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Aids

The cocktail hour

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Powerful, expensive new medicines can delay the development of AIDS for years, if they don't kill the patient first.

According to the mainstream American press, 1996 was the year when AIDS became a chronic manageable illness. "The end of AIDS?" asked a Newsweek cover suggestively in December, while AIDS researcher David Ho, [1] found his way on to the cover of Time as AIDS research poster boy "extraordinaire" and Time's "Man of the Year."

The cause of all this hoopla is a new class of drugs called protease inhibitors, which, when taken in combination with a regimen of previously available drugs called reverse transcriptase inhibitors, keep HIV at often undetectable low levels for lengthy periods of time, possibly several years. These combination therapies can consist of up to 20 pills a day, and are referred to euphemistically as "cocktails." For people who are sick, such cocktails probably extend life expectancy by several years.

Ho's attainment of poster boy status was spurred not so much by any leading role he held in the development of these drugs [2] as his advocacy of a "hit hard, hit early" treatment strategy. The idea behind such a strategy is that the earlier you counter an HIV infection, the more likely you are to contain the virus entirely inside blood cells; if you can contain it for a couple of years, those cells will die off, and the infection may disappear completely.

High risk

In practice, "hit hard, hit early" is an entirely unproved concept. Researchers made the same claims about AZT (the first reverse transcriptase inhibitor) when it came out. Subsequent research showed that although AZT makes people with AIDS healthier for longer, it is so toxic that it does not increase people's life expectancy. Those who were "hit hard" and "hit early" with AZT actually saw their life expectancies decrease.

The new cocktails are a bit more promising in this regard: They do appear to be able, in some patients, to disappear the virus for almost enough time. But just as these cocktails are dramatically stronger than AZT, the risks associated with a "hit hard, hit early" strategy are dramatically more dangerous. Already, more than ten percent of new HIV infections in the US are resistant to AZT, and these resistant strains of HIV are more powerful and more deadly than the non-resistant ones.

Strains that are resistant to AZT are also more resistant to other reverse transcriptase inhibitors, and even somewhat to protease inhibitors, a trait known as "cross resistance." The resistance and cross-resistance created by drug cocktails is manifold higher.

This means that people who "hit hard, hit early" and fail will be left in a few years with an infection that is more virulent, resistant to other available drugs, and probably resistant to many future drugs as well. AIDS service providers already report a new potential outbreak of resistant HIV as men on drug cocktails, whose viral load sometimes drops to undetectable levels, believe that they are not contagious and begin having unsafe sex with "and infecting" their partners.

Huge profits

What "hit hard, hit early" does unambiguously do is boost drug company profits, by putting people on expensive drugs who may not need them. And these profits have been enormous: The first protease inhibitor to be released, Hoffmann-LaRoche's Invirase (saquinavir), was priced at \$7,000 per year. Then, Abbott released Norvir (ritonavir) at \$8,200. Finally, Merck chose to distribute its protease inhibitor, Crixivan (indinavir) through a single pharmacy retailer, Statlander's, which marked up the drug 38% to over \$6,000 per year.

A co-ordinated effort by several AIDS activist organisations of fax zaps, meetings, and letter writing got Statlander's to agree to negotiate about the price. Finally, after four ACT UP/New York members were jailed for posting signs on Statlanders' store in a largely gay area of New York's Greenwich Village, the company agreed within 24 hours to lower the price to the still-ridiculous amount of \$5,000 per year.

The prices of Invirase and Norvir have not yet budged, so that someone on a regimen of several drugs can pay up to \$30,000 for a year's supply. Not surprisingly, Merck saw a 1995 after-tax profit rate of 22%, Abbott of 16%, and Hoffmann-LaRoche of 22%, even after amortising their research and development expenses for these drugs. These leading pharmaceutical companies are in full marketing mode, holding off on newly-developed life-saving drugs (like so many new model computer chips) until the current ones have run out their profitability.

Glaxo-Wellcome, the manufacturer of AZT, has already developed a new reverse transcriptase inhibitor known as "1592," which is supposed to be ten times as effective as AZT and dramatically less toxic. But the company does not want to begin large-scale (Phase II) clinical trials for "1592" until demand for AZT is exhausted.

How much is your life worth?

