



## Slippery AIDS Statistics: Why Loose HIV Numbers Create False Hope and Bad Policy

By Roger Bate

*Attempting to treat millions of HIV patients in developing countries is a noble goal that humanitarian organizations will probably eventually achieve. Currently, however, the World Health Organization (WHO) and the Clinton Foundation are making costly errors concerning the number of treated patients and the price of drugs. These inaccuracies encourage the belief that more widespread treatment is possible. This in turn leads to unsustainable programs. Moreover, the organizations' imprecise numbers for treatment and drug pricing are encouraging the use of low-quality, insufficiently tested drugs to fight HIV. This will result in misery for those not sustained by treatment and exacerbate drug resistance problems for all who are HIV positive.*

Roughly 40 million people are currently infected with HIV, 25 million of whom live in sub-Saharan Africa. The pandemic reaches 5 million more people per year, 95 percent of whom live in developing countries.<sup>1</sup> To counter this trend, the developed world increasingly provides aid to countries with high infection rates, paying for prevention, treatment, and care programs to slow the spread of the disease and to ameliorate its ravages. One such initiative, the World Health Organization's "3 by 5" program, seeks to provide 3 million AIDS patients with antiretroviral treatment (ART) by the end of 2005. Another, the U.S. President's Emergency Plan for AIDS Relief (PEPFAR), is a five year, \$15-billion project with the goals of treating 2 million infected persons with ART, preventing 7 million new infections, and providing care and support for 10 million persons infected with or affected by HIV, including orphans and vulnerable children. These programs are large in both scale and scope and have attracted necessary global

attention to the HIV/AIDS pandemic. This paper looks specifically at the treatment of HIV.

Owing to their high cost, treatment initiatives are unlikely to be as efficient as prevention initiatives in the poorest countries. Nonetheless, treatment is necessary, and we should commend the organizations, companies, and governments involved in providing it. The lives improved and prolonged by treatment strengthen the fragile social and economic fabric of developing countries. However, beyond the costs of drug acquisition, the higher cost of diagnostics and the costs of actively treating people (drug delivery by trained personnel) make treatment programs very expensive. Yet most commentators fixate on the price of drugs over all other costs.

Most treatment initiatives, like the WHO's "3 by 5" program and the Clinton Foundation's HIV/AIDS Initiative, emphasize achieving increased numbers in treatment by acquiring low-priced antiretrovirals (ARVs) and distributing them to as many AIDS patients as possible. The number of people on ART has increased as a result. But is the ambitious goal-setting of these programs the best way to deal with the AIDS problem?

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## WHO and Clinton Foundation: Redefining Numbers

**WHO.** The WHO's "3 by 5" initiative, announced on December 1, 2003, has set an ambitious goal that may in practice sacrifice quality of treatment for quantity. According to the WHO and the Joint United Nations Program on HIV/AIDS (UNAIDS), of the 40 million people with HIV, an estimated 6 million people in developing countries urgently need ART, which includes all HIV-infected people with less than 200 CD4 cells per cubic millimeter of blood (CD4 is a measure of the strength of the immune system).<sup>2</sup> At the end of 2003, only 400,000 of them were receiving ART, of whom 150,000 were in sub-Saharan Africa. Within one year, the WHO/UNAIDS effort claims to have increased the number of AIDS patients on ART to 700,000 globally, meeting 12 percent of the total need. Of that total, 310,000 are in sub-Saharan Africa, which means 8 percent of the 4 million people in need in the region receive ART.

This significant increase in the number of people on treatment seems to bode well for the WHO master plan, but there is concern that the organizations involved double-counted patients in treatment. AIDS specialists working within a couple of the agencies estimate that at least 63,000 of the quoted 700,000 on ARVs may have been claimed by more than one organization.<sup>3</sup> In other words, the treatment figures are inflated by nearly 10 percent.

