The High Cost of Living

The latest round of HIV meds may fatten up pharmaceuticals—and bankrupt drug assistance programs.

April 1, 1999 By Bruce Mirken

Just six days after DuPont Pharmaceuticals announced the price of its new HIV drug last September, 200 ACT UP demonstrators stormed the company's Wilmington, Delaware headquarters. Spirited crowds chanted, "We die, they make money!" and held banners proclaiming "Greed = Death," protesting the cost of the fifth antiretroviral to pass the $4,500-a-year mark—DuPont's efavirenz (Sustiva). With the approval of another costly new drug and price hikes on three older drugs waiting in the wings, the demonstration marked the latest skirmish in the AIDS drug price wars.

HIV therapy has been utterly transformed in the dozen years since ACT UP first descended on Wall Street to demand a lower price for AZT, and many who participated in that action are long dead. But the high cost of AIDS drugs still haunts us. Government programs created in the late '80s to help pay for the few treatments then available are now staggering under the costs of combination therapy, and observers worry that the bloated bill will become the target of a Congress bent on cutting social spending.

Disputes over drug pricing have broken out every year or two since 1987. Activists have challenged (with mixed results) the five-digit annual costs of the CMV drug foscarnet (Foscavir), the anemia drug EPO (Procrit) and wasting treatments human growth hormone (Serostim) and oxandrolone (Oxandrin).

But the 1995 introduction of the first protease inhibitor, saquinavir (Invirase), at a price of over $7,000 per year—and the need to use protease inhibitors with two or more other drugs—suddenly propelled the cost of anti-HIV therapy into the stratosphere. This time mainstream consumer advocates and the usually quiescent state AIDS Drug Assistance Programs (ADAPs) have joined AIDS activists in raising a voice of protest.

Last summer, with DuPont's nonnucleoside reverse transcriptase inhibitor (NNRTI) efavirenz and Glaxo Wellcome's nucleoside abacavir (Ziagen) nearing FDA approval, unnerving reports began to circulate. Treatment activists say they and state ADAP officials were being informally queried by the companies about prices thousands of dollars higher than existing nucleosides or NNRTIs. Those fears were heightened when both companies used the World AIDS Conference in Geneva to

highlight their new drugs as possible anchors for “protease sparing” regimens—likely implying protease-style prices. Activists worried that such pricing would open the floodgates, allowing the prices of all antiretrovirals to rush into protease territory. It was time to draw a line in the sand.

The amount of money spent on anti-HIV therapy had already been soaring as more people were taking regimens involving more drugs, often totaling $15,000-plus per year. One clear indicator of this has been the ballooning budget for ADAP, a program that provides medicines for those who lack private insurance but aren’t impoverished enough to qualify for Medicaid. (ADAP is run by the states but financed mainly through the federal Ryan White CARE Act.)

Until a few years ago, ADAP was so small it didn’t even rate a line-item in the CARE Act, says Bill Arnold, cochair of the ADAP Working Group, a community/industry lobby. ADAP’s total cost has been ratcheted up from $50 million in 1995 to an estimated three quarters of a billion dollars this fiscal year.

Even this increase hasn’t kept up with demand. In the protease era, ADAP funding crises have erupted over and over—especially where state governments don’t kick in significant contributions. In 1996, Illinois and New York dropped dozens of drugs from their formularies during a funding crunch, and at one point in early 1998 at least 10 states had closed enrollment. Arnold easily ticks off a list of problem states for 1999. “Texas will crash shortly. Colorado may crash again, as it did last year. Florida has a big waiting list,” he says. If he’s right, thousands will again be forced to do without medicine.

ADAP has become a boon for the drug industry, directing government monies straight into company coffers. But could growing enrollment—now over 65,000 nationwide—and the rising cost of HIV drugs kill the goose that lays the golden eggs? “Absolutely,” says Arnold. “ADAP is an emergency program. It’s not an entitlement. We have to show that dollars are being stretched as far as they possibly can.”

After all, there is no equivalent to ADAP for most other serious diseases, and conservatives already argue that AIDS gets too much money: In a December 1998 article in *The American Spectator*, Michael Fumento wrote, “The federal government spends tax dollars disproportionately on a chosen few diseases—notably AIDS and breast cancer—while underspending on bigger killers.” For now, an active pharmaceutical and community lobby has shored up Republican support, but congressional largesse may dry up.

