Bob Huff

Paying for Life

THE ISSUES BEHIND DRUG PRICING

Most people today appreciate the value of antiretroviral therapy, if not its price. This is because the price of expensive anti-HIV medications in the U.S. is largely, and thankfully, invisible. Although uninsured or underinsured people with HIV may have to pay for their drugs out of pocket, the cost of pharmaceuticals for most HIV positive Americans is borne by private insurance or by the government through Medicaid or a state AIDS Drug Assistance Program (ADAP). Copayments collected by the pharmacy—which can be a significant burden—are as close as many people get to the byzantine world of prescription drug pricing.

The happy fact is that thousands of people are alive today because of better medications and the generous access that came about during the strong economy of the 1990s. But with Congress feeling less charitable these days, there are disturbing signs of trouble ahead. Increasingly, it seems that if the political will to pay the price of quality health care does not soon find a powerful voice, the combination of shrinking funding and runaway drug costs could put the health of large numbers of people in this country who depend on life-giving medication at risk. The implications for those with HIV are considerable, since drugs are generally the biggest factor in the cost of HIV health care.

The Increasing Cost of Health Care

The U.S. is one of the only wealthy nations without government limits on the price of prescription drugs, and American health-care costs continue to spiral upward, with pharmaceuticals leading the way. Even though most consumers do not bear the cost of their drugs directly, rising prices affect the cost and quality of health care for nearly everyone in the U.S. by way of increased insurance premiums, larger copayment amounts, and growing limits to state-funded programs such as ADAP. As state governments explore ways to control prices, the powerful pharmaceutical industry has countered with its own tactics to preserve drug companies' freedom to set prices without such restraint.

Soaring health-care costs are partly due to escalating drug prices, but are also influenced by the increased consumption of expensive drugs. After restrictions on direct-to-consumer (DTC) drug advertising were relaxed in 1997, prescriptions for advertised medications began to climb as Americans started demanding treatments they saw in the media. As DTC ad spending rose from $1.1 billion in 1997 to $3 billion in 2001, drug prices rose, the pharmaceutical industry grew, and profits expanded significantly. Meanwhile, government entitlement programs dug deeper to pay for drugs, and private insurance premiums became all but unaffordable for anyone without a well-paying, full-time job. In today's troubled economy, with unemployment rising and many small businesses unable to meet the burden of high premiums, one in four Americans lacks health insurance, and their ranks are growing.

Over the past couple of years state governments have begun to fight runaway drug costs by attacking the problem on two fronts. First, there has been an attempt to limit utilization by requiring doctors to obtain prior authorization for expensive drugs that are not included on an approved formulary list. In practice, the hurdle of seeking approval to prescribe certain drugs means that doctors often select a similar, cheaper substitute. Problems arise when patients are told at the pharmacy that their prescription cannot be filled because it is not approved; many are likely to give up and go untreated. This sort of manipulation—along with cracking down on waste and fraud—may produce some savings, but in reality, people with complex chronic diseases risk having their care compromised by these restrictive rules. Certainly any effort to cut utilization of anti-HIV medications would be met with anger and outrage.

On the price front, some states such as Michigan and Maine have been trying to win discounts from pharmaceutical manufacturers in exchange for adding their drugs to the state's approved Medicaid formulary, thus removing the barrier to prescribing. This is a powerful stick to wield, since drug companies are loath to yield any market share to their competitors. The pharmaceutical industry deplores this strategy and is fighting back with court challenges, sophisticated public relations campaigns, and drug giveaways via company-run disease management programs aimed at Medicaid patients. In Florida, the pharmaceutical lobby prevailed on Governor Jeb Bush to water down state formulary restrictions by allowing drug companies to offer case management of "high utilizers" instead of discounts. But the industry recently suffered a setback when the Supreme Count voted to allow a program to go forward in Maine that seeks additional rebates for state Medicaid drug purchases. Companies that don't comply will see their products parked on a prior authorization list.

Why Is Price a Problem?

High prices can become a problem when a drug is available only as a brand-name product from a single manufacturer, as is the case with antiretrovirals in the U.S. Every approved anti-HIV drug sold in this country is

Drug Pricing Key Terms

340B (PHS) Price
The maximum price that manufacturers can charge covered entities participating in the Public Health Service's 340B drug discount program.