Most popular media outlets are content to regurgitate the official-sounding statistics without independent verification. *USA Today*, for example, stated that "Two-thirds more people . . . an estimated 700,000 people are now able to obtain AIDS treatment."<sup>4</sup> Since journalists are content to let such careless—or perhaps intentionally misleading—accounting stand without challenge, taxpayer funded humanitarian organizations like the WHO are free to pose information concerning their efforts in the most flattering light possible. In the case of ARV treatment, the WHO is no doubt tempted to meet its "3 by 5" by any means necessary, including fabrication. Though its 63,000 person "slip-up" seems small now, that does not bode well for the future.

In addition to their factual inaccuracy, the oft-quoted "3 by 5" numbers misleadingly imply that the WHO and other aid agencies are providing the funds for all this treatment. In reality, roughly a quarter of those on treatment (154,000 people at the end of 2004) in the developing world reside in Brazil, which funds its own program

and has done so since before the existence of "3 by 5." Furthermore, the Accelerating Access Initiative—which consists of seven research-based pharmaceutical companies that provide numerous free or nonprofit-priced drugs, which are then distributed by various multilateral agencies and national groups—is responsible for treating 333,000 patients as of September 2004.<sup>5</sup> It is fair for the agencies to claim to have served the vast majority of these patients, but a caveat should be applied. While it is possible for corporations to provide nonprofit drugs (which are in reality loss-making, given scarce manufacturing capacity utilization) for a few hundred thousand people, it is quite another thing for them to provide drugs to a vastly larger number of people (an order of magnitude more, given targets) because doing so would cause massive fixed and variable cost increases and would not be sustainable.

The WHO makes no effort to clear up the confusion. Instead of explicitly stating how it arrives at these numbers, it obfuscates even further. The December 2004 WHO "3 by 5 Progress Report" states that estimates of ART recipients are "based on data reported by countries in written reports or through personal communication with key informants."<sup>6</sup> The report cites weaknesses in private sector reporting, the time lag between global and country reporting, and local conditions. The estimated range of the number on ARVs is somewhere between 630,000 and 780,000, and the WHO report states that these estimates are "likely to be lower than the actual number on treatment because all the evidence indicates very rapid scaling up of both the numbers of sites and the numbers receiving treatment."<sup>7</sup>

**Clinton Foundation.** The Clinton Foundation's HIV/AIDS Initiative works with individual governments in Africa, Asia, and the Caribbean, providing technical assistance and mobilizing human and financial resources to scale up public health systems to ensure broad access to care and treatment. The most commonly cited obstacle to widespread treatment is the cost of antiretroviral therapy, which includes not only drug costs, but also diagnostic and monitoring costs. To overcome the cost barrier, the Clinton Foundation has established HIV/AIDS initiatives for procuring medicines and supplies at more affordable prices. The Initiative's cost experts worked with generic drug companies in South Africa and India—Aspen Pharmacare Holdings Ltd., Cipla Ltd., Ranbaxy Laboratories Ltd., and Matrix Laboratories Ltd.—to analyze processes and costs throughout the production chain from raw materials to the production

TABLE 1  
 LOWEST PRICES ALLEGEDLY PROCURED FOR ANTIRETROVIRAL DRUG THERAPIES

Drug	Clinton Foundation	MSF/WHO/UNAIDS (company source)
Lamivudine 150mg + Stavudine 30mg + Nevirapine 200mg	\$132	\$159 (Aurobindo)
Lamivudine 150mg + Stavudine 40mg + Nevirapine 200mg	\$140	\$167 (Aurobindo)
Lamivudine 150mg	\$57–\$59	\$60 (Hetero Drugs, Ltd.)
Stavudine 30mg	\$24–\$36	\$15 (Aurobindo)
Nevirapine 200mg	\$60	\$88 (Hetero Drugs, Ltd.)

