

*A Dollar A Day: Creating The World Market for Lifesaving AIDS Drugs*

*A Review of the Price Drop in ARV Drugs  
for The Open Philanthropy Project*

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I: Acronyms

AAI: Accelerating Access Initiative

ARV: Antiretroviral Drugs

API: Active Pharmaceutical Ingredient

CHAI: Clinton Health Access Initiative

CPTech: Consumer Project on Technology

DAI: Drug Access Initiative Program

FDC: Fixed Dose Combination

HAART: Highly Active Antiretroviral Therapy

MSF: Medecins Sans Frontieres (Doctors Without Borders)

PEPFAR: President's Emergency Plan for AIDS Relief

TRIPS: The Agreement on Trade-Related Aspects of Intellectual Property Rights

USTR: United States Trade Representative

WHO: World Health Organization

WTO: World Trade Organization

## II: Abstract

Numerous philanthropic organizations claim credit for the reduced cost of antiretroviral drugs (ARVs) for patients afflicted with HIV/AIDS (Human Immunodeficiency Virus / Acquired Immunodeficiency Syndrome). From 2000 to 2005, the cost of these drugs fell in price from approximately \$10,000 - \$15,000 per person per year to \$140 per person per year. This report examines the drivers of this significant price reduction.

This paper confirms previous scholarship that claims the price drop occurred in three stages. The first – in which ARVs dropped from \$15,000+ per person per year to approximately \$1000 per person per year between 2000 and 2001 – can be attributed to activists persuading pharmaceutical companies to offer philanthropic prices to pilot projects; the second drop, from approximately \$1,000 per person per year to about \$350 per person per year between 2001 and 2003, can be attributed to the active creation of a generic drug market; and the final drop, from \$350 to \$140 between 2003 and 2005, can be attributed to interventions into the existing generic market.

This report also offers the following claim: The most important and sustainable aspect of the price drop in ARVs came from the deliberate and hard-fought creation of a market for generic drugs, a market that relied on (1) the existence of companies, like Cipla Ltd., with proven expertise in making high quality, high volume, generic drugs; (2) a permissive legal environment for the production and purchasing of generic drugs; (3) the ability of the World Health Organization to offer quality control; (4) and the creation of substantial third party purchasers, like the Global Fund.

### III: Project Description and Findings

#### A) Project Description

From 2000 to 2005, antiretroviral drugs for HIV/AIDS (ARVs) dropped in price from \$10,000 - \$15,000 per person per year to \$140 per person per year. This drop was the result of intervention by patient activists, generic producers, politicians, multinational pharmaceutical companies, economists, and leaders in the nonprofit health community.

This report examines the drivers of this significant price reduction.

- Findings

There is a wealth of good actors that deserve credit for the success of the AIDS access movement. These findings are in no way meant to diminish the number of forces and people that had to align to build this movement. Since the purpose of this report is to understand exactly how, and through what mechanisms, the price of ARVs went down, I am obliged to offer some preliminary conclusions with the full acknowledgement that there is room for disagreement here.

In this report, I argue that the sustained price drop came through the establishment and growth of the generic ARV market. This market was created by producers in India, third-party buyers (first in Brazil and then later in other government or international entities), and activists who forced both the United States and the global pharmaceutical industry to loosen their grip on international patent law. The market was then refined through the intervention of economists working for Ralph Nader and staffers at the Clinton Health Access Initiative (CHAI).

This assessment acknowledges the valuable intervention of non-profit organizations that partnered with pharmaceutical companies to test access projects. For these projects, originator companies generously lowered the cost of their medications, from as high as \$15,000 per person per year to as low as \$1,000 per person per year. It is possible that these companies would have continued to lower their price to the current rate of \$140 per person per year, in the absence of further intervention by philanthropic actors and generic drug companies. However, I see no evidence to suggest that the philanthropic price would have come down without pressure from third-party buyers purchasing low-cost generics. While I was unable to reach parties within the pharmaceutical industry who could confirm or reject this thesis, my sources overwhelmingly agreed with this

assessment. It is also important to remember that the prices from the first drop were based on private negotiations and dependent on the largesse of specific companies.

Without a serious global commitment to permit and promote generic production, ARV prices would have remained irregular, opaque, and subject to the whim of companies holding patents. The scholars Ethan B. Kapstein and Joshua W. Busby agree with this assessment, arguing that the generic market was willfully created by a “constellation” of actors.

[E]conomists have generally argued that what brought down the price of ARVs around the world was entry by low-cost generic producers.... What this perspective overlooks, however, is that the groundwork for generic entry was laid by advocates who sought to show in the first instance that ARV delivery in the developing world was effective and who then helped to pool demand in order to create a market sizeable enough to be of commercial interest. Finally, they helped spur industrialized world governments to increase foreign aid funds that were earmarked for AIDS treatment, so that developing world governments could acquire the drugs at these reduced prices. Generic drugs, in short, did not ‘drop by parachute’ into the developing world; their entry was catalyzed by advocates, that at a minimum helped save many lives speeding drug delivery.

The most important and sustainable aspect of the price drop in ARVs came from the deliberate and hard-fought creation of a market for generic drugs, a market that relied on (1) the existence of companies, like Cipla Ltd., with proven expertise in making high quality, high volume, generic drugs; (2) a permissive legal environment for the production and purchasing of generic drugs; (3) the ability of the World Health Organization to offer quality control; (4) and the creation of substantial third party purchasers, like the Global Fund.

#### IV: Sources

In 2014, GiveWell commissioned Brian Coyne to conduct a literature review of the ARV price drop. This report draws heavily from Coyne’s thorough research into the available literature on ARVs and the access campaign (sometimes to the extent of using passages from his literature review in the main text). I have flagged sections that Coyne authored (or co-authored) with footnotes following the section header.

To supplement Coyne's research, I conducted in-depth interviews with actors involved in the creation and refinement of the generic drug market, including individuals from the Global Fund, the World Health Organization, and the Clinton Health Access Initiative (for a complete list see the *Selected Sources* section).

I supplemented these interviews with a limited literature review of my own. I focused my attention on the articles and books that were both easily accessible (through the web,

ProQuest, and an academic library) and provided the largest amount of relevant information. One book in particular proved immensely useful and deserves special mention: Ethan B. Kapstein and Joshua W. Busby's *AIDS Drugs For All*.

*AIDS Drugs For All* uses the ARV market to explore the effects of social movements on market transformations. I urge anyone interested in this topic to read this well-researched and complex synthesis of activism and pharmaceutical market transformation.

## V: Price Graphs

Throughout this paper, I reference the shifting price of ARVs. While various organizations report slightly different numbers, the trend is clear.