Acquisition Cost (AC)
The net cost of a drug paid by a pharmacy. It varies with the size of container purchased (e.g., ten bottles of 100 tablets typically costs more than one bottle of 1,000 tablets) and the source of purchase (manufacturer or wholesaler).

AIDS Drug Assistance Program (ADAP)
A federal program established in 1987 to provide anti-HIV and related medications to low-income Americans.

Average Manufacturer Price (AMP)
The average price paid to a manufacturer by wholesalers for drugs distributed to retail pharmacies. The Congressional Budget Office estimates AMP to be about 20% below AWP for more than 200 drugs frequently purchased by Medicaid recipients.

Average Sales Price (ASP)
A new system created by federal and state governments to ensure more accurate price reporting. ASP is the weighted average of all nonfederal sales to wholesalers and is the net of chargebacks, discounts, rebates, and other benefits tied to the purchase of the drug product, whether it is paid to the wholesaler or the retailer.

Average Wholesale Price (AWP)
A national average of list prices charged by wholesalers to pharmacies. AWP is sometimes referred to as a "sticker price" because it is not the actual price that larger purchasers normally pay, which is often considerably lower. AWP information is publicly available.

Best Price
The lowest price paid to a manufacturer for a brand name drug, taking

into account rebates, chargebacks, discounts, or other pricing adjustments, excluding nominal prices. Best price data are not publicly available.

Covered Entities
Facilities and programs eligible to purchase discounted drugs through the Public Health Service's 340B drug discount program. Covered entities include state ADAPs and hospitals owned by state and local governments.

Dispensing Fee
The charge for the professional services provided by the pharmacist when dispensing a prescription, which may include overhead expenses and profit.

Federal Supply Schedule (FSS)
The collection of multiple-award contracts used by federal agencies, U.S. territories, Indian tribes, and others to purchase supplies and services from outside vendors. FSS prices for the pharmaceutical schedule are based on the prices that manufacturers charge their "most-favored" nonfederal customers, which may not be the lowest prices on the market. FSS prices are publicly available.

Medicaid (known as Medi-Cal in California)
A program using state and federal funds to reimburse providers that offer medical care to low-income Americans who cannot afford health insurance. Medicaid serves 55% of people with AIDS and 90% of children with HIV/AIDS nationally. Medi-Cal is the largest payer of health-care services for people with HIV/AIDS in California.

Medicare
A federally administered system of health insurance available to people aged 65 and over and some others with disabilities.

Non-Federal Average Manufacturer Price (Non-FAMP)
The average price paid to a manufacturer by wholesalers for drugs

still under patent protection. A patent guarantees the holder an exclusive right to market the protected product without competition for a period of at least 20 years. After the patent protection period has expired, other manufacturers are free to produce a nonbranded, generic version of the product and sell it at a fraction of the price of the branded drug. In the pharmaceutical business, a good example is fluoxetine (Prozac), which sold for $2.50 per pill until its patent ended in 2001 and a generic manufacturer brought its version to market for only $0.25 apiece.

The first anti-HIV drug expected to lose U.S. patent protection is AZT (zidovudine, Retrovir), which could become available generically in the U.S. sometime after 2005. Since most people who use AZT these days take it with 3TC (lamivudine, Epivir) in the form of Combivir, generic AZT is unlikely to have much impact in this country. Several generic antiretrovirals are now produced in other parts of the world, helping to make treatment a possibility for the millions of people in countries without access to expensive branded medications. But generics have not yet directly affected the pricing situation for anti-HIV drugs in the U.S.

Historically, when a generic equivalent enters the market, the profit potential of the original branded drug virtually vanishes. The price of the generic is set at some margin above the cost of materials, manufacturing, and distribution, and the maker of the branded drug must lower its price or give up the market. The prices of generic equivalents can be set so low because their makers typically invest little or nothing in drug discovery, clinical research, and marketing.