SOURCES: Clinton Foundation, "Clinton Foundation Pricing," available at [www.clintonfoundation.org/pdf/arv-price-list-030705.pdf](http://www.clintonfoundation.org/pdf/arv-price-list-030705.pdf). MSF figures from "Untangling the Web of Price Reductions: A Pricing Guide for the Purchase of ARVs for Developing Countries," 7th edition, February 2005, [www.accessmed-msf.org](http://www.accessmed-msf.org).

of the final formulations. Based on this work, the foundation projected impressive potential cost advantages that could result from higher volumes.

On October 23, 2003, the Clinton-led initiative announced an agreement with four suppliers of generic ARV medications that promised dramatic cuts in the price of the most commonly used triple-drug therapy combinations to less than \$140 per person per year. "The agreement will allow the delivery of a triple-drug treatment at about thirty-eight cents, which is almost half the current price of inexpensive commonly used drugs," former U.S. president Bill Clinton said.

Despite Clinton's promises, however, other health organizations like Medecins Sans Frontieres (MSF) and the WHO are unable to acquire first line ARV regimens at such a low price. For one thing, the \$140 per person, per-year quote applies only to Triomune (d4T/3TC/NVP), a first-line regimen produced by the Indian company Cipla Ltd. and, although not tested by the U.S. Food and Drug Administration (FDA) or another competent testing agency, one of the few fixed-dose combinations (FDCs) pre-qualified by the WHO. However, according to an MSF study outlining available prices for triple-dose ARVs from India, no company offers any FDCs at \$140 per person, including Cipla's Triomune, which sells instead for \$214 to MSF. Other first line ARVs cost anywhere from \$169 to \$413, most of which are not pre-qualified by the WHO, and none of which are approved by the FDA.<sup>8</sup>

Additionally, the deals brokered by the Clinton Foundation involve extraordinary demands. Dr. Yusuf Hamied, president of Cipla Ltd., said each country must submit large, irrevocable purchase orders, pay cash, and bear the costs of registering each drug in each country, which might include lobbying the legislature

or fighting patent lawsuits. There also must be a guaranteed supply of the raw active ingredients at fixed prices. "If someone wanted to give me an advance of \$50 million and guarantee that I supply them for five years, I might do it for \$120," said Dr. Hamied.<sup>9</sup>

Publicly, however, the Clinton Foundation continues to promote its \$140 treatment price. At the recent World Economic Forum in Davos, former president Clinton stated that AIDS-infected people could be treated with ARVs for a mere forty cents a day (\$146 per year). The head of the initiative, Ira Magaziner, told *Scrip* magazine that the foundation "provided treatments to 80,000 patients in the developing world at the end of last year. The delivered prices have ranged from \$131 to \$149 for the triple combination. The price variation depends on the country, the volume of purchase, the type of packaging required, and whether the order is one or three pills."<sup>10</sup>

The Clinton Foundation claimed in February that it had 24,800 patients on ARVs in sub-Saharan Africa and expected to be treating a total of 110,000 people worldwide by the end of April 2005. Yet by implying that it delivers *all* drugs at the lowest price, the foundation continues to mislead the public about the true cost of achieving these large treatment numbers. Expecting that ART is available to everyone at the quoted price, activists understandably clamor for increased treatment numbers, and politicians responding to the demands of a misled public then make unsound decisions about priorities for AIDS funding.

## Implications of Numbers-Driven Programs

**Quality.** Though the accounting may be flawed, little doubt remains that a relatively quick scaling up of

treatment is occurring. Much of the credit lies with generic companies who have increased competition and lowered drug costs. But can such acceleration of treatment be done safely and sustainably?

