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Antiretrovirals as Merit Goods

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> The scale-up of antiretroviral therapy is the most ambitious public health undertaking of our lifetimes. We are making history...
>
> (Gonsalves 2008)

When antiretrovirals (ARVs) first came on the market in the 1990s, they were exceedingly expensive; the cost of treatment was upwards of US $10,000 per year.[1] These drugs were thus only accessible to those with high incomes or exceptionally good health insurance, and gay activist groups – notably the militant organisation ACT-UP – targeted pharmaceutical companies, insurance providers, and governments for changes in their home governments, rather than at the global level (d'Adesky 2004; Kramer 2003; Johnson and Murray 1988; Smith and Siplon 2006).

By the year 2006, however, the 'international community', meeting as a United Nations General Assembly Special Session (UNGASS), made an astonishing pledge to those who were infected with HIV. It declared that there should be *universal access to ARV treatment*. This UNGASS, following up on an earlier historic UN special session devoted entirely to AIDS in 2001, marks the first time in history that the international community has set a policy goal of chronic care for the ill – of establishing what Mead Over has labelled an international 'entitlement scheme' (Over 2008) – which in this specific case includes the approximately 30 million people around the world estimated to be HIV positive (UN General Assembly 2006). Political declarations have been backed by ample funding, as financial commitments to address the AIDS crisis in the developing world have grown from almost nothing in the 1990s to about US $8.7 billion in 2008 (Kates *et al.* 2009). While funds from the global community only put about 4 million HIV-positive individuals in middle- and low-income countries on ARV therapy by the end of 2008, this was up from 400,000 at the end of December 2003 (UNAIDS 2009; WHO 2008b).

How do we explain the transformation of ARVs from private goods, which only a very few of those infected with the HIV virus in developing countries could afford, into merit goods or entitlements, defined as goods that *should* be made available to everyone, irrespective of their ability to pay for them (Musgrave 1959)? In other words, how does a norm of 'universal access to treatment' – that no person should be denied life-extending drugs – become the ethical basis for global public policy with respect to pharmaceutical allocation?

Briefly, in this chapter we argue that the policy entrepreneurs and activists who promoted the creation of a universal access to treatment regime did so by using compelling moral arguments, while enjoying favourable material conditions or circumstances. From the ethical perspective, the task of these entrepreneurs was to convince political leaders and the broader public *that it was morally wrong to allocate antiretroviral drugs solely on the basis of an individual's ability to pay*. From a material standpoint, these arguments were greatly facilitated by the falling prices of ARVs after the turn of the millennium, coupled with increases in foreign aid spending devoted to HIV/AIDS and other diseases – changes that activists helped to bring about.

Making the market for ARVS

> 'You can't say to your patients, "sorry you are dying of market failure"'.
>
> (Zackie Achmat, Treatment Action Campaign quoted in d'Adesky 2005)

The AIDS crisis is a tragedy of epic proportions. By 2007, more than 25 million people had reportedly died from AIDS, 2 million of them in that year alone. Another 33 million were living with the virus. There were an estimated 2.7 million new infections in 2007, 1.9 million of them in sub-Saharan Africa, the epicentre of the pandemic (UNAIDS 2008). In 2004, AIDS was the leading cause of death worldwide for people aged 15–59 (Kaiser Family Foundation 2005). As AIDS worked its grim way around the world, leaving in its train a growing number of casualties, the United Nations Security Council in 2000 called it a threat to peace and security. Soon after, in July 2000, Durban hosted the first international conference on AIDS to be held in Africa. This gathering was widely regarded by the AIDS community as the decisive turning point at which the idea of extending treatment to the developing world was deemed both medically feasible and morally necessary, since many of the developing world success stories with respect to treatment were presented at this time (Garrett 2009).

With the idea of broader access to ARV treatment now advancing on the international agenda, policy entrepreneurs like Peter Piot, the director of UNAIDS, sought political support from the growing number of activist organisations such as Doctors without Borders, Oxfam, the Global AIDS Alliance and ACT-UP that were beginning to take up this global cause (Piot 2009). UN Secretary-General Kofi Annan picked up their call and sought donor approval for a new special fund to fight AIDS. In 2002, donors agreed that a new financing vehicle, the Global Fund to Fight AIDS, TB, and Malaria, should be created. Soon thereafter, President Bush announced the five-year, $15 billion President's Emergency Plan for AIDS Relief (PEPFAR), which would become the world's biggest vehicle for AIDS spending.