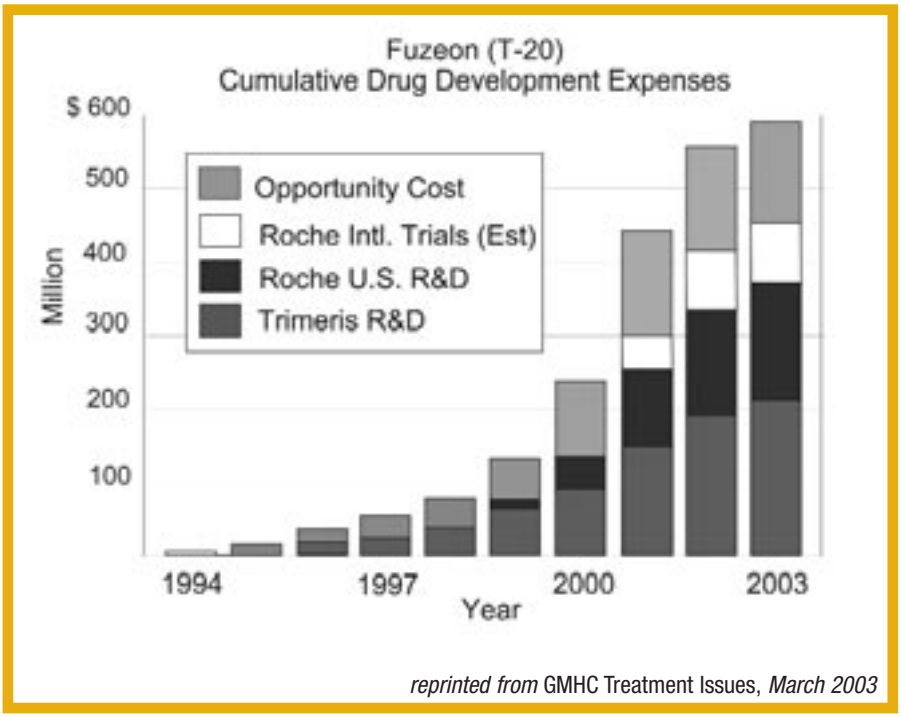
Major pharmaceutical manufacturers argue that the significant cost of bringing new drugs to market justifies the high prices they charge. Furthermore, since the window of premium pricing is limited by a product's patent life—a good portion of which is used up during the approval process—all of a drug's research and development costs must be recouped within a relatively short period of time. Critics of exorbitant drug costs point out that the pharmaceutical industry, despite its complaints, remains one of the most profitable sectors of the economy, and that development costs are overstated and are often subsidized by the government. Drug pricing, critics say, is driven by greed and by the monopoly protection allowed by patents. The true cost of high drug prices, they say, is measured in lives lost.

But the generic price advantage may not be a reliable solution to the current drug cost crunch. Consolidations among generic manufacturers are reducing competition, and generic manufacturers—seeing the gap between their prices and those of branded products as a wasted opportunity—recently have begun raising the sticker price on their knockoffs, thus further intensifying the squeeze on state and federal drug budgets.

Have I Got a Deal for You!

One of the hardest things to understand about pharmaceutical pricing is that not everyone pays the same price. And the prices for different payers are often secret. The only official price released by a pharmaceutical company is called the wholesale acquisition cost (WAC), which is the list price that industry middlemen are supposed to pay the pharmaceutical maker. The wholesaler, in turn, distributes the drug to pharmacies for retail sale.

A more widely quoted price for drugs is the average wholesale price (AWP), which is an average of list prices quoted by wholesalers to pharmacies. But because of an arcane system of discounts, rebates, and chargebacks, almost no one pays the "official" price. The acquisition cost (AC) is the actual amount a pharmacy pays for its drug inventory. This cost varies depending on the quantity purchased, as well as on the rebates and discounts available to the pharmacist. Large buyers can obtain significant discounts: you can almost be sure that a drugstore chain like Duane Reade is paying less for pharmaceuticals than an independent



reprinted from GMHC Treatment Issues, *March 2003*

neighborhood drugstore, although this may not translate into lower prices for consumers. A recent survey of 155 New York City pharmacies found the highest prices at the biggest chain stores, which charged, on average, 8% more than mom-and-pop stores. Shockingly, the report also found that chain stores in the poorest neighborhoods charged prices well above the citywide average, meaning that those who can least afford high drug prices in New York are paying the most.

After acquiring a drug, the pharmacy then resells it to consumers with or without an additional markup, plus something called a dispensing fee added on. The dispensing fee is a charge for the professional services of the pharmacist, plus an additional percentage of the drug's cost to cover overhead and profit. Each of these steps may be regulated or fixed by prior agreement. For example, some Medicaid programs may limit the dispensing fees charged by retail pharmacists.