One inherent concern is the quality of antiretroviral treatment. Providing another 2.3 million people with ARVs in the next year will allegedly require about \$3.8 billion; although, even if this money were available, it is unclear whether delivery would be possible. In any case, a study released by Action Aid warns that the WHO is facing a \$2-billion funding shortfall. A solution to this financial constraint, promoted by myriad groups, is to find still cheaper drugs to distribute. Generic drug companies, primarily in India, have seized this opportunity and are producing copies of AIDS drugs, although the quantities in production are far from clear. The most popular medications are FDCs containing Lamivudine (150mg), Stavudine (30–40mg), and Nevirapine (150–200mg).<sup>11</sup> Generic drug combinations are attractive because they can be cheaper than branded originals yet are supposed to have the same ingredients, formulation, and impact as their more widely tested equivalents.<sup>12</sup>

Less expensive copy drugs, however, are not necessarily exact replicas of rigorously tested, patented drugs. For example, FDC Triomune contains three ingredients that do not exist in any brand medication, which to experts Carol Adelman and Jeremiah Norris of the Hudson Institute makes Triomune an “investigational new drug,” not a generic. Additionally, pills that may have been tested individually can change absorption and excretion rates when combined. The disturbing result of using insufficiently tested drugs is that drug resistant HIV/AIDS emerges faster than it does when proper formulations are used. Poor quality drugs and suboptimal treatment means that the virus receives a sub-lethal dose, which encourages resistance. As Adelman and Norris assert, “the price of cheap, untested drugs is way too costly.”<sup>13</sup>

**Bioequivalence Testing.** In 2004, the WHO deemed many generic AIDS drugs non-bioequivalent to their brand name counterparts. Companies like India’s Cipla received WHO pre-qualification for its FDCs, only to have them withdrawn after their documentation failed to provide sufficient support for bioequivalence. In November 2004, Indian manufacturers Ranbaxy and Hetero pulled over a dozen antiretroviral medications, including both individual and combination regimens, from the WHO pre-qualification lists.<sup>14</sup>

Most FDCs that have been approved by the WHO under its pre-qualification system have not been tested by the FDA or an equivalent competent testing agency. However, on January 25, 2005, the FDA “tentatively” approved South African company Aspen Pharmacare’s co-packaged ARV drug regimen. The agency’s tentative approval means that although existing patents and exclusivity prevent U.S. marketing of Aspen’s product, the co-packaged ARV drug regimen meets the FDA’s quality, safety, and efficacy standards for U.S. marketing.<sup>15</sup> Aspen’s Lamivudine/Zidovudine FDC, prescribed along with Nevirapine tablets, are generic versions of Glaxo-SmithKline’s Combivir and Boehringer-Ingelheim Pharmaceutical’s Viramune tablets. Although the brand versions of each individual drug are FDA approved, combinations of drugs must undergo rigorous bioequivalence testing to ensure their effectiveness when taken together.

In May 2004, the FDA issued guidelines to fast-track applications for ARV products by speeding up paperwork and even waiving application fees. Yet only Aspen Pharmacare has taken advantage of this offer. The failure of Indian companies like Cipla and Ranbaxy<sup>16</sup> to provide bioequivalence and chemical stability data to the FDA indicates questionable testing of its FDCs. It is therefore not surprising that the United States has been reluctant to use money from PEPFAR to purchase and distribute generic FDCs.

At present, Gilead Sciences, GlaxoSmithKline (GSK), and Abbott Laboratories have obtained U.S. and European Commission approvals for combination AIDS-drug products. Gilead, Merck, and Bristol-Myers Squibb are currently developing a triple combination product of emtricitabine, tenofovir, and efavirenz. Of these, the only approved triple therapy drug in one pill is GSK’s Trizivir. No other triple therapy fixed-dose combination product has passed FDA-standard approval. Nevertheless, the WHO has pre-approved several products for use in Africa. These FDCs, which as individual drugs are safe and efficacious, would not be approved for use in any developed country without significant testing data to substantiate equivalence, yet the WHO has allowed them to be used in Africa. And in a very late and concerning development, Gilead and Bristol-Myers Squibb announced on April 26, 2005, that their FDC (consisting of brand drugs Truvada and Sustiva) had failed bioequivalence testing.<sup>17</sup> It is rather interesting that the companies that developed the best new drugs on the market have failed to achieve bioequivalence at their first try; this is why assiduous testing is so important.

