The Price May Not Be Right

Pricey AIDS drugs + fraying safety nets = threats to PWA survival.

April 1, 1997 By Victoria A. Brownworth and Bob Lederer

Every morning, 29-year-old Lonnie Williams* wakes up in his mother's house in the poor North Philadelphia neighborhood that has more AIDS cases per capita than any other part of the city. Williams' T-cell count has dropped below 200, and he's terrified he'll lose his job as a small-business clerk when he gets too weak to work. With the job will go the limited medical insurance he has -- a plan that includes no prescription coverage. Even now, he can't afford all the drugs in the combination his doctor has said could keep him alive another year or two or five, because the annual cost of the drugs -- -AZT, 3TC and ritonavir -- is almost as much as his salary. So while he manages to buy and take AZT and 3TC regularly, he can only afford to get ritonavir every few months. Talk about a prescription for disaster: Sporadic dosing of protease inhibitors can potentially produce virus resistant to treatment.

Williams is one of many casualties of a renewed skirmish in the AIDS war -- the battle over the high cost of drugs. Tremendous frustration edges into his voice when he says, "How come we've been struggling so long to hold on till there's the right drug and then you can't get it? It's there, but if you can't afford it, you can't get it and you're gonna die. It's a real shame."

Halfway across the country, Bill Peterson* doesn't think about dying. Diagnosed nearly 13 years ago, Peterson is, at 34, a long-term survivor. For the past year, he's been taking an anti-HIV drug cocktail that includes AZT, 3TC and saquinavir. Although his T-cell count is only 100, it has stabilized and his viral load, though still high, has dropped considerably. Physically he feels fine. But Peterson does worry about getting arrested for the insurance fraud he's been committing for four years. He has his doctor overprescribe for him and stockpiles medications in order to obtain lifesaving drugs for his lover and two friends -- all of whom have no insurance to pay for their treatment. Each owes Peterson his life; they might be dead without him. Yet each month when the reimbursement envelope arrives from his insurance company, Peterson fears it will be a letter informing him that the insurance company has uncovered the fraud.

Welcome to the brave new world of pharmaceutical roulette, where a dicey mix of exorbitant prices, inadequate insurance and dwindling public-health services keep powerful, potentially life-extending drugs out of reach for thousands who need them. While magazine headlines herald the supposed twilight of the AIDS epidemic, many PWAs are left frustrated and angry because the drugs they've been waiting and praying for -- though on pharmacy shelves -- may not be available

to them.

Meanwhile, health care safety nets such as Medicaid and the state-by-state AIDS Drug Assistance Programs (ADAPs) are fraying badly, and growing legions of PWAs are falling through the holes. Williams, for instance, makes $275 per month too much at his job to qualify for free medications through Pennsylvania's ADAP. And Peterson's lover and friends live in a state -- like many others -- whose ADAP doesn't cover the drugs they need. As calls for guaranteed treatment access escalate from AIDS care workers, physicians and PWAs, the controversy over high drug prices has moved to center stage in the AIDS community.

Just how high are these prices? An estimated 200,000 U.S. residents with HIV have taken protease inhibitors, most in cocktails of three, four or more antiretroviral drugs each day, at a combined cost from $12,000 to $20,000 a year per person. The protease inhibitors alone have average annual retail prices ranging from $5,900 for indinavir (Crixivan) to $7,200 for saquinavir (Invirase) to $9,000 for ritonavir (Norvir). IMS America, a market-research firm, estimates that the three drugs are selling at a combined annual rate of $500 million in this country alone, with future growth likely.

Then there are additional drugs many PWAs must take for periodic symptoms and opportunistic infections (both prophylaxes and treatments). Among the most expensive (annual retail prices): Ganciclovir (Cytovene) for CMV, $18,000; G-CSF (Neupogen) for white-blood-cell depletion, $26,000; and human growth hormone (Serostim) for wasting, $36,000 (a price halved after months of pressure by ACT UP/Golden Gate). Many PWAs take up to a dozen drugs, cumulatively costing up to $70,000 per year.