There are three major price drops. The first, and I would argue the least sustainable, took place in the early 2000s when pharmaceutical companies made discreet deals with countries and nonprofits to see if ARVs could be used effectively in resource-poor nations. While the magnitude of the drop is significant (the price of ARVs arguably dropped from between \$10,000 - \$15,000 per person per year to approximately \$1,000 per person per year), it is important to keep in mind that these prices were negotiated privately and relied on the generosity of particular companies.

The second price drop occurred from 2001 to 2003 and can be attributed to the creation of a viable market in generic ARVs. Here it is important to note that this market was forged by activists, political leaders, and company leaders. While scholars often estimate the magnitude of the second price drop at about \$700 (prices fell from \$1,000 per person per year to around \$300 per person per year), it is valuable to remember that these were the first transparent public prices, so the exact magnitude of the drop is not known.

The third price drop, from approximately \$300 per person per year to \$140 per person per year, occurred when the Clinton Health Access Initiative intervened to rationalize the generic drug market in ARVs (see section IX for further discussion of CHAI).

The first graph below (figure 1), from *Medecines Sans Frontiers* (Doctors without Borders), displays the price drop between 2000 and 2003, the second graph (figure 2), from the Clinton Health Access Initiative, displays the price drop between 2003 and 2005, and the last graph (figure 3), from AVERT, displays the price drop between 2000 and 2002. I will be referencing these graphs throughout the report.

*Figure 1: ARV Prices Between 2000 and 2003*

*Figure 2: Comparison of 2003 and 2005 ARV Prices*

*Figure 3: ARV Prices Between 2000 and 2002*

## VI: Background

### A) Highly Active Antiretroviral Therapy (HAART)

In 1996, after a decade of activist pressure and pharmaceutical research, an effective therapy for the AIDS virus became available. HAART (highly active antiretroviral therapy), a combination of antiretroviral drugs (also called ARVs, or a "triple cocktail"), transformed HIV and AIDS from a death sentence to a chronic disease in countries where patients, their insurance companies, or their governments could afford to pay for treatment. Four years after the introduction of HAART, death rates caused by AIDS-related illnesses in developed countries had dropped by 84 percent." By the 21<sup>st</sup> century, AIDS had become a manageable, if expensive, disease to treat in the United States and Europe. The drugs themselves cost between \$10,000 - \$15,000 per person per year.

In Africa, AIDS stricken individuals were dying at an alarming rate. In 1999, the World Health Organization (WHO) stated that HIV/AIDS had become "the fourth biggest killer worldwide and the number one killer in Africa." WHO approximated that 33 million individuals were currently infected with the virus. AVERT reported that "Five years after HAART was introduced in the West, only 2 percent of people in developing countries were receiving the life-saving drugs."

In the mid-1990s, numerous public health professionals believed that ARVs could not be

appropriately distributed in resource constrained countries. Experts also feared that partial adherence to ARV drug regimens would encourage the development of ARV-resistant strains of the disease. To transform this consensus, and push for the value of universal access, activists would have to prove that ARVs could lower in price and that the drugs could be administered properly in resource-constrained economies.

There is no single starting point of the ARV price drop story. For the purpose of this report, I will begin, as the economist and intellectual property policy expert Jamie Love does, with the partnership between Brazil and Indian generic pharmaceutical companies, which built the first low-cost market for the active ingredient in generic ARV drugs.

## B) Building the Generic Drug Market

In Brazil, healthcare is a right established in the country's constitution. Once AIDS therapy became effective in the mid-1990s, the Brazilian government had an obligation to provide AIDS treatment to its citizens. It did so by manufacturing and purchasing large quantities of generic ARVs. Brazil was not the first country to manufacture generic ARVs. It was, however, the first country to purchase ARVs in bulk for its citizens. In Love's words, "The [Brazilian] government was providing insurance for people with AIDS and that created a market.... They were spending in the 90s about 150 million dollars on ARV drugs per year. That was almost all of the developing countries purchasing of AIDS drugs."

In the 1990s, Brazil could manufacture the drugs but had a limited capacity to produce the necessary active ingredients. Generic drugs, my sources agree, are relatively easy to manufacture (for the process see figure 4).

### *Figure 4: Pharmaceutical Production Process*

The hardest aspect of generic drug production is producing (or purchasing) the Active Pharmaceutical Ingredients (APIs).

In 1996, the Brazilian government turned to India, a crucial world source for generic drugs and APIs, to purchase active ingredients for local production of ARVs.

Since the early 1970s, India had forbid patents on pharmaceutical chemicals (product patents) but permitted patents on manufacturing methods (process patents). This approach helped create the country's vibrant generic drug industry, which, by the 1990s, had begun reaching beyond domestic clients to the international market. As Love argues, due to the focus on innovation in manufacturing, "Indian companies became better than European-American companies at making the drugs...[and] became the dominant

supplier of active pharm ingredients for the world.” Mainak Mazumdar, author of *Performance of Pharmaceutical Companies in India*, concurs, “Because of the competence gained by the Indian pharmaceutical companies in process engineering, the Indian companies...gained a reputation in the international market as a low-cost producer.”

In 1992, the Indian company Cipla, spurred by its managing director Yusuf K. Hamied, began reverse-engineering AIDS drugs. Hamied told the *Wall Street Journal* that he did so because “he realized the epidemic would hit India hard.” In 1996, when HAART therapy was introduced, Cipla was well poised to produce the active ingredients, and started, along with other Indian generic firms like Ranbaxy, to create enough volume to supply the Brazilians.

This partnership between the Brazilian government and Indian generic pharmaceutical companies would become the model for universal access. As Kapstein and Busby write, “In an important sense this Brazilian approach to ARV treatment, which combined universal access on the one hand coupled with efforts at restructuring pharmaceutical markets on the other, became the ‘model’ which the treatment advocacy movement sought to expand on a global basis.”

The partnership model was challenged from the start. New international patent law, established at the World Trade Organization (WTO) in 1995, made the Brazilian purchasing arrangement with Indian companies extremely precarious.

### C) International Patent Protection and TRIPS

In 1995, three years after Cipla began reverse engineering AIDS drugs, and one year before HAART became available, the WTO implemented a new set of intellectual property laws called TRIPS (The Agreement on Trade-Related Aspects of Intellectual Property Rights). TRIPS ensured that countries with different types of patent laws would comply with the patent system set up in developed countries like the United States.

In 1996, Brazil changed its patent laws to comply with TRIPS. Drugs that were invented before the new patent rules went into effect (such as AZT, an antiretroviral drug) could still be produced. Under TRIPS, India had a grace period and could manufacture generic ARVs and APIs until 2005, at which point the country would have to be TRIPS compliant. The purchasing arrangement between Brazil and India would be quickly challenged as it spread to South Africa in the late 1990s.