FDCs can be useful, but they must be tested. They potentially lower costs and lower drug resistance by increasing the likelihood that patients will continue to take the drugs as prescribed (one pill is easier to keep track of than three). But rushing to distribute untested FDCs can be counterproductive.

## Profitability and Supply Constraints

In March 2001, Merck developed a pricing policy for Crixivan and Stocrin (efavirenz) applicable in developing countries. In the least developed countries and those hardest hit by the AIDS epidemic, Merck makes no profit on the sale of these medicines.<sup>18</sup> Without an incentive to maintain research and development, production companies will exit.<sup>19</sup>

Industry insiders claim that both the generic and research-based industry are reaching supply constraints in production of ARVs. Merck's Jeffrey Kempres says that production of its drug efavirenz has increased significantly over the past year and that the company is adding new production capacity in anticipation of higher demand. Forecasts, however, are not very reliable, which makes long-term planning difficult. Cipla says that supply constraints can be overcome if buyers make upfront purchases or at least guarantees.

Eric Noehrenberg of the International Federation of Pharmaceutical Manufacturers Associations explains that the main reason for companies not ramping up production even further is that the current drugs are not all reaching their intended patients, since the capacity to deliver drugs sustainably is lower than the capacity to manufacture the drugs. So industry is unhappy discussing further production hikes given these constraints. Indeed, all sectors of the industry concur that plans to expand production are greatly complicated if current supplies are not being delivered; reliable forecasts would be helpful to manufacturers who contemplate investment in production capacity.

## Barriers to Treatment in Sub-Saharan Africa

All treatment initiatives must take into account the inherent limitations of trying to scale up treatment rapidly and the drawbacks of ignoring those limitations. Multiple barriers to successful implementation exist, particularly in sub-Saharan Africa. Overcoming demand and supply-side constraints to treatment requires realistic goal-setting and comprehensive program development.

**Inadequate Delivery Systems.** Poor countries often entirely lack medical infrastructure, such as clinics, hospitals, and distribution networks that deliver medicines to dispensing outlets. Insufficient numbers of trained medical workers, low doctor-to-patient ratios, and lack of funding also render the successful delivery of ART difficult.<sup>20</sup>

According to Dr. Eric Goemaere of MSF, South Africa alone needs as many as 100,000 trained health care workers to handle growing programs. Between 2000 and 2003, according to the South African Nursing Council, the total number of registered nurses grew by only 3.7 percent to 96,715.<sup>21</sup> The majority of countries in sub-Saharan Africa do not meet the WHO's recommended minimum ratio of twenty physicians per 100,000 people, and the U.S.-based Physicians for Human Rights estimates that thirteen countries in the region have fewer than five physicians per 100,000 patients.<sup>22</sup> Dr. Nomonde Xundu, the new HIV/AIDS director for South Africa's national health department, stated recently that South Africa has found only 111 out of the 220 doctors needed, as the low average salary (190,000 rand or U.S.\$32,000) and working conditions in South Africa are not attracting doctors.<sup>23</sup> Even when doctors are available, some are not trained to administer ARVs, leading to improper prescription doses. In Lesotho, Dr. Tonny Mwabury reported that out of twenty-four patients he saw, six were on mono or dual therapy.<sup>24</sup> One patient had been prescribed just ten doses of Nevirapine, which is meant to be taken indefinitely in conjunction with other drugs.

ARV provisions are pointless if there are no personnel to distribute them properly. In Guinea-Bissau, a shipment of Brazilian-made antiretroviral drugs that arrived last month remains at the airport because the country does not have trained health workers to distribute them.<sup>25</sup> The main reason for these infrastructure limitations is the paltry level of health care funding in Africa, which stems from both significant poverty and also inappropriate prioritization of government expenditure. Additionally, even if programs distribute free ARVs, many patients are too poor to travel to dispensing clinics.