A complex system of rebates for government purchasers has been negotiated to help control drug costs. The size of the rebates paid by the manufacturer varies depending on who pays the bill when a prescription is filled. The average manufacturer price (AMP) is a government-calculated average of prices for a drug actually paid by nongovernment purchasers. Although not officially disclosed, the AMP is estimated to run about 20% below the AWP. Government programs use the AMP as a baseline to calculate rebates, with the Medicaid rebate statutorily (by law) set at 15.1% of the AMP.

For programs that distribute drugs directly to their clients, the Public Health Service has established a discount plan that guarantees something called the 340B price, which at minimum matches the Medicaid 15.1% price break, although participating programs are free to negotiate better discounts. Such federally approved 340B participants include hemophilia treatment centers, family planning clinics, and ADAPs that run their own distribution systems. Most big ADAPs, however, distribute their drugs through pharmacies and are organized as reimbursement programs. This means that, for each covered drug dispensed, the state reimburses the pharmacy the AWP minus any special discounts, plus the dispensing fee. The state then collects its negotiated rebate directly from the manufacturer.

distributed to nonfederal purchasers. The Big 4 are entitled to discounts on brand-name drugs of at least 24% off of non-FAMP. (The Big 4 are the four largest purchasers of pharmaceuticals within the federal government: the Veterans Administration, the Department of Defence, the Public Health Service, and the Coast Guard.) Non-FAMP is not publicly available.

Opportunity Cost
The difference between the return on a given investment and the return on foregone alternatives.

Pharmacy Discount Price
The price paid to the pharmacy by a program (e.g., ADAP, Medicaid) for drugs. Brand-name drug prices are typically paid relative to AWP (for example, AWP minus 10%). The price covers the pharmacy's payment to the wholesaler, operating costs, and profit.

R&D
Research and development.

Unit Rebate Amount (URA)
The rebate amount paid by a manufacturer to ADAP and Medicaid for each unit (e.g., capsule) of a drug. Information on URA is not publicly available.

VA National Contract Price
The price the Veterans Administration has obtained though competitive bids from manufacturers for select drugs in exchange for their inclusion on the VA formulary. Because the VA is entitled to something called the Federal Ceiling Price (FCP), VA national contract prices are often the lowest in the nation. These prices are publicly available.

Wholesale Acquisition Cost (WAC)
The price paid by a wholesaler for drugs purchased from the wholesaler's supplier, typically the manufacturer of the drug. WAC is the price manufacturers release publicly, and is sometimes called the "list price." Publicly disclosed or listed WAC amounts may not reflect all available discounts.

The Best Is Not Good Enough

The "best price" is a proprietary federal determination of the lowest price paid by a manufacturer's best customers after rebates and discounts have been applied. Best price is one of the factors used to calculate the rebates owed to state Medicaid programs. Yet certain customers getting some of the best deals are left out of the best price equation.

For example, some government agencies that purchase drugs directly from manufacturers may enjoy extra discounts, which, if included, would bring the average best price down. Another large government purchaser, the Veterans Administration, negotiates a price that is published as the Federal Supply Schedule (FSS) price. The FSS price is based on what drug makers charge their "most favored" nonfederal customers—which, again, may not be the lowest price on the market if, for example, Wal-Mart negotiates a special deal on atorvastatin (Lipitor). Both the 340B and the FSS prices are excluded from the best price calculation.

So what is the price of any particular drug? It depends on who's paying and who's asking, since neither the government nor the manufacturers disclose that information. For example, take tenofovir DF (Viread), produced by Gilead Sciences. The published WAC is $360 for a 30-day supply; an online pharmacy advertises it for $435; and a state ADAP program may pay $380. As a point of comparison, Gilead has offered tenofovir to antiretroviral treatment programs in developing countries at $39 per month, roughly the company's cost of manufacturing.

Other Factors Affecting Price

Another aspect of a drug's price is less often discussed: what is it worth to the individual? The advent of the eBay online auction model has rationalized the pricing of all kinds of products and services by offering them to a wide market and letting individual buyers decide what they are willing to pay. But for products that are necessary to preserve human health and life, society has decided that some unregulated markets are unacceptable. Governments and large private health systems such as Kaiser Permanente use their clout as huge purchasers of pharmaceuticals to demand lower prices, and the states are attempting to control prices with rules, legislation, and group bargaining power. Yet there are ways around these pressures. Statutory discounts can be thwarted by raising the base price until the discounted price matches what the company would prefer the customer to pay. Where price increases for existing products are capped, a company may introduce a reformulation of an old drug at a new benchmark price.