Before turning to the South African story, it is important to assess the relative importance of TRIPS. Accounts of the AIDS Access Campaign (an activist movement to expand access to ARVs in developing countries) often focus on the methods activists used to lobby governments to revise TRIPS leading up to the 2001 Doha Declaration. My research does not overturn this narrative, but it does temper its centrality to the larger price reduction story.

Anil Soni, an expert who has worked at almost all of the major institutions involved in



the ARV price drop, including the Global Fund and CHAI, argued that TRIPS was never the crucial barrier to price reduction. “If you look back at TRIPS... not even India, none of the [relevant] countries needed to respect patents yet [under the TRIPS agreement].” Technically, Soni is right – TRIPS was not a meaningful barrier to entering the ARV generics market in the late 1990s.

In the late 1990s, pharmaceutical companies used TRIPS to challenge generic ARV production. By so doing, they created a unified target vulnerable to attack by activist groups. In 1997, 39 pharmaceutical companies sued South Africa over a TRIPS violation. This lawsuit galvanized disparate AIDS activists and increased the public profile of the low-cost ARV access issue.

#### D) South Africa

In the mid 1990s, South Africa had one of the world’s highest rates of HIV infection, close to 20 percent, with 4.7 million people living with the disease. The South African government, under Nelson Mandela, resolved to try to make ARV drugs more widely and cheaply available in the country. In 1997, the South African Parliament passed a law giving the Minister of Health the authority to take two kinds of actions to increase the availability of HIV/AIDS medications: compulsory licensing of patented ARV drugs and parallel importation of ARVs from other countries. Compulsory licenses allow a generic manufacturer to produce a limited batch of a patented drug to combat a specific public health issue. Parallel importation allows countries, under certain conditions, to import drugs from countries where that drug might be cheaper.

After the law was passed, a group of 39 pharmaceutical companies sued South Africa, arguing that it was violating its obligations under TRIPS and violating their rights under the South African constitution.

The United States government initially supported the lawsuit. A bipartisan group of 47 members of Congress signed a letter asking the United States Trade Representative (USTR) to “pursue all appropriate action” against South Africa’s policy. With the Clinton Administration on board as well, the USTR placed South Africa on a “watch list” of countries suspected of violating intellectual property agreements, an action that automatically suspended beneficial trade terms that had previously been approved for a number of South African products. Congress also suspended bilateral aid to South Africa and explicitly demanded repeal of the country’s patent law as a condition for the resumption of aid.

In addition to pressuring South Africa through diplomatic and legal channels, the drug companies applied their own economic pressure to South Africa. Merck dropped a planned \$10 million investment in the country, and Bristol-Myers Squibb, Pharmacia & Upjohn, and Eli Lilly all shuttered their factories in South Africa.

### VII: The First Price Drop – the Access Campaign and Pharma Philanthropy

## A) The Access Campaign

The South African lawsuit “had a catalytic effect on the global AIDS movement,” inspiring a wide array of philanthropically funded non-governmental organizations (NGOs) to fight for access to ARVs. This section examines this fight, which has often been called the access campaign.

The access campaign NGOs began a multipronged public relations initiative aimed at pharmaceutical companies and politicians involved in the South African lawsuits. The NGOs feared that a successful lawsuit against South Africa would have a chilling effect on the efforts of other developing countries to use compulsory licensing and parallel imports to increase ARV access.

Oxfam, ACT UP, and MSF issued press releases and took out ads critical of the pharmaceutical industry. MSF started an online petition demanding that the drug companies drop the lawsuit. ACT UP organized demonstrations in New York City against the pharmaceutical companies outside their corporate offices, featuring slogans like “Stop Medical Apartheid of AIDS” and “Drug Company Greed Kills.” The access NGOs’ “name and shame” campaign was widely considered a success, and the lawsuit became a “public relations nightmare” for the pharmaceutical companies.

The access NGOs also worked, both publicly and privately, to change the US government’s position on the issue. Prior to 1999, the United States, home to many of the major international pharmaceutical corporations, had been one of the more hardline defenders of strong patent rights for medications. When the pharmaceutical companies first sued the South African government over its patent law in 1997, the United States strongly supported the lawsuit. However, in 1999 the Clinton administration withdrew its support – President Clinton issued an executive order instructing the USTR to henceforth prioritize access to essential drugs over intellectual property rights for medicines. The United States later became a major supporter of the Doha Declaration of 2001, which advocated for TRIPS flexibilities to increase access.

Al Gore, while running for President, similarly changed his position and began supporting increased access to ARV drugs. The popular press at the time largely credited the access campaign with this policy turnaround. Our assessment of the situation based on the information publicly available is that Gore was moving, slowly and behind the scenes, toward a more access-friendly position, but the access campaign pushed him to support access more quickly and publicly.

Deprived of support from the US government, and under withering criticism from the access NGOs and others, the pharmaceutical companies admitted defeat. In April 2001, the pharmaceutical companies not only agreed to drop the lawsuit against South Africa but also took the unusual step of reimbursing the South African government for its legal expenses.

- Pharma Philanthropy and the First Price Drop

After the win in South Africa the AIDS activist community settled on prices and access “as the heart of the strategy.” Kapstein and Busby date convergence to the 2000 Durban AIDS Conference where lower drug prices “seemed like a winning, reachable, position.”

This strategy seemed feasible because of three major changes in the ARV landscape that took place in the late 1990s: tiered pricing, shift in public opinion, and proof of concept programs.

*Tiered Pricing:* In the 1990s, the pharmaceutical industry consolidated and globalized. Over 10,000 alliances were formed as the industry began to expand internationally. With expansion came the idea of ‘tiered pricing’ (sometimes referred to as differential pricing). Drugs would now be priced appropriately for different classes of consumers living in different regions of the world. Due to tiered pricing, activists could visually see that drug prices were negotiable.

*Public Opinion:* Contemporary news accounts make clear that by early 2000, executives at the major pharmaceutical corporations were deeply aware of the changes in world opinion and reeling from the negative publicity, which *the Guardian* described as “one of the great PR disasters of all time.” *The Washington Post* portrayed the pharmaceutical industry in March 2000 as “a \$350 billion industry on the run” and wrote that “Two years of public censure, with charges of profiteering on history’s worst pandemic, had brought the manufacturers of AIDS medicines close to pariah status in U.N. forums” and in global public opinion more generally.

*Proof of Concept Programs:* For much of the 1990s, explained Anil Soni, scientists and public health experts stressed the “challenges of putting individuals outside of the first world on the complicated ARV regimen.” In the late 1990s, “a series of programs would dispel the world of that assumption.” These programs proved that HAART therapy could be delivered and followed anywhere in the world.