**Testing.** A symptom of poor medical infrastructure and scarce funding is the lack of availability of HIV testing. No more than 10 percent of HIV-infected people in developing countries are aware of their infection.<sup>26</sup> It is extremely doubtful that programs scaling up access to ART can be successful without a prior expansion of HIV testing.

At the moment, estimates of infection rates come from models based on antenatal blood testing on samples left over from syphilis tests of pregnant women. Population estimation from such a small specific grouping is bound to be highly inaccurate. More accurate infection numbers based on expanded testing would prove valuable to ART programs, but impediments like poor infrastructure render the task challenging. Additionally, the stigma and discrimination associated with HIV-positive status (especially among women and girls) discourages voluntary testing, not to mention the pursuit of treatment. The alienation of HIV-positive members of the community is often harsh, especially for the already vulnerable female population.

**Taxes.** In the main, both brand and generic producers have reduced ARV prices to the benefit of many. Unfortunately, some countries' finance departments see the import of these life-saving drugs as a way of raising revenue.<sup>27</sup> Southern Africa can claim to do relatively well in this respect compared with the rest of the continent: most countries have no import duties on medicines, although Malawi charges a 15-percent import duty and South Africa a 14-percent sales tax.

Until recently, East African countries imported many drugs at a zero tariff rate. However, on January 1, 2005, the East Africa Customs Union Protocol imposed a 10-percent duty on antiretrovirals entering Uganda, Tanzania, and Kenya. This increase makes treatment more expensive, encourages a black market in drugs, and essentially imposes a tax on projects funded by donors. Other African governments—for example, Nigeria, Morocco, and Algeria—maintain significant levels of taxes and tariffs as well. However, some places exempt ARVs from tariff and customs, but not other drugs needed for opportunistic infections and other diseases. The result is that the lowest prices people pay are sometimes far higher than the figures usually quoted in the press.

## So What?

Setting goals for HIV/AIDS relief can be valuable as it places pressure on the international community to act. At the same time, planting false hope and chasing unrealistic numbers can be dangerous. According to Merle Sande and Allan Ronald of the American Medical Association, “to scale up antiretroviral therapy for HIV without ensuring infrastructure, including trained practitioners, a safe and reliable drug delivery system, and simple but effective models for continuity of care,

would be a disaster, leading to ineffective treatment and rapid development of resistance.”<sup>28</sup> Ineffective drugs, specifically untested and improperly prescribed FDCs, encourage resistant strains of HIV and render the path ahead more treacherous. Antiretroviral initiatives hinged on low-priced drugs that do not include funding for infrastructure improvements, staffing, testing, and counseling will not successfully treat large numbers of patients.

The Clinton Foundation may indeed have brokered phenomenal deals on medication, but in that case, why are other organizations denied access to lower ARV prices? Public demands that pharmaceutical companies deeply discount much-needed ARVs in areas such as sub-Saharan Africa, coupled with the political will to defend these offers against exploitation in rich and emerging market countries, are a powerful force for change. Indeed, public-private partnerships have enabled companies to offer high quality medicines to poor countries.

In publishing the availability of first line ARVs at a mere \$140 per year, the Clinton Foundation has fueled speculation that still lower prices are possible. But the fight against HIV/AIDS requires more than placing millions of HIV-infected people on less expensive (often inferior quality) medication in a short period of time, even if that were possible. Programs need to recognize the high cost of second line treatments for those who develop drug resistance, the lack of ARVs for children, and the costs of testing and transportation above and beyond cheap medication. Setting short-term goals may enroll large numbers in treatment and prove that programs like “3 by 5” are “working,” increasing access to further funding. However, long-term planning is what will ultimately extend lives and reduce the devastating impact of the HIV/AIDS pandemic.