By fall 1998, as concerns over the price of abacavir and efavirenz mounted, a high-powered group of treatment activists including Project Inform cofounder Martin Delaney, GMHC *Treatment Issues* editor Dave Gilden, *AIDS Treatment News* publisher John James and Los Angeles activist Linda Grinberg joined forces to form the Fair Price Working Group. FPWG quickly got hundreds of organizations and individuals to sign a letter telling DuPont and Glaxo that “the only acceptable prices for these drugs must be in accordance with their respective classes.” The letter spelled out three main points: that, as far as could be determined, development costs of abacavir and efavirenz “were not comparable to those of the first protease inhibitors,” that the potentially large

market for the drugs meant extensive profit opportunities, and that despite all the “protease sparing” talk, many would use the drugs to supplement protease-based regimens, driving the overall cost of therapy skyward.

The activists made a common-sense argument: A drug’s price should reflect the costs of research and manufacturing. Though drug companies rarely release such figures for individual drugs, the industry has defended the price of the protease inhibitors in part by citing real complexities in their development and manufacture. Merck says it spent more than $1 billion to develop indinavir (Crixivan), and had to completely refit an entire factory to handle the drug’s 20-step synthesis process. DuPont and Glaxo have yet to raise such arguments about their new, nonprotease drugs.

How much a new drug actually costs to bring to market is a matter of dispute. PhRMA, the Pharmaceutical Research and Manufacturers Association, estimates the industry’s total 1998 research and development (r&d) costs at just over $17 billion, against total sales of $81 billion. Patricia M. Danzon, PhD, professor of health care systems at the University of Pennsylvania’s Wharton School and associate editor of *The Journal of Health Economics*, says that total r&d estimates “now run from $500 million to $600 million” per drug, similar to the figure cited by PhRMA. The congressional Office of Technology Assessment (OTA)—which based its estimate on drug company accounts —put the maximum tag in 1993 at a much smaller $359 million.

Investment analyst Jim McCamant, editor of *The Medical Technology Stock Letter*, says drug companies sometimes cite these ballpark r&d and manufacturing costs when criticized for the price of a particular drug, “but those numbers are pretty hard to defend.”

James Love of the Ralph Nader– founded Consumer Project on Technology agrees. In a January 1997 article in *Marketletter*, Love compared industry-accepted estimates of clinical trial costs to the documented costs of 58 trials run by the federal government or drug companies that qualified for Orphan Drug Act tax credits (as some HIV drug trials do). He found that documented costs were two-thirds less than industry estimates, though, he said, some factors complicated the comparison.

Consumer advocates note that the drug industry’s growing marketing budgets have helped to inflate costs—with over $1 billion a year now spent pitching prescription medicines directly to consumers (little of it, so far, for HIV drugs). And the congressional OTA has estimated that drug company marketing expenses (a fraction of them direct-to-consumer) equal 22.5 percent of their total sales revenue.

What no one disputes is that the pharmaceutical industry is one of the most profitable sectors of American business. While some small and start-up drug companies struggle, the giants that produce most of the drugs purchased by Americans are doing well indeed.

The 1998 Fortune 500 list (based on 1997 figures) tells the story: Merck, the largest U.S. drug company, ranks 46th in terms of total revenues but raked in the ninth-highest profits, $4.6 billion. Bristol-Myers Squibb ranks 78th in revenues but 23rd in profits. Pfizer and Abbott are among the

top 50 profitmakers, though they aren't even in the top 100 in revenues.

When profits are stated as a percentage of revenues, the picture becomes even more dramatic (see chart). Of the top dozen companies in terms of profit percentage, five are drug makers. Through September 1998 (the last figures available at press time), pharmaceutical profits continued to grow.