Pilot programs, like the United Nations funded Drug Access Initiative (DAI) and its larger successor the Accelerated Access Initiative (AAI) assisted countries by establishing nonprofit organizations that purchased, using funds from UNAIDS and other donors, ARV drugs from manufacturers at discounted prices. By 2000, numerous pharmaceutical companies were interested in pursuing this strategy, which I refer to as Pharma Philanthropy. As Soni explains, the companies had three major motivations to invest in these programs. The first was the simple fact that they “had nothing to lose. There were no sales in Africa and they had no expectation of sales.” The second was “that if there were poor quality products out there and the companies didn’t act, then there was the possibility of diversion, which would undermine their principal high income markets.” Finally, multinational pharmaceutical companies needed to insure that they could still capture middle-income markets like Brazil or South Africa with strong patent laws for other drugs.

DAI, AAI, and numerous other pilot projects successfully established the viability of access programs and demonstrated that pharmaceutical companies would lower the cost of ARV drugs for discreet, viable distribution projects.

### C) Summary of the First Price Drop

By 2001, due to pressure from activists, pharmaceutical companies offered philanthropic prices for pilot projects. In some instances, the price of ARVs dropped to \$1,000 per person per year. The lower prices were both financially strategic and motivated by the goodwill of pharmaceutical company leaders. I have not encountered any evidence that suggests these prices would have come down further without the introduction of generic ARVs.

Pharmaceutical philanthropy would not become the long-term solution to the access problem. Major price drops would be achieved in the coming years through the creation of a competitive generic market for ARVs. As Kapstein and Busby conclude:

Major pricing reductions on ARV drugs would not be achieved until generic competition came on the ARV scene after 2000, a few years after the DAI scheme was launched. And it was the promise of cheap generics, rather than the differential prices of branded products, that really made the idea of ‘universal access to treatment’ more than a pipedream.

The value of the first price drop for the long-term success of the access movement was arguably not in the lowered price of ARVs. Rather, pharmaceutical companies and the nonprofits they partnered with proved that ARVs could be successfully distributed and taken in countries throughout the world.

### VIII: The Second Price Drop – Creating the Generic Market

- Cipla

While some activists were pressuring pharmaceutical companies to slash their prices, others, such as Jamie Love, were working with generic companies to create a low enough offer on ARVs that the entire health care community would have to switch tactics. They sought to transform the market from a high-cost low-volume model that relied on originator companies to a low-cost high-volume model that relied on generics. This strategy hinged on an Indian pharmaceutical company Cipla and its CEO, Yusaf Hamied.

By 2001, Cipla was the “market leader in AIDS drugs in India” and a singular authority, due to its connection with the Brazil purchasing program, on how to scale up generic ARV production. For Jamie Love, an economist specializing in knowledge-based goods working for Ralph Nader and head of the Consumer Project on Technology (CPTech), Yusaf Hamied and Cipla provided an opportunity to counter high-price branded drugs with low-cost generics.

In the late 1990s and early 2000s, Love began asking experts (both inside and outside the U.S. government) “what it would cost to manufacture AIDS cocktails without the

patents.” He wanted to uncover the exact dollar amount it cost to manufacture the drugs. “What was incredible to me at the time,” he said, “was that nobody seemed to know.” The White House “said they have no idea.” “How could they not have an idea?”

Love decided to find out. With expenses covered by Nader, he started to travel to countries that were producing generic ARVs, such as Thailand, and decided that what he really needed to do was contact a major generics producer, like Cipla.

After reverse-engineering ARVs for a decade, Indian pharmaceutical companies had developed a major innovation in ARV production. There were dozens of patents covering the complex ARV cocktail therapy. Since Cipla and Ranbaxy (another Indian pharmaceutical company making ARVs) did not have to respect those patents, they were able to combine multiple drugs into one pill. As Anil Soni explains, “Fixed-dose combination started in India. At the time, this was incredibly novel. You could take one pill twice a day instead of multiple pills multiple times a day.” The combination of “three antiretrovirals (patented by different pharmaceutical companies) into a single pill [became] known as a fixed dose combination (FDC).” As described on the AVERT website, “[FDCs] were a significant innovation as they reduce the number of pills taken each day. Because FDCs are easier to manage – for both patients and health workers – they increase adherence, thereby reducing the incidence of drug resistance. The drugs were also available in heat resistant forms, which proved extremely valuable for use in the developing world, where often there is scarce access to refrigeration facilities.”

Cipla had developed the drug, but it had not yet found a large market for it. There were two reasons for this: 1) besides the Brazilian government, there were no major third-party buyers, even in India, and 2) until the Doha Agreement, international patent law restricted sales. As the WSJ reported, “In August, Cipla canceled a shipment of its Combivir AIDS drug to Ghana after getting a letter from GlaxoSmithKline warning that the product was under patent. Ghanaian authorities disagreed, and even Glaxo officials now concede they were in error. Even so, Cipla decided not to stay and fight.” In the summer of 2000, ARV medication was still a high-cost, low-volume product, even for generics.

Love and William “Bill” Haddad, an affordable drug activist, flew to London to meet Hamied to change that equation. In the summer of 2000, Hamied, reports the WSJ, impressed the group “with his offhand recitation of the costs of making AIDS drugs. Asked about AZT, he said ‘Talk to the Koreans, they’re cheaper than the Indians.’” Love recalls the group discussing in detail “how to identify sources of raw materials for drugs that were not controlled by branded drug companies.” Hamied and Love worked out on paper how Cipla could supply ARVs at the lowest cost possible. As Love recalls,

He kind of showed me how to breakdown the price and what cocktails we could and couldn’t get. That eventually became the basis of the Cipla offer that I negotiated in January and early February in 2001 for MSF. I worked out the price in the summer of 2000. I didn’t think it was a big deal at the time. Everyone knows if you buy in bulk you would get a great price. It’s straightforward.

On September 28, 2000, Hamied arrived at the European Commission meeting in Brussels to announce his offer. Seated between representatives from Merck and Glaxo (two major pharmaceutical companies), Hamied, the sole representative from a generic company in attendance, rose and said:

We strongly believe that in the third world there should be no monopolies for vital, lifesaving, essential drugs. We are the only manufacturers today of one of the triple drug combinations proven to be effective. We are ready to offer this combination internally at U.S. dollars at \$800 per person per year.