To understand the political economy of the universal access policy, we seek to conceptualise ARVs as a class of 'merit goods'. It is crucial to recognise that merit goods could be, and indeed often are, produced by the private sector in something akin to a 'free market' setting. Unlike classic public goods like clean air and national defence, which are non-rival and non-excludable, merit goods are more like club goods, exhibiting qualities of both scarcity and excludability.[2] *The significant ideational and material challenge facing activists and policy entrepreneurs who wish to promote universal access to a particular good, therefore, is to transform private goods into merit goods.*

Why doesn't society simply transfer income to the poor so that they can buy what they so desire? As James Tobin pointed out many years ago, the merit goods argument provides an example of what he calls 'specific egalitarianism', meaning that society is often willing to

provide specific interventions (e.g. vouchers and food stamps) rather than general income support, since the recipients of the merit good might not choose to buy the desired goods on their own (Tobin 1970). Another way to phrase the merit goods argument is in terms of 'paternalism', meaning that some members of society (say, public officials or even activists) know better than other individuals what people really need in order to live a better life. In the global context, paternalism often takes the form of 'activists' or 'policy entrepreneurs' in wealthy societies deciding what it is that consumers in 'poor societies' *really* need, and providing funding for certain goods and services that effectively shape a given society's consumption in a way that might well be different from the consumption that would be generated by consumers who were instead given additional income directly. *In short, the production of merit goods generally requires some degree of interference in the marketplace in order to match supply and demand* (Musgrave 1959).

So what specific types of interference in markets might be required to match merit good production and consumption? On the supply side, it is apparent that several possible solutions present themselves, assuming for the moment that constrained demand or under-consumption is mainly a function of high prices or inadequate incomes. First, a given 'home' society can raise taxes and transfer income via foreign aid, enabling the 'foreign' society to buy more of the merit good at the home price. Second, the home society can induce donations from wealthy individuals (e.g. via tax breaks) to pay for the merit goods which are then transferred overseas. However, the funding from such organisations like the Gates Foundation is likely to be small compared to the level of global needs that exist. Third, the home society can induce its firms to donate the merit goods overseas; this approach will have similar shortcomings to those noted above with any philanthropy, and vary depending upon general market conditions. Fourth, the home society can produce the merit good in question and then donate it overseas, or it can encourage competition from other producers (e.g. generic manufacturers in the case of drugs) so that the monopoly price falls to the level of marginal cost, say by reducing the amount of intellectual property protection that the monopolist can claim on its products. Fifth and finally, the home society can encourage its firms to engage in 'differential pricing' of the merit goods such that prices in developing countries are lower than they are in the home market. It is the combination of solutions four and five – generic competition and differential pricing – that became the economic basis for ARV delivery in the developing world.

Why is that the case? The argument made by ARV activists at the turn of the millennium was that drug donation and charitable giving programmes were basically 'not sustainable' (CPT *et al.* 2001). Sustainability, the activists claimed, required a pricing scheme that reconciled the needs of the poor for cheap drugs, with incentives to induce the pharmaceutical companies to continue their investments in research and development (R&D). Differential pricing, with the price in developing countries equal to something like marginal cost, was touted as reconciling profits with the provision of merit goods (Kremer 2002). Health economists also made the analytical case that differential pricing, also known as Ramsey pricing, reconciled the needs of profit-seeking firms with the demands of the poor for low-cost drugs (Danzon and Towse 2003; Jack and Lanjouw 2005).

Ramsey pricing works as follows. We assume that the company produces everywhere at the same marginal cost, and the firm exercises monopoly power, say through a patent. If it exercises monopoly power it can therefore price differently in each market, *so long as it can effectively segment these markets*, setting high prices in wealthy countries and lower prices in developing countries. The multinational pharmaceutical companies had not engaged in Ramsey pricing up to this time because they doubted whether the developing world provided a large enough market for these drugs at any price. Furthermore, they were concerned whether they could

enforce market segmentation and prevent the illicit re-exportation of low-cost drugs back to the industrial world.

On the demand side, poor countries had no interest in importing high-cost ARVs because the price was much more than they could afford. The absence or deficiencies in health infrastructure also meant that extending access entailed substantial costs beyond the purchase of drugs, placing a strain on stretched health budgets, and, in any event, it was unclear whether ARV purchases would be or even should be the first priority of developing world health ministries. Even if they were, procurement and delivery mechanisms would have to, in many cases, be created from scratch, delivering drugs to rural areas over poor roads, with irregular electricity to areas that needed clinics and storehouses and procedures to manage all of that activity (Kremer 2002, summarises market failures for pharmaceuticals in the developing world).