Some prices are set where they are because that is how much other, similar products cost. For example, there are probably few similarities between the operating costs of cable and satellite television, yet remarkably both services are priced the same. And why does high-speed Internet access via DSL cost the same as access via cable? Well, providers reason, if that is what people are willing to pay, then why should they be charged less? When protease inhibitors (PIs) first entered

Risky Business:
THE CASE OF T-20

Although the pharmaceutical industry has remained profitable despite the tough economic climate of the past few years, the costs and risks associated with identifying and shepherding a new anti-HIV drug to market are considerable.

The latest antiretroviral approved for sale in the U.S. has brought the issue of drug pricing to center stage. T-20 (enfuvirtide, Fuzeon), discovered by Trimeris and developed and marketed in partnership with Hoffmann-La Roche, entered the market in March 2003 as the most expensive anti-HIV drug ever. With an announced wholesale acquisition cost (WAC) of $20,000 per year, the cash-and-carry price at the pharmacy reaches $26,400 annually, or $2,200 per month.

The development of T-20, the first in a new class of entry inhibitor drugs, began over ten years ago, and it took five years and $50 million to demonstrate it was a viable therapy in humans. Finally, after ten years and $600 million invested, the drug made it to market, but it remains unclear how accepting consumers will be of a drug that must be injected twice daily and causes injection-site nodules or irritation in most people who use it. Presumably, the population for whom T-20 is intended—those who have developed resistance to most other available antiretrovirals and have run out of therapeutic options—will be willing to put up with the discomfort and inconvenience for a chance at survival. But will that willingness extend to government programs that pay for life-saving medications for people with HIV, especially in parlous economic times? The risk for Trimeris and Roche is that after all the money and time invested, only a limited number of people will be able to benefit from T-20. The risk for those with multidrug-resistant virus is that a useful therapy will remain out of reach because the price is simply too high. *–B.H.*

the market in December 1995, they established a new benchmark for the price of HIV/AIDS medication, and the industry hasn't looked back since. This seems to be a lesson the generic drug industry is now putting into practice.

Price also reflects the value offered by a drug. For hepatitis C virus (HCV), for example, the price of a yearlong course of treatment includes the chance that one's infection may be permanently cleared. Currently, the newest and best HCV therapies can run upwards of $35,000 per year. But with HIV, there is no cure, and the need for therapy lasts a lifetime. The average yearly cost of anti-HIV therapy in the U.S. currently runs between $10,000 and $15,000. The price of drugs may also be weighed against the cost of hospitalization and care for untreated HIV, and thereby judged to be a bargain. A new, pricier drug may have fewer side effects and require less medical management than its cheaper predecessors. In the big picture, it is a money-saver (though in the short term it is still a drain on state budgets). Some economists have calculated the value of drug therapy in relation to lost productivity due to early death from AIDS. Few people who lived through the bad old days before PIs would say that the latest antiretrovirals aren't worth the cost.

Pressure Politics

But we may be entering an era in which political leadership demands more reasonable cost controls. There are powerful forces influencing political leaders today. On the one hand, health-care costs are soaring out of control and the political will to pay for them may be diminishing. On the other hand, the biggest contributor to rising costs—the pharmaceutical industry—is represented by an extensive and pervasive lobby that makes significant contributions to influential members of Congress and the Administration. In the ongoing struggle between those who wish to downsize government spending and the big donors, it looks increasingly as if something has to give.

ADAP IN CRISIS

The AIDS Drug Assistance Program (ADAP), established in 1987 to provide anti-HIV and related medications to low-income Americans, is a cornerstone of U.S. treatment efforts. Nationally (including U.S. territories), ADAPs serve about 140,000 people who could not otherwise afford these critical treatments. While paying for ADAP is primarily a responsibility of the federal government, Congress and the president have failed in recent years to provide adequate funds to assure unlimited access to the program. In fiscal year (FY) 2003, Congress appropriated $719 million for ADAP, an increase of $80 million over 2002. However, this increase fell $80 million short of what was needed. In FY 2004, President Bush has proposed spending $739 million on ADAP, but this amount is a massive $260 million below the $999 million needed to guarantee access to treatment for those who rely on ADAP.

