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Patient Care Squeezed by Soaring Drug Prices

By Bob Huff

First Michigan and now Massachusetts have thrown down the gauntlet to the pharmaceutical industry over high drug prices and runaway healthcare costs. Will New York be next? Unable to sustain ballooning Medicaid drug budgets, these states are telling pharmaceutical makers to either bring prices down or face banishment to a list of medications that will require third party approval before they can be prescribed. In a highly competitive market, prior approval is a steep hurdle that effectively means the other guy's drug gets Medicaid's lucrative business; unfortunately, prior approval can create big hurdles for patients as well.

This is a high stakes game and an industry unaccustomed to being bullied has pulled out all stops to undercut its foes with lawsuits and public outcry. So far, judges have allowed the cost containing experiments to go forward, and after years of manipulation by the industry's public relations machine, their latest disaster alerts ring false. Still, many legitimate consumer organizations are alarmed about the impact these plans might have on the country's most vulnerable citizens: the elderly, the disabled and people with complicated treatment needs, including those with HIV.

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According to a new report by the National Institute of Health Care Management, spending on prescription drugs in the U.S. increased faster than any other aspect of health care last year, hitting a new high of $154 billion. Medicaid expenditures on drugs have gone up by 18% per year for the past four years. Shrinking state and federal budgets have put Medicaid programs under tremendous pressure to hold down costs. Last year at least eighteen states passed laws designed to contain state or consumer drug expenditures and a number of experiments in tighter administration of public drug spending are underway. These responses are important to watch because trends in Medicaid often soon spread to other public health plans such as ADAP, the states' AIDS Drug Assistance Programs or New York's drug assistance plan for low income seniors (EPIC).

For a large healthcare payer, there are really only two ways to rein in mounting drug expenditures. The hit to a state's drug budget is determined by this equation: Price x Utilization = Cost. If you can lower the price, you lower your overall costs; lower the quantities consumed, and costs also go down. Lower them both... Excelsior! In Medicare and Medicaid, drug pricing is addressed by laws that say companies must offer their best wholesale prices to government programs. This is supposed to insure that government programs pay no more than any other large purchaser of drugs does. But because of a complex set of classifications and pricing tiers, some programs, such

as the Veterans Administration (VA) get better prices than Medicaid. Still, government doesn't have a lot of leverage to bring prices lower than what manufacturers are willing to offer.

Cut Prices?

Efforts to bring drug prices down in the U.S. range from pitiful to quixotic with no really promising solutions in between. Several pharmaceutical manufacturers are boosting the idea of discount cards for seniors that would afford a 10 to 40 percent break off the suggested retail prices of their products. As one critic noted, a 10 percent discount on a Ferrari won't help someone who can barely afford a used car. President Bush has personally voiced his support for a national discount card.

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At the other end of the spectrum, many patent reform advocates see excessive terms of market exclusivity as the culprit. Some have called for cutting back patent protection from 20 years to as little as three years before lower cost generic drugs are allowed to compete. The strength of patent rights may also be conditional upon the source of the underlying research. U.S. research dollars very often contribute to the discovery of drugs that are subsequently developed by industry then sold back to government programs at monopoly prices. In effect, taxpayers are paying twice for these medications. Any other ground floor investor would be richly rewarded, advocates say, so why should the public good benefit less? Many are pressing the administration to apply an existing law that could compel drug companies with products derived from federally funded research to sell them at reasonable prices. This legislation, part of the Bayh-Dole Act, was passed in 1980 but its provisions have never been exercised.

Meanwhile, state governments, which bear much of the burden of escalating Medicaid drug prices, are searching for new, practical ways to hold down costs. Private prescription plans, hospitals, HMOs and other volume purchasers have been able to bargain with drug makers and pharmacists to get better deals. Last year several states decided to pool their purchasing power and improve their bargaining clout. But again, if prices are exorbitant to begin with, then few savings are possible and the discounts won are often soon erased by price hikes.

A few states have started to demand additional rebates from manufacturers. One approach is a kind of frequent buyer plan where credits for money spent on a particular company's drugs can later be exchanged for free product. Some rebate plans seek across the board discounts that demand similar sized cuts from every maker and every drug, its base wholesale price notwithstanding. Rebate plans may save money, but they don't alter the disparity in pricing between similar drugs in a therapeutic class. This leaves the door open for preferred formularies and prior authorization schemes that try to steer patients and doctors away from using the higher priced drugs. Not surprisingly, both consumers and the pharmaceutical industry dislike these plans.

The Industry Fights Back

The pharmaceutical industry's answer to all of these schemes is to call for open formularies and the freedom to raise prices at will. In Florida, rather than give back rebates, companies negotiated to invest the equivalent of rebate dollars in disease management education programs. The net effect of this maneuver — as is intended from the industry's professional education efforts — was to actually increase the utilization of drugs that year.