Cipla's bold offer rattled the pharmaceutical companies without actually increasing sales. As Hamied lamented following the meeting, "No one took us seriously and I was absolutely disillusioned." The price, claimed Jamie Love, wasn't bold enough. Love wanted to find a price that was so low that it would convince governments and international bodies that they could actually afford to purchase ARVs in bulk from generic companies rather than negotiating with brand-name pharmaceutical companies.

#### B) A Dollar A Day

Jamie Love continued to press for a generics market. He traveled back to India in December 2000 to see how trade rules could be revised to support generic competition. There, he encouraged Cipla to draft letters to drug companies that held patents on AIDS drugs for a voluntary license to produce the drugs. He also continued working with Hamied to get what he called "a dramatic price."

In January, Love met with Bernard Pécoul, then the Medical Director of MSF, and "suggested that a \$350 annual per patient ARV price might be possible." Love and Hamied had been talking for months. Love knew that if Cipla agreed to swallow production costs, a price of \$1 a day was possible. Cipla was already producing the raw materials and production costs in India were low. Love saw that Hamied could still turn a profit if MSF would purchase in bulk, pay cash, and take care of distribution." As Love explained, under those conditions "it wasn't a humanitarian price. They would be making a profit." Love also anticipated that the \$1-a-day price would spur demand, competition, and increased efficiency in the generics market, all of which would keep the price down. Nine months after the offer, "\$1 a day had fallen to about \$240 a year. It was about \$140 a few years later."

In emails reported by the WSJ, Love wrote to Hamied regarding the \$350 price he had offered to MSF, "Cipla could call it a donation or whatever it needs to," Mr. Love said in one such message. "This will be a very closely watched price quote, and will go directly to the question of whether or not Africa should pursue a generics strategy, or negotiate endlessly with the big pharma players." The January 26<sup>th</sup> earthquake in Gujarat created the emotional backdrop that convinced Hamied to go through with the offer, which he settled on February 6<sup>th</sup>.

On February 7<sup>th</sup>, 2001, Hamied sent MSF “a faxed confirmation letter ... offering [the] \$350 price, so long as the drugs were distributed free of charge.” Love called Donald McNeil, a reporter who had been covering AIDS access and the story ran on the front page of *The New York Times*.

The offer, which came to be known as a *\$1 A Day*, and the media frenzy it created, transformed the ARV market and offered the feasibility of broad international access to AIDS medication. In Love’s words, “It was the magic number. It completely changed things.”

For the first time, large governing bodies realized they could actually afford to purchase ARVs in bulk. It also, as Love predicted, pushed access advocates to support generic production rather than lobby for philanthropic prices from pharmaceutical companies. As the WSJ reported, “Health-care advocates in the U.S. are paying attention, too. Cipla’s price, \$350 a year per patient for a one-three-drug cocktail known to extend lives of AIDS patients, is 1/30 of the treatment’s costs in the U.S. Paul Davies of AIDS activist organization Act Up/Philadelphia says his group has decided to lobby against big drug companies’ patent extension in the U.S. in order to pressure them to sell drugs cheaply in Africa.”

In response to the Cipla’s offer and international attention, major drug companies started reducing the price of their drugs. As reported in *The New York Times*: “Last week, in an effort to encourage African nations and international donors to begin buying or subsidizing the drugs, but also partly in response to Cipla and its Indian rivals, Merck & Co. slashed its prices by an additional 50%. New price cuts from other big companies are expected to follow.”

### C) Doha and Reinterpreting TRIPS

Cipla’s offer also put increased pressure on international patent law.

As early as 1999, a group of representatives from 350 NGOs from 50 countries met in Amsterdam to plan their strategy for the upcoming WTO meetings in Seattle and Doha. The group produced a document called the “Amsterdam Statement,” which spelled out their desired changes to TRIPS, including strengthening the ability of developing countries to use compulsory licensing and parallel imports, encouraging research into diseases predominantly affecting developing countries, and assisting developing countries in building domestic pharmaceutical industries. While we cannot be certain, the evidence suggests that the access NGOs were instrumental in pushing international actors to revise TRIPS at the November 2001 Doha conference.

This effort was helped by a change in the way the WTO worked. NGOs did not have much of an opportunity to participate in the Uruguay trade talks that produced TRIPS. However, by 2000, the WTO was allowing NGOs to attend trade talks. 674 NGOs were officially accredited to participate in the Doha talks, including MSF, the French affiliate

of ACT UP, and seven branches of Oxfam. Once they were “embedded” in the process, the access NGOs helped developing countries organize as a bloc.

By this point, the United States had also changed its position. Prodded into action during the run-up to the 2000 Presidential election, President Bill Clinton had prioritized access to essential medicines over pharmaceutical patent rights, and President George W. Bush reaffirmed this stance when he took office.

Brazil, with its large population, growing economy, and substantial generic pharmaceutical industry, emerged as the leader of the bloc of developing countries, and the final text of the agreement was hashed out predominantly by the United States and Brazil. They agreed that, rather than amend or rewrite TRIPS, the WTO would adopt a definitive statement about how the ambiguous provisions of TRIPS should be interpreted.

The resulting Declaration on TRIPS and Public Health began with statements recognizing the seriousness of the public health problems in developing countries and, in its main operative clause, declared that “We reaffirm the right of WTO Members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.” This meant that any contested provision of TRIPS should be interpreted in the way that helps improve access to essential medicines.

Doha thus effectively foreclosed the possibility of WTO sanctions over compulsory licensing and parallel imports and, crucially, put all of its signatory countries on record as supporting these provisions.

Nine months after Cipla’s offer, patients across the globe could now legally purchase generic ARVs. Legal permission, however, did not immediately transfer to increased sales. In the countries hardest hit by the AIDS epidemic, \$350 a year was still too much for most patients to afford. In the coming years, third-party international buyers would step in, inspired by the low cost of generics, to purchase and dispense ARVs to the world’s needy patients.

#### D) The Global Fund and Third Party Purchasers

At the end of 2002, despite proof of concept programs, pharma philanthropy, low offers by generic companies, and changes to international patent law, “the number of people on ARVs was still paltry, hovering well below 500,000. “[O]nly one in a thousand people living with HIV in Africa had access to treatment.” By 2010, in contrast, in excess of 6 million people were estimated to be on treatment.” Viability and lower prices did not automatically increase demand.

Affordable medicine and proof of concept programs were not enough to solve the access problem, but they were enough to prompt the creation of “bilateral and multilateral funding mechanisms” that would. Kapstein and Busby write, “Given that many patients lacked purchasing power to buy drugs on their own, credible commitments of money to purchase ARVs were essential for the universal access market to function.” In 2002, the



Global Fund, in 2003 PEPFAR (the U.S. President's Emergency Plan for AIDS Relief), and in 2006 UNITAID would start purchasing bulk orders of ARVs and distributing them directly to non-profits and countries capable of reaching patients. From the outset, these organizations had to decide which drugs to purchase – branded or generics.