Confusion over how many people are being treated with ARVs and over the prices of those ARVs is a symptom of a larger problem. Honorable mandates seeking financial and media support often use numbers to attract attention and outline clear-cut goals. The media, and therefore the public, cling to figures like \$140 and 3 million without appreciating what these numbers mean: \$140 means a supply of the copycat, non-bioequivalent fixed-dose combination drugs available, if taxes and lack of infrastructure do not hinder their free delivery; 3 million means the rapid dispensing of complex, toxic, sensitive therapy to people in the short run with little regard for long-run resistance and moral hazard problems. These numbers are not irrelevant, but they must

be interpreted carefully. Numbers, if inaccurate or unrealistic, can be very hazardous, especially in the case of HIV/AIDS treatment.

## Notes

1. As reported on [www.unaids.org](http://www.unaids.org), [www.usaid.gov](http://www.usaid.gov), and [www.who.int](http://www.who.int).

2. Healthy individuals usually have CD4 counts higher than 800.

3. PEPFAR claimed 172,000 while Global Fund claimed 130,000. The total 302,000 was above the actual 239,000 that were treated. 63,000 people were claimed by *both* organizations, a point that both agencies explained at the World Economic Forum meeting in Davos, Switzerland, in February 2005.

4. Steve Sternberg, "Two Thirds More People Now Get AIDS Treatment," *USA Today*, January 26, 2005.

5. Accelerating Access Initiative, "New Data Show More than 333,000 HIV Patients in the Developing World Are Being Treated by Medicines Supplied by the Accelerating Access Initiative (AAI) Companies," news release, January 25, 2005 (available at [www.ifpma.org/site\\_docs/Health/AAI\\_PRelease\\_250105.pdf](http://www.ifpma.org/site_docs/Health/AAI_PRelease_250105.pdf)).

6. "3 by 5 Progress Report," World Health Organization, December 2004 (available at [www.who.int/3by5/en/numbers.pdf](http://www.who.int/3by5/en/numbers.pdf)).

7. *Ibid.*

8. It is important to note that most pharmaceutical companies sell ARVs at lower prices in Africa than they do in the rest of the world, so many prices quote an average of global sales. Prices do not include shipping and handling. And according to Matabele Sefali from the National Drug Service Organization in Lesotho, between 15 and 20 percent of the cost of drug prices is freight charge.

9. Donald G. McNeil, "Plan to Bring Generic AIDS Drugs to Poor Nations," *New York Times*, April 6, 2004.

10. Elizabeth Sukkar, "Clinton Foundation Defends AIDS Drug Figures," *Scrip*, no. 3032 (February 25, 2005). The sub-Saharan Africa numbers come from an anonymous contact at the Clinton Foundation, e-mail conversation with author, February 16, 2005.

11. Combination therapy for the treatment of HIV/AIDS maximally and durably suppresses the virus to allow recovery of the immune system and reduce the emergence of HIV resistance. At least three active drugs, usually from two different classes, are required to suppress the virus, allow recovery of the immune system, and reduce the emergence of HIV resistance. In the United States and developing countries, simplified HIV regimens in the form of co-packaged drugs (such as blister

packs) or FDCs may facilitate distribution and improve patient adherence. For treatment-experienced patients, the choice of combination regimens is more complex and individualized. Therefore, triple FDCs or co-packaged products are probably most useful for treatment-naive patients; however, this may change as treatment guidelines for treatment-experienced patients evolve. Source: "Guidance for Industry Fixed Dose Combination and Co-Packaged Drug Products for Treatment of HIV," U.S. Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research (CDER), May 2004."

12. One Hudson Institute study last year, however, found that on average, discounted originator drugs were less expensive than generics. See Carol Adelman, Jeremiah Norris, and Jean Weicher, "Myths and Realities on Prices of AIDS Drugs," Hudson Institute, May 11, 2004 (available through [www.hudson.org](http://www.hudson.org)).