Abacavir manufacturer Glaxo Wellcome, a British firm, isn't eligible for the Fortune 500, but is robustly profitable as well. Glaxo's sales for the first six months of 1998 were $6.3 billion, with profits of $2.0 billion—a profit rate of 32.2 percent, more lucrative than the top U.S. pharmaceutical by this measure, Schering-Plough at 21.3 percent. And HIV drugs have become important to Glaxo. They accounted for about 10 percent of the company's 1998 sales and, even more important, represented one of Glaxo's strongest areas of sales growth: Sales of AZT, 3TC and Combivir increased 18 percent last year, and the company's November 18, 1998, press release notes, "It is anticipated that the group's two new anti-HIV products [abacavir and the protease inhibitor amprenavir, awaiting FDA approval at press time]...will provide further impetus to growth."

By contrast, earnings of DuPont Pharmaceuticals—a comparatively small piece of the chemical giant's sales—were down substantially through September, since at that point efavirenz had generated much expense but no income. As new sales figures appear in the coming months, the picture may change.

When the FDA approved efavirenz September 18, DuPont announced a "list price to wholesalers" of $3,942 per year. That number translates to an "average wholesale price" (the standard measure, roughly equivalent to retail) of $4,730 per year—a tag 57 percent higher than nevirapine and nearly double the price of delavirdine, the other NNRTIs, and only 13 percent below Crixivan, the least-expensive protease inhibitor.

The bar had been raised. In October, Agouron Pharmaceuticals hiked the price of its protease inhibitor, nelfinavir (Viracept), by 4.6 percent. On December 10, Bristol-Myers Squibb announced a 4.5 percent increase for ddI (Videx) and d4T (Zerit)—the fourth price jump for the two drugs since March 1996—though spokesperson John Kouten hastened to note that even with the increase the company's drugs remain among the cheapest antiretrovirals.

And, counterintuitively, the trend toward less-frequent dosing may further raise combo therapy costs. For example, the twice-a-day regimen being tested for nelfinavir (as opposed to the currently recommended three times a day) involves taking about 11 percent more drug overall—and paying at least that much more.

DuPont met with FPWG members before announcing its efavirenz price, but nothing concrete came of it. After the announcement, ACT UP responded with not only the September protest at the company's offices, but another one in October. Meanwhile, several state ADAPs delayed adding efavirenz to their formularies, citing its expense. In an unheard of move, some AIDS groups—which

had often fought to get drugs added to ADAP lists—encouraged the delay, hoping to increase the pressure on DuPont. In mid-October, the company offered ADAPs an additional 5 percent discount (on top of the standard 15.1 percent ADAP price break) if they added efavirenz immediately—but there were few takers. Spokesperson Sandra James insisted that DuPont had named "a fair price."

On December 1, with an ACT UP march on the company scheduled for that afternoon, DuPont tried to make peace by announcing two concessions: The company made the 5 percent ADAP discount permanent and pledged not to increase the drug's price for at least three years. DuPont senior vice president of public policy Bob Perkins called his company's action "unprecedented," and in some ways it was. But his defense of the price remained firm: A federal panel had recently made efavirenz "the first NNRTI on the list of preferred treatments," Perkins says, validating DuPont's "protease-sparing" pitch. Perkins adds that such a regimen "costs about 28 percent less than a regimen using the most commonly prescribed protease inhibitor."

FPWG's Grinberg called the price freeze a "token gesture," saying that DuPont was still charging more than was needed to make a reasonable profit. But the battle was effectively over: The holdout ADAPs, including California and New York, moved to add efavirenz shortly after DuPont's announcement.

Still, the fight was never just about efavirenz. Glaxo Wellcome's abacavir was following close behind in the FDA approval process, and the loud protests against DuPont were intended in part to send a message to the other drug maker. Glaxo spokesperson Doug Stokke insists that his company's decisions were "independent" of the DuPont showdown, but adds, "Certainly we were aware of what was going on." In any case, Glaxo struck a cooperative tone, meeting with the FPWG weeks before announcing abacavir's price.

That same December 1, World AIDS Day, Glaxo made a surprise announcement of its own. Abacavir would have a list price of $3,540, or an average wholesale price of around $4,200. This news was greeted with sighs of relief. Rumors, reportedly floated by company staffers in the preceding weeks, indicated that Glaxo had considered charging $6,000 per year. California ADAP officials cited its unexpectedly low price as a reason they were able to start covering the high-priced efavirenz last December. Glaxo's press release gleefully quoted Martin Delaney saying, "Glaxo Wellcome clearly listened to our concerns and has sent a message that they share those concerns."