The Global Fund to Fight AIDS, Tuberculosis and Malaria, is a financing instrument “created in 2002 to save lives and direct the world’s money to those most in need.” G8 leaders acknowledged the need for such a fund at the 2000 summit in Okinawa, Japan and Kofi Annan, then the U.N. Secretary General, officially called for its creation at the African Summit on AIDS in Abuja, Nigeria in 2001. The funding pool initially drew from government and private sectors donors, such as the United States and The Bill & Melinda Gates Foundation. By the time the Fund was official in 2002, experts working at the WHO recall that it “struggled to use its funds wisely. For new generic medicines, the Fund and other donors needed assurances that quality was acceptable.” Anil Soni, who worked at the Fund during this period, recalls their first board meeting in April of 2002, “at that time, we said to the Board we don’t have a policy on what we were allowed to buy.” The rise of rigorous quality assurance by WHO would give the Fund the needed assurance to purchase generics.

#### E) The World Health Organization and Prequalification

The WHO began offering quality assurance for pharmaceutical products in 1999, when a study showed that the active ingredients in some tuberculosis (TB) medications were not being absorbed in patients, thereby allowing the TB to spread. Activists reached out to the WHO about ARVs after Cipla’s \$350 offer in 2001. Kapstein and Busby relate one example:

Within the week, Dr. Hamied, the leader of Doctors without Borders and I [Bill Haddad] went to the World Health Organization and laid out our case. If WHO did not create a one-stop approval process, the multinationals would drag us from one courtroom in one country to another courtroom elsewhere, trying to wear us out. WHO agreed and Canada, the EU, Scandinavia and South Africa created an airtight regulatory pathway that was as stringent as any in the world including the FDA....

According to Dr. Jonathan Quick, the Director of Essential Drugs and Medicines Policy at the WHO, experts at the WHO understood that there would be “gridlock in the Global Fund,” without an “independent quality certification of ARVs.” WHO staff began creating a prequalification program in the early 2000s. As explained in a paper on the subject by 't Hoen et al., “The term ‘prequalification,’ refers to the outcome: after WHO approval, a product is deemed ‘prequalified’ to participate in UN procurement tenders. Products that have received approval by a stringent regulatory agency are already eligible for procurement.” Despite pushback from the International Federation of Pharmaceutical Manufacturers (a trade organization representing the interests of large pharmaceutical companies), which “was quick to question whether WHO’s assessment standards were sufficiently strict,” In March of 2002, the WHO “published its first list of

41 approved formulations of ARVs and other HIV medicines.”

The WHO prequalification program gave the Global Fund an opportunity to allow its grantees to purchase generic ARVs. This, explains Soni, was the final piece in the “jigsaw puzzle” of attaining global access to ARVs. In his words, “The generic companies created it, the Global Fund said they could buy it, and WHO would approve it.” This process had the added benefit, he explained, of making the price transparent. Tiered pricing and philanthropic pricing by pharmaceutical companies had left the price of ARVs opaque – now there was an open market and a serious buyer.

#### F) Third Party Procurement

Inspired by the Global Fund and the magnitude of the AIDS health crisis in Africa, President George W. Bush announced the U.S. President's Emergency Plan for AIDS Relief (PEPFAR) in his State of the Union Address in January 2003. This plan authorized the U.S government to spend \$15 billion in five years towards HIV/AIDS treatment programs.

In his address to the nation announcing PEPFAR, President Bush quoted the generic price for ARVs, stating, “AIDS can be prevented. Anti-retroviral drugs can extend life for many years. And the cost of those drugs has dropped from \$12,000 a year to under \$300 a year, which places a tremendous possibility within our grasp. In fact, explains Love, the feasibility of a reasonably priced generic actually inspired the U.S. government to act. Love recalls Mitch Daniels, who was then the Director of the U.S. Office of Management and Budget, telling him that “when the price was a couple thousand they just figured no way. They couldn’t justify it from a cost-benefit ratio. When the price got down to a \$1 a day they had to do something. They became big believers in AIDS treatment.” The pharmaceutical industry reacted negatively to Bush’s announcement and PEPFAR began its purchasing program by buying brand-name ARVs. PEPFAR eventually moved towards purchasing generics after 2004.

By 2006, when UNITAID was formed, funded by a tax on plane tickets, third-party procurement of generic AIDS medication had become a productive norm facilitating the goal of universal access. Kapstein and Busby write:

What the various procurement programs under the Global Fund, PEPFAR, and UNITAID have in common is that they have delivered affordable medicines to patients at scale. With the Global Fund and PEPFAR each taking credit for 3 million-plus patients on ARVs, and UNITAID providing ARV services to almost a million people, that was demonstrated. While branded pharmaceuticals have been crucial sources of ARV supply, particularly for PEPFAR before the FDA expedited approval for generics, low-cost generic ARVs, aside from procurement and distribution systems, have enabled these programs to ramp up to wider numbers of people.

#### G) Summary of the Second Price Drop

By 2002, the global community had the low, transparent price of \$300 per person per year from generic companies. With the second price drop the major attributes of the global ARV market had solidified. Generics would be produced by generic companies, evaluated for efficacy by the WHO, and purchased by large third-party buyers (the Global Fund, PEPFAR, and UNTAID), and distributed to patients across the globe through nonprofit organizations and national health ministries. The combination of international organization purchasers, like UNTAID, and individual country purchasers, created a competitive and sustainable market for low-cost and high-volume ARVs.

## IX: The Third Price Drop – CHAI and the Market-Shaping Approach

### A) Clinton Health Access Initiative (CHAI)

In our investigation of this topic, the Clinton Health Access Initiative (CHAI) came up numerous times as the cause of a final price drop (from around \$300 per person per year to \$140 per person per year). While I contend that CHAI's actions in the generics market helped move the price from \$300 to \$140 per person per year, some Open Philanthropy and GiveWell analysts are not convinced, and argue that the price would have continued to go down without CHAI's intervention. Below is my summary of the events.

By 2002, Jamie Love, Bill Haddad, and Yusaf Hamied had proven that a certain kind of market manipulation could work. The *\$1 A Day* offer spurred international bodies to become reliable and major buyers of generic ARVs, which in turn drove down the production costs. ARVs were on the way to becoming a low-price, high-volume business. By the end of 2001, claims Love, purchasers could acquire ARVs for as low as \$250 per person per year. Still, in 2002, 6 million people were in need of treatment and only 300,000 patients were receiving medication.