Essentially, policy entrepreneurs like Peter Piot of UNAIDS – along with activists based within such organisations as Doctors without Borders, Partners in Health, Oxfam, and later the Clinton Foundation – brought together the pharmaceutical manufacturers with developing world governments by negotiating the lower prices at which demand would kick in and by showing through 'proof of concept' demonstration efforts that ARV uptake was medically feasible in poor country settings. In 1997, Brazil began to provide ARV therapy to people with HIV, including locally manufactured generic drugs, while in Haiti, Partners in Health, led by Dr Paul Farmer, extended treatment to another resource-poor setting. Among the other significant programmes in this respect was the UN's Drug Access Initiative of 1997–1998, which used Cote D'Ivoire, Vietnam, Thailand, and Chile as pilot countries for exploring the feasibility of universal access to treatment (UNAIDS 1998). So long as the prices paid by governments or philanthropies covered production costs, at least some firms would be prepared to increase output; and so long as prices were low enough the countries (perhaps using foreign aid funds) would be able to buy the drugs. *Again, the role of the activists was to construct the market for merit goods by matching demand and supply. On the supply side, drug companies were encouraged to lower the prices on their patented ARVs, while generic drug suppliers were encouraged to enter developing world markets. On the demand side, activists won substantially higher amounts of foreign aid funding from the US and other industrial world governments, specifically targeted at ARV purchases.*

Indeed, the activists' cause of advancing universal access was, paradoxically, assisted by ongoing developments regarding the Trade in Intellectual Property Rights (TRIPS) provisions of the Uruguay Round trade agreement of 1993 and its specific application to public health. These provisions required all members of the World Trade Organization (WTO), including developing countries, to put into place effective protections on intellectual property (IP), including patents on pharmaceutical products. The least developed countries, however, were given until 2006 (later extended to 2016) to create enforceable TRIPS mechanisms. The TRIPS agreement, reinforced by the Doha Declaration of 2001, allowed countries in principle to retain the possibility of issuing compulsory licences for drugs to generic manufacturers (Fink 2008).

In the meantime, as a Federal Reserve Bank of New York economist reported, competition from Indian and Brazilian generics producers put pressure on brand-name pharmaceuticals to lower the prices of ARVs in low- and medium-income countries. The average branded price of AIDS triple-combination drugs fell from nearly $10,500 per year to less than $1,000 per year in 2000. '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 ... 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' (Hellerstein

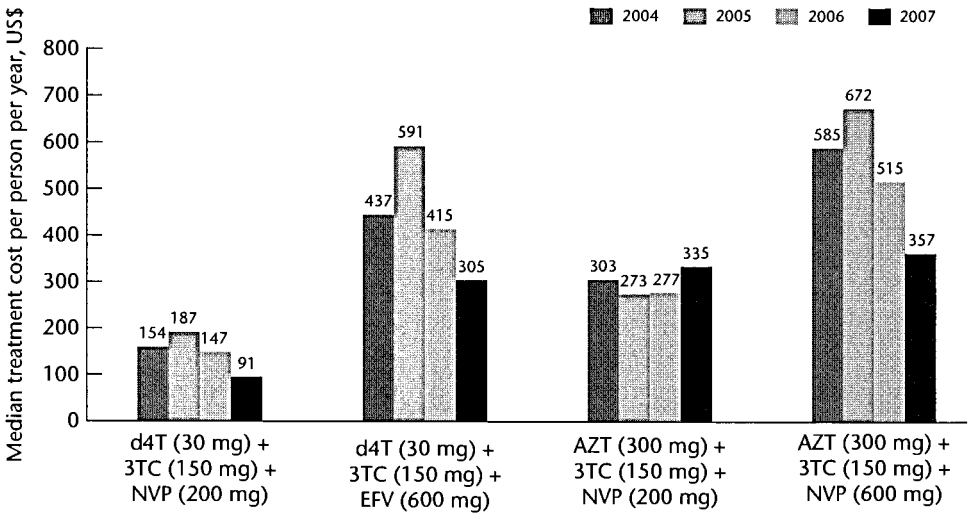

Figure 45.1 Median price (US$) of first-line antiretroviral drug regimens in low-income countries, 2004–07
Source: http://www.who.int/hiv/data/Universal_Access_Report_2008_Figures.ppt.