The Bureau of Labor Statistics reports that between 1980 and 1993, pharmaceutical prices rose 216 percent -- more than four and a half times as fast as the overall cost of living. Under pressure from cost-cutting managed care plans, the drug-inflation pace has recently slowed somewhat, but sudden price jumps continue to occur.

Take, for instance, oxandrolone (Oxandrin) -- a formerly inexpensive steroid drug approved by the Food and Drug Administration (FDA) in the mid-1960s to treat wasting due to chronic illness or surgery. In 1995 the FDA approved its use for AIDS wasting and granted "orphan drug" status (offering seven-year exclusive marketing rights and tax breaks to companies selling drugs for limited-market diseases). Marketer BTG promptly boosted the price 12-fold, with an annual supply costing up to $44,000 (later capped under pressure at $15,000).

Of course, the AIDS drug most famous for accusations of price-gouging remains AZT. Developed largely with federal research funds, the drug was first marketed by Burroughs Wellcome (now Glaxo Wellcome) in 1987 at $10,000 a year -- a price later significantly lowered after repeated ACT UP protests and congressional investigations. According to a recent article in *The Economist*, AZT has made a total of $2.3 billion so far. A 1993 study by Dr. Thomas McLaughlin of Harvard Medical School estimated that the company had reaped a whopping 43 percent profit -- the excess above expenses that goes to stockholders -- on sales up to that time. Last September, after clinical trials

showed that cocktails including AZT and 3TC packed a potent antiviral punch, Glaxo boosted the price on both drugs -- combined 1996 sales of which *The Wall Street Journal* estimated at $600 million -- by 2.9 percent. Also hiked was the price of the hot-selling herpes drug acyclovir (Zovirax), last increased to compensate for the 1989 AZT price reduction.

The higher these drug prices go, the faster tight-fisted governments and HMOs run out of money for benefits -- leaving PWAs holding the bag. (See "Med Money Management" for options to pay for drugs.) The AIDS Action Council, a Washington, DC lobbying group, has described an "escalating cost squeeze" on both public and private insurance that includes "impossibly low prescription drug caps, restricted formularies (lists of covered drugs), unreasonably high prescription co-payments and burdensome prior authorization procedures." Meanwhile, in many states, Medicaid -- the federally funded health care program that covers 53 percent of PWAs -- is imposing various prescription limits, and faces presidential and congressional proposals for severe budget cuts, including per-capita funding caps that will inevitably lead to further access restrictions.

Worst off are the estimated 25 percent of HIV positive people in the United States with neither health insurance nor Medicaid -- plus the thousands of others such as Lonnie Williams with inadequate insurance to cover drugs. They will soon be joined by many now on Medicaid about to be ejected from public-assistance rolls under draconian new federal and state welfare restrictions.

All these PWAs are precisely the ones for whom ADAP was theoretically designed. But even with this fiscal year's much-increased congressional appropriation of $167 million -- a product of intense community pressure -- the ADAP Working Group (a Washington-based industry/community lobby group) estimates that funding will still fall $270 million short of the growing demand for the new high-priced drugs. The result is increasing cutbacks in both the people and drugs covered by many states' ADAPs. Waiting lists are common; some programs have gone bankrupt.

While destitute PWAs get sick -- and die -- for lack of treatment access, investors thrive on pharmaceutical stocks. Peter Arno, associate professor of health economics at the Einstein Medical College in Bronx, New York and coauthor of the Pulitzer-nominated book, *Against the Odds: The Story of AIDS Drug Development, Politics & Profit* (Harper Collins/New York City), cites figures in *Fortune* showing that "from 1988 through 1995, [the pharmaceutical industry] surpassed all other Fortune 500 industries in profit rates, and it has ranked either first or second in 31 of the past 39 years." In fact, drug-company profits average four times the Fortune 500. Last year, the three protease-inhibitor manufacturers -- Merck, Abbott and Hoffmann -- La Roche -- had net (after-tax) profit rates of 22 percent, 16 percent and 22 percent respectively.

So if drug companies are so firmly in the black, how do they justify their high prices while the AIDS-care crisis worsens? None of the above-mentioned AIDS-drug manufacturers had returned numerous calls from POZ at presstime. Pharmaceutical companies routinely refuse to release specific figures on the costs of developing and producing a specific drug, claiming competitors could use the data against them. Yet every drug patent grants its holder at least a 17-year legal monopoly on that product.

