial x_{2t}}{\partial p_{2t}}}\right) \quad (8)$$

If national markets were perfectly segmented, each country's price would be a function of the marginal cost and the demand elasticity in that country alone. The first term of equation (8) indicates that country 2's price is less responsive to changes in the marginal cost  $mc_t$  than it would be with completely segmented markets where the  $\frac{\frac{\partial x_{1t}}{\partial p_{2t}}}{\frac{\partial x_{2t}}{\partial p_{2t}}}$  term would equal zero. The third term of equation (8) indicates that country 2's price responds to changes in country 1's price, which would not be the case with completely segmented markets. If the monopolist raises the product's price in country 1, it should also raise it in country 2 to maximize profits:  $\frac{\partial p_{2t}}{\partial p_{1t}} \geq 0$ . The sign of the third term as a whole is positive as  $\frac{\partial x_{1t}}{\partial p_{1t}} < 0$ ,  $\frac{\partial x_{2t}}{\partial p_{1t}} \geq 0$ , and  $p_{1t} \geq 0$ . The monopolist considers the cross-price demand elasticity with country 1 as well as the own-price demand elasticity in country 2 when setting country 2's price. The cross-price elasticity is a step function: it is zero for all values of  $p_1$  until a threshold is surpassed (determined by the  $\xi$  function) when it takes on the value of  $D$ , which signifies that the whole structure of consumer 1's demand changes to reflect

the imposition of price controls.

### 7.3 Discussion

Market segmentation fails in one important and unconventional way in this model. The ability of consumer 1 to learn costlessly the price paid by consumer 2 implies a loss of market segmentation of the type associated with theories of globalization. Increased flows of information across national borders mean that consumers in one country are more likely to know what foreign consumers pay for a given product than they did previously. Consumer 1 does not know the monopolist's marginal cost and hence his markup. If one assumes that the manufacturer always sets its price to be greater than or equal to its marginal cost, then the lowest price charged in another country provides an upper bound on the manufacturer's marginal cost.<sup>12</sup> Consumer 1 has a notion of a fair markup over marginal cost: when this fairness ideal is violated, he will punish the monopolist by imposing price controls even if he must bear some cost to do so.

In this model, the monopolist does not want to lose profits in country 1 so it chooses to push up the price in country 2, if necessary, to the point where it exceeds consumer 2's income. This is simply profit-maximizing behavior given consumers in country 1 with imperfect information about manufacturers' production costs and with a fairness externality in their utility function. These characteristics of consumer 1 erode market segmentation across countries even without any opportunity for them to import the product from country 2 to country 1.

## 8 Conclusion

This paper finds that *ARVs*' prices had little relationship to developing countries' per-capita incomes in the year 2000 before the onslaught of generics competition and political pressure in this market. By the year 2003, the dramatic changes in the international distribution of *ARV*'s prices significantly strengthened the relationship between *ARVs*' prices and per-capita income. The paper shows that drug prices do not vary with consumers ability to pay in low-income countries when patents are enforced. The paper then motivates and develops a model in which

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<sup>12</sup>This assumes zero transport costs between markets which is a useful simplification of the model but one that does not change the basic result.

the imperfect information and the fairness concerns of wealthy consumers cause a monopolist to consider their reactions when setting prices for poor consumers in a separate segmented market.

It is always profit-maximizing for firms to price discriminate given the conditions to do so. Cross-border information flows erode the conditions necessary for price discrimination in the pharmaceutical market as firms' profits depend in part on imperfectly informed consumers in high-income countries. Firms' profit losses in high-income markets following the release of information about their production costs likely outweigh any profit gains from setting prices that poor countries' consumers can afford to pay.

This paper's findings have several policy implications. Policymakers should take measures to support the complete segmentation of markets between rich and poor countries. First, policymakers should streamline the regulatory process to facilitate firms' repackaging of their products for low-income countries. At present this process is slow and cumbersome.<sup>13</sup> Second, policymakers should create economic incentives for originator companies to refrain from action (legal or otherwise) to stop generic production of their patented products in low-income countries. Consumers' information acquisition costs rise with the number of producers, brand names, and formulations of a drug – Generic production for poor countries thus supports market segmentation between poor and wealthy countries. A voluntary example of this type of approach is *Roche's* "Global Initiatives in Caring" is a pledge by the company not to hinder generic production of its patented *ARVs* in sub-Saharan Africa or the UN's *LDCs*.<sup>14</sup> *TRIPS* will only be implemented without prohibitive price hikes in poor countries if steps are taken to deal with the impact of the rapid flow of price information across borders on market segmentation.

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<sup>13</sup> *GlaxoSmithKline* discusses the regulatory barriers to repackaging in Gregory Crouch. "Europeans Investigate Resale of *AIDS* Drugs." *The New York Times*, October 29, 2002.

<sup>14</sup> See [http://www.roche-hiv.com/roche-in-hiv/1386\\_Ket\\_Roche\\_HIV\\_leaflet.cfm?link=protease](http://www.roche-hiv.com/roche-in-hiv/1386_Ket_Roche_HIV_leaflet.cfm?link=protease)

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