2004: 3). As Figure 45.1 suggests, the price of three out of four 'first-line' cocktails has fallen substantially since 2004 (and indeed, since 2001) thanks to pressure from generic competition, coupled with bulk purchases made possible by such organisations as the Clinton Foundation.

As prices fell, activists moved to increase public (and charitable) spending to buy ARVs for those with AIDS in the developing world, and the Global Fund and PEPFAR were soon launched. To explain the successful creation of these multi-billion dollar procurement vehicles, we must take a closer look at how activists were able to build a coalition of political interests that bridged AIDS activists and development campaigners on the left with the evangelical community on the right.

Why the AIDS treatment campaign succeeded

The success of the AIDS advocacy movement in generating a massive scale-up of ARV treatment naturally leads to the question, why was this particular campaign successful while many others both within and outside global health policy (e.g. the elimination of small arms, the reduction of carbon emissions, the Save Darfur Coalition) have failed or enjoyed much less success? This question is of intense interest for other campaigns for global public health and international development that are seeking to emulate the success of the AIDS campaign.

Permissive material conditions

While moral and ideational motivations may sometimes convince policymakers to embrace costly commitments (Busby 2007), campaigners must also often make utilitarian or cost-benefit arguments that they are not throwing taxpayer funds down the proverbial rat-hole. To that end, even if HIV/AIDS did not exhibit the characteristics necessary for successful disease

eradication, like smallpox or polio, the proof of concept demonstrations in Brazil, Haiti, and other countries succeeded in showing that treatment could be effective in the developing world. These early programmes were especially important in overturning the presumption that poor people would not adhere to the drug regimen as faithfully as those in the advanced welfare states. The dramatic decline in drug prices brought about by competition from generic ARV suppliers also persuaded policymakers that treatment was now within the realm of affordability. Furthermore, unlike prevention programmes, the number of ARV treatments being provided to patients could readily be counted; politicians could thus set numerical targets whose progress could easily be followed.

Still, despite the favourable circumstances fostered by the combination of successful demonstration projects, declining drug prices, and a healthy global economy, a permissive material context was not enough to build a broad political coalition in support of the campaigners' aims. Why did decision-makers decide to promote and fund AIDS programmes and not something else?

The politics of AIDS treatment

Potentially, there are a number of different answers to explain why AIDS treatment campaigners were able to convert permissive material conditions into widespread political support: the degree of policy consensus; the attributes and expertise of AIDS activists; and, related, their ability to win over potential opponents in building a big tent for their cause. None of these on their own is sufficient to explain the emergence of the access to treatment regime, instead AIDS activists relied on each factor as they worked to forge a broad political coalition.

Degree of policy consensus

Other authors have highlighted that campaigns have failed due to their failure to forge a consensus on a policy prescription (Shiffman and Smith 2007; Youde 2008 discusses the failure of the universal primary health care norm). When too many ideas are at play, policy change is less likely. Thus, if this hypothesis is correct, the AIDS treatment campaign was ultimately successful because the movement coalesced towards a single consensus view of what was needed – greater access to ARVs – while other health concerns and other campaigns for maternal mortality, population control, or arguably the AIDS prevention agenda have lacked a single defining prescription.

Activist attributes and expertise

It is difficult to deny that much of the ARV treatment regime's relative success ultimately has to do with the quality of the individuals involved in this campaign, just as it would be hard to imagine modern Singapore without Lee Kuan Yew or South Africa without Nelson Mandela. One could argue that the characters involved in this story, such as Peter Piot, Bono, Franklin Graham, Paul Farmer, Jonathan Mann, and many others, had unusually strong persuasive skills. They combined substantive expertise with evangelical fervour, and they also exploited diffuse social networks that extended throughout the political and economic realms. Busby suggests that the personal attributes and expertise of advocates like the evangelist Franklin Graham and rock star Bono were persuasive because they shared a number of attributes (religion, ideology, gender, age) in common with key decision-makers like George W. Bush (Busby, ms). A different argument about advocate characteristics would focus on the shared scientific expertise of medical professionals (Haas 1992). As already noted, AIDS experts like Peter

Piot and Paul Farmer were converted early to the belief that ARV treatment should be extended globally, and they helped create an 'epistemic community' of like-minded advocates.