Last fall, the Pharmaceutical Research and Manufacturers of America (PhRMA), a lobbying group for the industry, issued a statement including its standard defense for high prices: “It costs an average of $500 million to research and develop a new medicine. In order to fund ongoing research, manufacturers must be able to reap returns on existing drugs, including AIDS medicines.” PhRMA particularly cites Merck, claiming it spent more than $1 billion over a 10-year period to develop Crixivan, including building a new factory for the drug’s complex manufacturing process.

But independent experts challenge these claims. As for the Merck example, Arno notes manufacturing costs are not properly considered part of research and development (R&D) expenditures. And James Love, an economist who directs the Washington-based Consumer Project on Technologies, labels PhRMA’s $500 million figure an exaggeration on three levels: First, it’s higher than the $359 million estimate of the cost to bring a new drug to market, cited in a 1993 report by the congressional Office of Technology Assessment (OTA); second, “even that figure was the ’upper bound on the full cost’ -- not the average cost”; and finally, “many readers of the OTA report were struck by the reliance upon pharmaceutical-company consultants for the core findings. Congress never issued a subpoena to get financial data directly from the companies.” PhRMA spokesperson Jeff Trewhitt responds, “We strongly believe in the integrity of the OTA report. We think it’s a representative estimate by responsible professionals.”

Arno also questions the assumptions underlying the OTA calculations, particularly as they apply to AIDS drugs. He notes, for example, that the protease inhibitors’ unprecedented fast-track FDA approval greatly reduced clinical trial costs (while also starting a profit stream from sales far sooner in the research process than for any previous drugs). Arno further contends, “A very large proportion of the R&D costs for most HIV-related medications have been borne by the taxpayers, not the companies. A vast array of federal research grants, tax credits, subsidies and marketing privileges have been provided to drug manufacturers.” Love’s analysis suggests that when subsidies from federal clinical trials and tax credits are included, “direct industry outlays on R&D for many drugs may be far less than imagined.” Trewhitt counters, “That’s a misstatement. A study by Tufts University found that 90 percent of the 191 new drugs approved between 1981 and 1990 were researched and developed by private companies using their own money.”

Love explains why it’s hard to analyze industry claims: “We’re always having to argue with industry because we don’t have our own numbers. That’s why information is so tightly controlled. We require more financial information from a woman on food stamps than from someone who wants to charge $1 billion for a lifesaving drug.” Adds Don Howard, a San Francisco management consultant who co-authored a study on drug pricing by ACT UP/Golden Gate, “Companies keep this data secret not so much because it’s competitive in nature, but because once we know a drug’s R&D and manufacturing costs, we can figure out whether they’re making unreasonable profits.”

Indeed, at the height of the AZT controversy in 1989, just as the House Subcommittee on Health was preparing to subpoena Burroughs Wellcome’s financial records, the company cut the price -- and the investigation stopped cold. Tim Westmoreland, the subcommittee’s then-counsel and a longtime expert on drug pricing, cites other examples of this phenomenon. “Rather than charging

the actual cost of an experimental drug (which is allowed before approval by FDA), almost all companies would rather give it away, so their profit margins will never be known."

Westmoreland argues that neither R&D nor manufacturing costs are the actual basis for picking a drug price. Rather, he says, prices are based on "a comparison with what will be the cost of not having the drug, such as the cost of a hospital stay. If the drug genuinely prevents a symptom that would require hospitalization, the drug company can price the drug at 'Enormous Hospital Bill Minus One Dollar' and still have a market among insured people. What happens to insurance costs, Medicaid budgets and people without insurance doesn't seem to be the company's concern."

A glaring example of this occurred in 1990 when government research found that levamisole, an anti-worm drug for sheep, was effective in treating people with colon cancer (the drug is currently being tested as an immune modulator for PWAs). Overnight, manufacturer Johnson & Johnson (J&J) hiked the price from 6 cents to $6 a dose. When questioned by ABC's *PrimeTime Live*, J&J's Vice President Robert Gosson said, "A sheep farmer probably would not pay $6 a pill," while "someone dying of cancer who pays $1,200 for a treatment regimen, whose life is saved, is getting one of the most cost-effective treatments ever."