With these kinds of prices, drug companies have excluded all but the wealthiest Americans, and those lucky enough to have good insurance, from effective, up-to-date treatment. [3] There is a joint federal-state program, known as the AIDS Drug Assistance Program (ADAP), which provides drug assistance to middle-income people with AIDS. However, in 35 of the 50 American states, ADAP does not cover protease inhibitors (coverage was saved in New York only through the dramatic and persistent interventions of AIDS activists), and is already running bankrupt in states that do cover them.

The federal government was forced to inject \$167 million more into ADAP midyear in order to pay its share of the costs for protease inhibitors, but even so, the ADAP Working Group (a Washington-based industry/community lobby group) estimates that this money will fall \$270 million short of demand. Without help from ADAP, Americans with AIDS are forced to spend themselves down to extreme poverty levels, so that they qualify for the social health program, Medicaid.

Meanwhile, AIDS is increasingly a disease borne by the poor and people of colour; new CDC estimates suggest that seven of ten newly-infected gay men are black or latino, and the numbers are even higher among IV drug users and heterosexuals.

To protest such high drug prices, ACT UP held a march last October in Washington, DC., on the weekend that the AIDS quilt was being displayed. In a deeply moving political funeral, protesters threw the ashes of about twenty-five people on the White House lawn to protest the federal government's lack of action. In response to ACT UP's actions, outgoing National AIDS Policy Co-ordinator Patsy Fleming promised, "I would be happy to meet with [drug

companies] about lowering their prices."

However, she did not indicate whether Vice President Al Gore brought up price gouging when he met with pharmaceutical manufacturers twice last year. Nor has she since announced any concrete action on the topic.

Far less noted, but just as profound, is the ideological coup that the new drugs have created for the corporate research agenda. Only two years ago, it was widely accepted that the government had pursued high-tech drugs at the expense of a basic research agenda, while promising but unprofitable treatments were widely ignored. Studies of the effects of various vitamins and nutrients were not widely performed until 1994, while cheap clinical trials of widely available substances that some people with AIDS were using, but had not been clinically tested. [4] There was an effort in 1995 to restructure entirely the Office of AIDS Research (which was made acutely more difficult when right-wing senator Jesse Helms used this effort as an excuse to attempt to abolish the office), and move more funds into basic research (the way HIV causes AIDS is still not entirely understood) and broader treatment studies.

AIDS-activists had been able to seize the government's failure as an opportunity to gain a great deal of publicity for some points they had been making all along: How the research agenda is governed by corporate interests, how its decisions are based on profitability and not the needs of people with AIDS, and how a more participatory program, directed by a wider range of doctors, epidemiologists, and people with AIDS - and notably not by corporate interests and representatives - could solve some of these problems.

Two years later, with drug cocktail makers promising miracles, AIDS activism has been largely reduced to issues around drug pricing and access, while larger questions of the research agenda will be ignored for as long as the current wave of high-tech drug lasts.

The purpose of this research agenda has been clear for some time. To quote ACT UP/Boston Member Rich Rochon, who gave the opening presentation for the VIIIth International Conference on AIDS in Amsterdam in 1992:

"Often I'm asked if I believe a cure will come and I strongly say "No!". I do believe that we, and I hope it's we [it wasn't; Rich died a year later], will see AIDS progress into a chronic, manageable disease. Just because I believe this does not mean that I'm not fighting for a cure. In my theory, imagine how much money a single drug company would make if it comes up with a cure. Imagine the profits. Imagine how much several drug companies can make by coming up with treatments for infections, keeping people with AIDS alive, allowing us to continue to get sick and be treated with drugs on an ongoing basis. Imagine the profits."

As long as drug pricing and access to treatment are the immediate and pressing issues, activists will be fighting for them forcefully. But when the glory of the current set of high-tech drugs begins to fade, we must again raise the larger issues of who controls AIDS research and where those people are taking it.

[1] Fully rebounded from his recent courtly disfavour (his research funds had been threatened the year before by those closer to the centre of the AIDS power structure), allegedly because he supported reform at the National Institutes of Health's Office of AIDS Research.

[2] The idea of using protease inhibitors against HIV has been around for at least a decade, and those currently available were developed by several different companies.

[3] Currently, 53% of PWAs are covered by Medicaid, 22% by private insurance, 25% by neither. Of those insured, about 3/4 get their protease inhibitors covered.

[4] For example, curcumin, an extract of turmeric that was claimed to boost levels of CD4; anti-depressants that seemed to delay the onset of disease progression were not supported at all by the federal government.