While the degree of policy cohesion and activist attributes are important and attractive in their simplicity, these alone cannot explain why policymakers were persuaded to support the demands of AIDS treatment activists, especially given the number of other health conditions in the developing world that are responsible for as many, if not more, premature deaths than AIDS, and whose solutions are relatively straightforward. For example, diarrhoeal disease – which can readily be reduced by access to clean water and better sanitation and for which effective treatments already exist – killed 1.81 million people in 2004 compared to 1.51 million who died from AIDS (WHO 2008a).

Building coalitions and overcoming opposition

In order to succeed politically, campaigns have to have broad support while overcoming the major sources of potential political opposition. One way they build political support for their cause is by framing the problem in ways that various groups find compelling. For example, HIV/AIDS has been framed as a public health issue, a human rights issue, a justice issue, a moral problem, an issue of intellectual property rights, and a security problem. The ethical/human rights-based argument was perhaps the most central frame that animated advocates' demands internationally, but there has been some local variation, with the moral frame having a decidedly more Christian religious flavour in the United States. While advocacy groups often adopt a dominant frame, they may also employ multiple messages to appeal to different groups, building political coalitions in the process.

From this perspective, the nature of the issue area can have a big effect on the relative success of different campaigns by changing the balance between coalitions and opponents. For example, advocates of climate change policy have sought to build a broad coalition drawn from both environmental and industrial groups, but they have confronted influential interest groups in the power generation sector. Who were the potential opponents of extending AIDS treatment programmes? These included pharmaceutical companies that were worried about profits, social conservatives who identified AIDS with a sinners' disease, and fiscal conservatives opposed to foreign aid spending. AIDS activists succeeded by reducing the political costs of supporting AIDS treatment. By creating a campaign with some cachet on both left and right, AIDS activists made their cause broadly attractive. Given that the potential opposition in the United States was concentrated on the political right, it was especially important to make inroads among evangelicals and social and fiscal conservatives who could vouch for the policy.

In sum, we would expect campaigns to be more successful when they (1) enjoy permissive materials conditions; (2) provide a coherent policy prescription; and (3) build a broad political coalition, on the one hand, while facing few influential political opponents on the other. With the AIDS case, activists were favoured in each of these three dimensions.

Conclusions

We have demonstrated the role of activists and policy entrepreneurs in building a market for ARVs in the developing world. By naming and shaming pharmaceutical companies and by promoting generics, the price of this treatment was greatly reduced, making the goal of universal access seemingly feasible. With lower prices, the activists pressured governments to provide more foreign assistance for the purchase of ARVs, bringing the supply and demand sides of the

equation together. Activists thus succeeded in transforming ARVs from private goods into merit goods that everyone had the right to consume.

In thinking about the future, the AIDS treatment campaign raises several important questions for policymakers. First, can ARV treatment access continue to be extended? Second, can other campaigns (e.g. for universal access to education and clean water) replicate the success of the AIDS treatment campaign politically?

With respect to maintaining and extending ARV access, the answer is not a simple one. To the extent that the virus that causes AIDS will continue to mutate and generate drug resistance, branded pharmaceuticals companies are needed to develop new drug therapies for AIDS. These companies continue to press for maximal protection of intellectual property rights, and as drug resistance among first-line ARV drugs becomes more prevalent, it will become increasingly expensive to provide second-line drugs, since these are facing less competition from generic producers.

At the same time, the failure of AIDS prevention strategies is straining budgets at a time when governments are under unprecedented pressure to cut costs, especially given the 'Great Recession' that began in 2008, 'donor fatigue' with respect to AIDS, and the emergence of other priorities. For these reasons, a growing number of observers are expressing concern about the future sustainability of the global AIDS regime (Over 2008). Reneging on the commitments made to the more than 3 million people on ARV therapy would be morally indefensible. But advocates for AIDS broadly need to spur a renewed focus on prevention since the funds available for treatment will never be large enough to cover those in need, so long as the HIV-positive community continues to swell.

For other causes to replicate the AIDS campaign's success to date on treatment, activists must build broad coalitions of interests, including private sector generators (and copiers) of intellectual property. Mustering political support is likely to require very specific development programmes (like PEPFAR), which are much more politically popular than broad-based financial assistance to well-run governments to spend as they see fit (i.e. the Millennium Challenge Corporation). This coalition, in turn, must be joined by a convergent idea of what *can and should* be done. It is only through the fusion of a compelling set of ideas about how the world should work with favourable material conditions that activists will bring change to the global economy.

Notes

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2 Club goods are goods that are only provided to members of a particular group while others are excluded.

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