PhRMA is quick to offer the defense that "major pharmaceutical firms have long-standing patient-assistance programs, and most AIDS medicines are included in these programs." But Steven Schondelmeyer, professor of pharmaceutical economics at the University of Minnesota, says, "Yes, these companies provide small amounts of drugs for a few patients. But the eligibility criteria are never published and are often very stringent. The secrecy makes it hard to assess their value." And Arno sees another side to this charity: "Patient assistance programs are important to industry because they allow unfair pricing practices to go unchecked. By undercutting criticism about access, the company is able to extract its unconscionable prices from the taxpayers [via government drug-purchase plans] and the privately insured."

With powerful drugs that stave off death for at least some PWAs, the stakes are now higher than ever. So advocates' current efforts proceed on two fronts: Insisting on full government coverage of AIDS drugs -- regardless of cost -- through Medicaid and ADAP, while also challenging the prices themselves. For mainstream AIDS organizations weary of growing reports of PWAs denied access to lifesaving drugs, last year's price jump by Glaxo was the last straw. This winter, the AIDS Action Council coordinated an open letter to the pharmaceutical industry, endorsed by more than 250 service, advocacy and clinical groups (including *POZ*) demanding lower drug prices.

This was the most broad-based of a wave of recent protests against alleged price-gouging. Several speakers at last June's International AIDS Conference in Vancouver decried the problem, and ACT UP staged daily disruptions of drug-company display booths there. Periodic well-publicized demonstrations have since been held in several cities, and a national ACT UP march on Wall Street is planned for March 24.

ACT UP's Howard says, "We want companies to develop drugs, and the profit motive is the best

incentive to do so. But we want to ensure that companies with a legal monopoly on a lifesaving technology don't abuse that position to extract unfair profits." He adds, "The only mechanism to force disclosure is public hearings -- just as other monopolies like utilities must face when seeking rate increases."

The open letter by the 250 AIDS groups warns that without price reductions,"congressional hearings on this issue may be unavoidable." But most observers believe such hearings are highly unlikely without massive grass-roots pressure. Still, there are rumbles of congressional discontent with the status quo. Last year, an amendment offered by Rep. Bernard Sanders, a Vermont independent, to require "reasonable prices" for new drugs developed with substantial federal research funds, got 180 votes in the House, just 38 short of passage. Rep. Dana Rohrabacher (R-California), one of several conservative supporters, told the House, "The American people should not be... forced to pay for the research of a company who then turns around and gouges them for the price of the product that has been developed."

Sanders has also introduced a more sweeping bill that would require drug companies to fully disclose financial data on any FDA-approved drug, and would mandate federal programs buying drugs to negotiate prices discounted for government research investments. To prevent any adverse effect on new drug development, the bill also mandates a minimum level of R&D spending by price-regulated companies, with specific allocations left in corporate hands.

And some are talking of even-more-drastic solutions. A scholarly paper written by a team of economists and consumer advocates (including Arno, Love and Derek Hodel, deputy director for policy at Gay Men's Health Crisis) includes this highly controversial proposal: "A national price review board, which exists in some form in most European countries, should be established to ensure that drugs are priced fairly in the United States." Trewhitt responds, "When they're tried, price controls don't work -- they put a damper on drug innovation."

The bottom line remains the same as a decade ago when ACT UP first demonstrated on Wall Street. As Arno says, "What determines drug prices can be summed up as 'what the market will bear.'" So it falls to consumers and taxpayers to absorb the high cost of staying alive -- which leaves many HIV positive people priced out of the market and out of luck. Bill Peterson, the PWA sharing his drugs, puts it bluntly: "I've been turned into a felon because I want my friends to live. My father, a physician and a Republican, asked me if I have a moral dilemma about what I'm doing. I told him I'm not the one who has a moral question of right or wrong. I hope I'm saving lives. If the drug companies felt the same way, I wouldn't have had to become a criminal."

**These names have been changed.*

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