In October of 2002, CHAI “was created to bring care and treatment to people living with HIV/AIDS and to strengthen health systems in resource-poor countries.” When CHAI entered the sector, high-volume, low-cost production of generic ARVs was becoming the norm. They looked at this growing sector and realized that they could further lower the costs of ARVs by rationalizing the market. As Soni, who moved from the Global Fund to CHAI in 2005, puts it: the CHAI team got together and asked, “Now that we live in a world that has generic ARVs, how can we get the price down as far as possible?”

For Ira Magaziner, the CEO and Vice Chairman of CHAI, ARV price was never the only issue. As Soni explains, “If countries know that the price will go down it will create confidence that people can afford treatment and will go on treatment. The impact will be greater than the dollar saved because by communicating to the world that the price will be that cheap you actually create the momentum to put people on treatment.” This logic had worked before with Cipla and the Global Fund. From 2002 to 2005, CHAI would learn how to insert itself into the relationship between buyers and producers, in order to increase market size while lowering production costs even further.

CHAI developed its approach while talking with governments about scale up. Magaziner

realized that even companies like Cipla were having a hard time increasing demand, which would in turn lower prices. The normal lag time of the market was preventing countries from moving forward with purchase orders. As Soni describes:

Rather than having a passive approach to the market and waiting essentially for volume and competition to bring down the price, [we thought] why don't we actively engage manufacturers and bring the price down. Why don't we explain the volume they will see in three years? Why don't we forward price. Why don't we agree to a price now that reflects a weighted average view of your cost structure over time; and also let's advise you [on] how you allocate things like overhead and sales marketing, so you are not biasing the price of your ARVs by higher margin products in other markets.

To begin this process, CHAI created a team that came predominantly from the world of management consulting. Soni explains, "...we hired a lot of consultants. I had worked at McKinsey; Ira had consulted with chemical companies. We understood the value chain and we know that there are different levers we can pull to get costs down."

CHAI decided to intervene in the pharmaceutical markets in a number of ways. On the supply side, it convinced manufactures to accept smaller margins but produce more drugs, it helped source cheaper ingredients, and eventually it even paid chemists to develop less expensive manufacturing and synthesizing techniques. Soni recalls:

We engaged with manufacturers to say, "Can we work with you upstream if we can bring the intermediary prices down?" So I went with colleagues to China and we said how can we get the price down... We started looking at the chemistry. Some of the manufacturing process is inefficient. You are not getting the [largest] chemical yield [that you could], or you are using solvents that are too expensive. We worked with professors in the U.S., and post-docs in labs in the U.S. on these chemistry challenges. We also developed the [intellectual property] to get costs down, and then transferred that to manufacturers.

CHAI persuaded manufacturers to sign deals that it had secured with organizations on the demand side. The team realized that even for generic companies, "sale volumes were unpredictable, and purchasers often paid late or defaulted altogether." To persuade the manufacturers to accept slimmer margins, CHAI would have to ensure large and reliable purchasing orders. Soni writes:

What did CHAI and its purchasers agree to in return [for manufacturers offering lower prices]? The agreements require prompt and secure payment terms, such as letters of credit. Further, they reflect principles of sound procurement, each tied to assumptions about cost savings. These include aggregated national orders; ongoing forecasting of product volumes; reliance on international quality standards like WHO prequalification or U.S. Food and Drug Administration approval;

expedited national registration based on those standards; secure distribution of product in country (to avoid leakage into high-income markets); and, finally, movement toward the use of multi-year tenders and splitting high-volume orders across two or more suppliers.

Generic companies knew that they would be paid for the volume on time by responsible governing bodies. Soni summarizes, “This insight gave us credibility with manufacturers, whom we approached with a commitment to stimulate demand and improve procurement practices in partner countries.”

When CHAI first approached Ranbaxy, a generic producer in India, Sandeep Juneja, then a top executive at the company, said that while demand was picking up it was “still weak.” Kapstein and Busby report that CHAI then “suggested that they could put the developing countries together in a kind of pooled procurement. Their idea was to put the people together to form a sort of ‘buying club.’ CHAI, Juneja argued, ‘brought us into their vision of having a very low mark-up.’ He said CHAI asked us to ‘take a leap of faith that this will happen. And we did.’”

The first CHAI agreement on this consortium model contained three major rounds of price cuts. The first came from the high volume, the second came from generic companies willingness to accept slighter margins, and the third came from ‘forward pricing.’ CHAI was able to secure prices that anticipated volumes three years down the line. Soni explains:

API suppliers, in particular, were able to do this because they had confidence that in addition to the volume-based manufacturing savings we assumed, they would be able to achieve higher yields over time (as they gained experience) and, therefore, require fewer raw materials. Knowing the costs would fall, suppliers agreed to forward pricing to help stimulate demand and to gain market share.

“On the basis of these savings,” Soni describes:

CHAI signed agreements in October 2003 with five suppliers specifying prices for nine formulations of the most common ARVs: zidovudine (AZT), lamivudine (3TC), stavudine (d4T) and nevirapine (NVP). Partner API suppliers – Matrix and Hetero – would supply at or below the specified prices when selling to partner formulators. And the partner formulators – Cipla, Ranbaxy, Hetero and Aspen Pharmacare – would sell at or below the specified formulation prices when selling to CHAI purchasers (at the time, a dozen countries which represented a third of HIV prevalence in Africa and 90 percent of prevalence in the Caribbean).

Predictable volumes had a palpable impact. Kapstein and Busby report:

For governments, the new prices meant that ‘[a]ll of a sudden, they could treat six times as many people for the same amount of money’ (Dugger

2006). *The Wall Street Journal* concluded that '[e]ssentially, the Clinton Foundation is becoming a market maker' (Schoofs 2003). For generic firms, this was critical, as Yusuf Hamied of Cipla notes, 'This is the first time a group has come forward with predictable volumes. (Schoofs 2003).

CHAI negotiated agreements pushed the price of ARVs down to \$140 per person per year. This had the added effect of bringing down generic costs generally. In CHAI's estimation, generics went from \$384 per person per year in 2003 to \$192 per person per year in 2005. The CHAI price steadied at \$140 per person per year.

Moreover, according to CHAI, from 2003-2005, access to prices as low as \$140 per person per year, "had been extended to 48 countries, representing 70 percent of people worldwide living with HIV. To date, 25 countries have completed orders for a total purchase of more than 200 million pills, so that more than 180,000 patients on treatment today (2005) are benefiting from medicines purchased under our agreements."

The CHAI approach lowered the overall costs of generic ARVs while increasing international demand. Kapstein and Busby summarize, "Leaving aside the technical role played by CHAI representatives, the initiative has been an important agent in driving down drug prices. One study looking at transactions conducted between July 2002 and October 2007 found that for 9 or 13 dosage forms, CHAI-negotiated prices were statistically significantly lower than non-CHAI purchases."