To guarantee access to ADAP and make up for the lack of sufficient federal funding, many states have allocated their own money to the program. But in an era of severe budget deficits, most states are finding it difficult to keep up with growing drug costs and ADAP enrollments. In response, some states are creating waiting lists to enter the program. Others, including Texas, are tightening income requirements to cover only some of the people who were previously eligible. Still other states are making important drugs unavailable. California's governor recently proposed that ADAP clients—including those unable to work—make copayments to participate in the program, but advocacy efforts appear to have stymied this development.

The San Francisco AIDS Foundation (SFAF) is working with many partners to assure that ADAP is fully funded, both at the national level and in California. To join in efforts to maintain this crucial program, please contact the SFAF Policy Department at 415-487-3080 or dvangord@sfaf.org. *–Dana Van Gorder*

The major battlefield is turning out to be the question of whether Medicare, the medical insurance program for seniors (and some people with disabilities), will be able to offer a prescription drug plan. Currently this government program does not cover prescription drugs. Unless they have supplemental insurance, people who rely on Medicare pay for their medications out of pocket—which means that those who can least afford it often pay higher prices than almost anyone else.

The plight of seniors has received high-profile coverage on the nightly news, complete with footage of old folk boarding buses bound for discount pharmacies in Canada. Internet sites that fill prescriptions at the more affordable Canadian prices have come under attack as some major pharmaceutical companies have refused to sell their products to Canadian pharmacies that ship drugs back to the U.S. It is not clear whether there is a significant benefit to shopping in Canada for people with HIV: the listed Canadian pharmacy price for a month's supply of 3TC is US$230, compared with Walgreens' U.S. price of $295.

Despite the pain inflicted on those least able to pay, large drug companies are fighting against a Medicare drug benefit with all of their political muscle, mainly because they fear the leverage the government would gain if it

were able to negotiate prices for seniors, the largest sector of drug consumers. As a paragraph from Pfizer's 2002 annual report cautions investors:

"In the U.S., many pharmaceutical products are subject to increasing pricing pressures, which could be significantly impacted by the outcome of the current national debate over Medicare reform. If the Medicare program provided outpatient pharmaceutical coverage for its beneficiaries, the federal government, through its enormous purchasing power under the program, could demand discounts from pharmaceutical companies that may implicitly create price controls on prescription drugs."

While such behavior could be attributed to greed, a more charitable view is that pharmaceutical companies are driven by insecurity about unknown risks. Chief among these risks is that revenue streams could dry up if outside forces unexpectedly impinge on prices. Yet the next line in Pfizer's report recognizes that change may present opportunity: "On the other hand, a Medicare drug reimbursement provision may increase the volume of pharmaceutical drug purchases, offsetting at least in part these potential price discounts."

[Ed. note: both the House of Representatives and the Senate have recently passed legislation that would provide a limited prescription drug benefit through Medicare. While the two plans are different, neither is comprehensive and each would require significant out-of-pocket expenditures for Medicare recipients by way of premiums, copayments, and coverage gaps.]

Virtually everyone agrees that mounting drug costs are causing distress, but no one has yet developed a political accommodation that can ensure access to needed medications for all, while continuing to support research into newer and better drugs for those who will need them tomorrow. Meanwhile, budgets continue to strain as more and more people come to depend on life-giving pharmaceuticals whose prices rise with no end in sight.

Bob Huff is the editor of *GMHC Treatment Issues*, published by Gay Men's Health Crisis in New York City.

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HIV ADVOCACY • GET INVOLVED •

AIDS Treatment Activists Coalition (ATAC)

ATAC is a dynamic new coalition of people working together to improve HIV research and treatment access in the U.S.

ATAC encourages greater, more effective involvement of all people with HIV in decisions—made by the pharmaceutical industry, government, and others—that affect their lives. To bolster the ranks of treatment activists, the coalition is committed to identifying, mentoring, and empowering new activists in all communities affected by the epidemic.

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JOIN THE E-MAIL LISTSERV—
send a message including your real name and a description of your AIDS treatment activism to:
info@atac-usa.org

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