ACT UP/Philadelphia's Paul Davis, central to the protests, grumbled that what Glaxo had done was "not great, but a lot better than we thought it would be." When all was said and done, however, abacavir's "low" price was only about 10 percent below that of efavirenz. And abacavir is now the most expensive nucleoside on the market.

With HIV drugmakers topping national profit lists, activists cannot shake their suspicion that prices charged for AIDS drugs could be cut far more drastically. Certainly there is little evidence that the price you pay for a drug bears any direct relation to the cost of developing, testing and producing it.

A drug's r&d is one factor in its price, says Wharton's Danzon, but, "to break even, companies must cover *all* the r&d expenditures in a company, including all the research and development money spent on 'dry holes' that didn't pan out, spreading that over all the drugs that do get to market."

"In the pharmaceutical industry, pricing is based more on an attempt to estimate value to the customer," Danzon continues. "What you can charge in the marketplace, not looking back at costs." An article in the December issue of Project Inform's *PI Perspective* slams drug makers as "opportunistic" for charging "what the market will bear." DuPont VP Perkins may disagree with the article's tone, but when asked about the price of efavirenz, he echoes its substance: "I think you explain it by talking about the specific benefits a drug brings to the market or to any individual patient. We think with Sustiva the value is tremendous." DuPont declined to give r&d figures for the drug.

Danzon defends high profit margins, saying greater profit potential spurs more r&d—and indeed more new drugs are developed in this country than anywhere else. Besides, she says, "Any manager of a pharmaceutical company who is not maximizing the value of the company to their shareholders is going to lose his job."

But ACT UP's Davis asks why drug companies need to be more profitable than any other sector of U.S. business. He yearns for "a large-scale campaign for federal price controls and patent law reform." Such proposals have been floated, but have gone nowhere in the Republican-dominated Congress. So he expects that for now activists will "hold the line" by "targeting a few of the companies most egregiously price-gouging."

Though the recent campaigns may not be a triumph, FPWG's Gilden sees progress in the fact that the drug makers budged at all. Indeed, at a February 3 meeting with the FPWG, Bristol-Myers too announced a cut in its prices to ADAPs—3 percent off ddI and d4T. "The biggest victory," Gilden says, "is that we've forced our way into dialogue with the companies on the pricing issue."

BUNDLE OF JOY

One of 1998's fiercest drug pricing battles wasn't over an HIV drug, but over a treatment for hepatitis C, a virus that co-infects large numbers of people with HIV. The drug is ribavirin, a nucleoside developed by ICN Pharmaceuticals and tested over a decade ago to treat HIV. (The drug never got FDA approval for that use.)

A few years ago, Schering-Plough was licensed to develop ribavirin as a hep C treatment. Since interferon is the standard therapy, Schering tested the drug in combo with its brand of interferon, Intron A, and obtained an unprecedented license from the FDA: a "bundled" drug approval allowing Schering to sell ribavirin only when packaged with Intron A, under the brand name Rebetron. So doctors and patients who want to use ribavirin with another brand of interferon still must buy Intron A. Ribavirin isn't sold separately in the United States.

And it’s expensive. A one-month supply of Rebetron retails for about $1,440 (a six-month course—totaling about $8,600—is the FDA recommendation). In response, San Franciscan Brian Klein, who has both HIV and hep C, cofounded the Hepatitis C Action and Advocacy Coalition (HAAC) to do its own kind of acting up. He calls the price tag on the ribavirin part of the combo “outrageous”—at approximately $1,000 a month, it’s more than double what the drug sells for in Mexico, where it has long been sold separately by ICN.

Schering-Plough spokesperson Bob Consalvo defends the bundling as “a safety issue,” since the company never tested ribavirin with other interferons. And he says the Mexico comparison doesn’t take into account Schering’s development costs for the bundled product.

But Klein, whose group recently sprouted a New York chapter, doesn’t buy it. And neither do AIDS activists, who fear the bundling could set an ominous precedent for HIV drugs. Discussions between HAAC and Schering-Plough have produced little movement thus far.

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