While mirroring aspects of the Cipla offer, the CHAI market intervention strategy was innovative for a nonprofit. As Soni argues, "No one had done anything like this before. The cooperation between a non-profit and a pharmaceutical industry at that level was completely novel."

#### B) Lessons Learned from the Market-Shaping Approach:

One issue that came up for CHAI was the problem of arriving at sustainable profit margins. Soni explained:

You can't make the prices too low. What we have done for the last ten years is get the prices down. What you don't read is that there is a lowest price past which you can't go. ARVs represent 8% of total HIV/AIDS spending per year right now. We are not the driver of costs for the system for HIV/AIDS, yet because prices of drugs are such a visible target and because there has been such good progress, we continue to be the target of ongoing price reductions to the point of potential unsustainability. We are the victims of our own success.... The price can't be too thin for us [if it is] we could have supply shortages, which has happened this last year and what you can have is manufacturers leaving the market. Cipla and Rabaxy today represent very limited market share. Now it is largely Mylan, Hetero and Aurobindo. With only three manufacturers if one or two falls out and then we are expected to scale up and to double supply, [we have a problem.]

CHAI staffers explained that the goal always had to be a sustainable price. If the market always goes to the lowest bidder it might save money in the short term but constrict the market to a single supplier. A better solution, they explained, is to give 60-80 percent to the lowest bidder and 40 percent to other supplies to keep the market robust and healthy, as competition reduces prices in the long run.

Another significant issue that came up as CHAI attained expertise in procurement was the value of working within governments rather than building a separate supply chain. Although logistically challenging at first, this approach allowed CHAI to create sustainable healthcare infrastructures that could continue to provide care.

CHAI has developed an approach, informed by the logic of financial consulting, that can be applied to numerous health crises. Experts learn about every angle of a market and then productively intervene to eliminate inefficiencies and cut costs. They then work with government institutions on procurement and distribution.

### C) Summary of the Third Price Drop:

Skeptics of the impact of CHAI's intervention argue that the ARV market was already moving towards lower prices and that CHAI-negotiated price cuts were nominal at best. Three responses offered by those involved with CHAI, which were corroborated by other sources, that respond to this objection: (1) the market for ARVs is not a well-functioning market and required intervention; (2) CHAI functioned like other pivotal third party purchasers; (3) CHAI's capacity to offer cost cutting agreements freed up crucial funds that countries could then redirect towards scaling up care.

(1) Soni summarized the first response: "Some would say a well-functioning market would do this anyway. But the challenge is that this is not a well-functioning market." "For example", he explained, "at many pharmaceutical companies the 'intellectual horsepower' is invested in products that make us money." ARVs simply do not make companies enough money. "Moreover, in the early 2000s," Soni continues, "The market was also irregular because it was highly unpredictable. No one knew there would be 13-14 million people on treatment 10 years ago."

(2) It is possible to read CHAI's impact as part of the larger movement of third-party purchasers. As Kapstein and Busby relate, "at the time CHAI began its operations, the Global Fund was new and PEPFAR had yet to launch, so there was no major funding source for ARV purchases in the international community, providing a major inducement to generic entry."

(3) CHAI staffers argued that the cost cutting approach allowed countries to scale up care and reinvest funds that otherwise would have been spent on medication to bolster national healthcare infrastructure.

Even if one argues that prices were going down due to the natural course of generic competition, in my view the CHAI-negotiated cuts helped ensure the third price drop, by

assisting in the expansion of a sustainable generic ARV market.

*Appendices:*

Appendix A: Timeline

**1981**

- *First AIDS case reported in Center for Disease Control's Weekly Morbidity and Mortality Report*

**1987**

- *First AIDS drug AZT approved for use*

**1995**

- *TRIPS (trade-related aspects of intellectual property rights) Agreement enters into force, 10-year phase-in for developing countries (signed in 1994)*

**1996**

- *HAART (Highly Active Antiretroviral Therapy) introduced and proven effective in stopping the progression of HIV*
- *HAART costs between \$10,000 - \$15,000 per person per year*
- *Brazil begins universal ARV therapy*

**1997**

- *UNAIDS DAI (Drug Access Initiative) launched*
- *South Africa passes Medicines Act, patent law to give Minister of Health authority for compulsory licensing and parallel importation*

**1998**

- *February: South African government sued over its 'Medicines Act'*
- *June-July: International AIDS society meeting in Geneva*
- *December: South Africa's TAC formed*

**1999**

- *November: MSF Access Campaign Initiated*
- *MSF, HAI, and CPTech host Amsterdam meeting on access to medicines*
- *December: Seattle WTO meeting, Clinton announces administration will support TRIPS flexibilities*
- *ACT UP and other organizations make pharmaceutical intellectual property policy into an issue in the U.S. Presidential election.*

**2000**

- *September: Cipla announces \$600 - \$800 per person per year at European Commission Meeting in Brussels*
- *January: UN Security Council meeting on AIDS*
- *May: AAI (Accelerating Access Initiative) introduced by five UN organizations*



and six (later seven) pharmaceutical companies.

**2001**

- *February:* Cipla announces a dollar a day triple cocktail
- *March:* WHO prequalification created
- *April:* South African lawsuit withdrawn
- *June:* UN General Assembly meeting on AIDS, political declaration supports universal treatment access.
- *November:* Doha health exception accepted

**2002**

- *January:* The Global Fund created
- *October:* Clinton Health Access Initiative created

**2003**

- *January:* PEPFAR announced
- *October:* CHAI first agreements announced

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## B) Interviews

- Email exchange with Sadeep Juneja, Business Development Director, Medicines



Patent Pool, Geneva, Switzerland (we were never able to schedule a formal interview).

- Interview with Jamie Love, Director, Knowledge Ecology International, December 4, 2014.
- Interview with Dr. Jonathan Quick, President and Chief Executive Officer, Management Sciences for Health and former Director of Essential Drugs and Medicines Policy at the World Health Organization, December 17<sup>th</sup>, 2014.
- Discussion (over email) with Stuart Schweitzer, Stuart O. Schweitzer is Professor of Health Policy and Management at the UCLA Fielding School of Public Health. September 29<sup>th</sup>, 2014
- Interview with Anil Soni, VP, Global Leader for Infectious Diseases at Mylan previously Chief Executive Officer, Clinton Health Access Initiative, and former Advisor to the Executive Director, The Global Fund, October 21<sup>st</sup>, 2014.
- Interview with anonymous staffers at the Clinton Health Access Initiative (CHAI) December 3, 2014.