13. Carol Adelman and Jeremiah Norris, "Fighting AIDS on the Cheap," Hudson Institute: *American Outlook Today*, March 12, 2004.

14. If the companies had not acted, the WHO would have probably stripped the drugs from the list. Following the removal of three Ranbaxy ARVs, the WHO sent a warning letter to all manufacturers of HIV/AIDS medicines participating in the pre-qualification project urging companies to verify submitted data and compliance with good clinical practices and good laboratory practices. On November 11, 2004, Ranbaxy pulled seven of its ARVs "after the company found discrepancies in the documentation relating to proof of the products' bioequivalence with originator medicines." Shortly thereafter, Hetero withdrew six ARVs from the prequalification list after realizing that the contract research organizations (CROs) that had tested for bioequivalence did not meet current standards. See "Removal of Antiretroviral Products from WHO Prequalification," World Health Organization, November 11, 2004 (available at [www.who.int/3by5/amds/amdsnews10/en](http://www.who.int/3by5/amds/amdsnews10/en)), and "Hetero Drugs Ltd. Withdraws Antiretrovirals from WHO Prequalification List for Further Review," World Health Organization, November 19, 2004 (available at [www.who.int/medicentre/news/notes/2004/np24/en/print.html](http://www.who.int/medicentre/news/notes/2004/np24/en/print.html)).

15. "FDA Grants Tentative Approval to Generic AIDS Drug Regimen for Potential Purchase under the President's Emergency Plan for AIDS Relief," U.S. Food and Drug Administration, January 25, 2005 (available at [www.fda.gov/bbs/topics/news/2005/NEW01152.html](http://www.fda.gov/bbs/topics/news/2005/NEW01152.html)).

16. Ranbaxy claims to be filing data with the FDA for an eventual review.

17. Gilead, "Gilead Provides update on development of FDC of Trivuda," press release, April 26, 2005.

18. Merck website, "The Accelerating Access Initiative," [www.merck.com/about/cr/policies\\_performance/social/access\\_initiative.html](http://www.merck.com/about/cr/policies_performance/social/access_initiative.html).

19. See Roger Bate's paper *Saving Lives Today and Tomorrow* (working paper, Africa Fighting Malaria, April 2003) [www.fightingmalaria.org/research.php?ID=7&month=](http://www.fightingmalaria.org/research.php?ID=7&month=).

20. HIV resistance builds fairly quickly to Nevirapine even in the best of conditions; under poor conditions, resistance is likely to flourish.

21. "The Treatment Era: ART in Africa," UN Office for the Coordination of Humanitarian Affairs (available at [www.plusnews.org/webspecials/ARV/print/p-afrhea.asp](http://www.plusnews.org/webspecials/ARV/print/p-afrhea.asp)).

22. Ibid.

23. Carole Landry, "South Africa Once Again Stumbles on AIDS Treatment Plan," Agence France Presse, March 14, 2005.

24. Nicole Itano, "Concern in Africa over Private Doctors Giving AIDS Drugs," *Christian Science Monitor*, February 22, 2005.

25. John Donnelly, "Staff Level Hurts AIDS Fight," *Boston Globe*, February 24, 2005.

26. UNAIDS/WHO, "UNAIDS/WHO Policy Statement on HIV Testing," June 2004 (available at [www.who.int/hiv/pub/vct/statement/en/](http://www.who.int/hiv/pub/vct/statement/en/)).

27. Roger Bate, Richard Tren, and Jasson Urbach, "Taxed to Death," (AEI-Brookings Joint Center for Regulatory Studies Related Publication 05-04, April 2005) [www.aei-brookings.org/publications/abstract.php?pid=930](http://www.aei-brookings.org/publications/abstract.php?pid=930).

28. Merle A. Sande and Allan Ronald, "Treatment of HIV/AIDS: Do the Dilemmas Only Increase?" *Journal of the American Medical Association* 292, no. 2 (July 14, 2004): 267.