Pharma protests that the problem with pharmaceuticals in America is underprescribing, not overutilization; that many people who could benefit from new drugs are not yet aware that they are suffering. Direct to consumer advertising has caused demand for anti-depressants, ulcer drugs, allergy medicine and Viagra to surge. The industry is spending mightily, not only to grow the market for their products, but also to enlist consumer voices in the fight against drug limits. Recent news stories have detailed the manufactured nature of some of these so called astroturf grassroots groups. A spokesman for the Pharmaceutical Research and Manufacturers of America (PhRMA), quoted in the Boston Globe, described his organization's response to the roll out of a prior approval plan in Massachusetts: "We will launch a grass-roots education campaign, so they're aware of what the state's trying to do, before it's implemented." (See Pharma Speaks! in this issue)

Some analysts believe that maintaining market share is ultimately more important to pharmaceutical makers than short term maximization of profits. If three similar drugs in the same therapeutic category are in the market at different prices, then there will likely be a fierce battle among them to preserve market share. A company will swallow lower profits rather than give up even one sale to a competitor, the theory goes. And with profit margins as steep as those in the prescription drug industry, a maker may well find price cuts preferable to ceding even a fraction of their drug's space on the pharmacy shelf.

Michigan Rebels

Against this background, the State of Michigan rolled out an aggressive plan to secure significant cost savings through rebates, without overtly intending to restrict consumer or provider choice about which drugs can be used. The Michigan plan created a preferred drug list with forty therapeutic categories. Within each category, the State's drug advisory panel chose the "best in class" drug as a benchmark. Drugs were selected by multiple criteria, not just by price, and in some categories, the best in class drug was not the cheapest contender. The state allows drugs that are on the approved list to be prescribed without prior authorization; drugs not on the list can be prescribed, but the doctor must justify the choice. So far, this is not unusual for a PA scheme, but Michigan took an extra step. They said that makers of other drugs in a particular therapeutic category could have their products added to the preferred list if they were willing to cut prices to match that of the index drug. This is intended to bring the price of more expensive drugs in line with that of the best priced product in each class. The result is supposed to level the playing field for manufacturers and control costs for the State, all without creating artificial prescribing restrictions for patient or doctor. Companies might profit less, but they'd retain market share.

Michigan's plan was developed in secret then rolled out as a fait accompli. Not surprisingly the pharmaceutical makers were apoplectic. The industry spends billions on marketing and lobbying and plays hardball when forces intervene in their freedom to pursue market share. Lawsuits have been filed to prevent Michigan's program from going forward, but so far, the State has been upheld. This idea could yet be sunk if industry leaders stage a walkout rather than submit to additional rebates. Several large manufacturers have refused to lower prices to participate in Michigan's list, effectively abandoning market share by boycotting the system. The industry may decide that giving up market share in one or two states is an acceptable price to pay to stop this plan from spreading elsewhere. It remains to be seen if these tactics will work, but for now, some Medicaid patients in Michigan will certainly face restrictions and drug denials.

Michigan hopes this system will save them $42 million during its first year with PA. In March, Massachusetts announced that they were adopting a similar strategy and New York State is rumored to be next in line. Meanwhile in Washington, the powerful pharmaceutical lobby is hard at work mobilizing Congress and consumer groups against any effort to meddle with the sacred bonds between doctor, patient, and Madison Avenue.

Cut Utilization

Since prices are so tough to tackle, an easier path for government programs is to tighten up on utilization. Usually waste and fraud are the first to come under scrutiny; no one can complain about limiting those. Next come stricter controls over a short list of extremely expensive drugs and other treatments such as human growth hormone. Finally, discussion turns to plans designed to steer patients from expensive brand medications to equivalent generic versions or better-priced competitors. While ostensibly about price savings, these switching efforts may have unintended negative consequences on utilization and access. These solutions sound good in legislative chambers but they are creating a new wave of problems for patients — especially when drug limits are implemented crudely or without regard for the consequences to those denied treatment or treated improperly.

Prior authorization (PA, also known as prior approval [or in California, TAR=treatment authorization request]) was born in the private health plan industry as a way to assure that the prescription of super-expensive drugs was justified. It requires an agent of the payer to review a drug prescription and approve its use for that patient before it can be dispensed. PA is supposed to be a checkpoint between the pharmacy and the consumer to insure that the rules for dispensing drugs are followed. These rules may have their origins in concerns about drug safety, mandates to restrict waste and abuse, the desire to make drug selections more rational, and ultimately, the need to hold down costs. But it didn't take long for bureaucrats to recognize that utilization of the listed meds tended to drop significantly as the PA process increased the burden on doctors, patients and pharmacists. Doctors tended to choose a path of less resistance rather than deal with complicated forms and exasperating phone calls—even if it meant not prescribing a drug they were convinced was appropriate for an individual patient.

So the true impact of PA on utilization may not come from rationalizing the prescribing practices of doctors as much as from installing a mechanism that puts savings ahead of patients' needs. And it's foreseeable that PA schemes will cause the most trouble for people who use drugs the most—usually the sickest and most vulnerable patients, such as seniors, cancer patients, or people with chronic illnesses such as AIDS who need multiple drugs to control side effects and prevent complications.

Prior Authorization: How *NOT* to do it.

Example of an actual prior authorization procedure used by an HMO in Texas.

Applying for Prior Authorization

If you are currently taking one of the restricted medications, your doctor may request a review by calling the Plan's pharmacy benefits manager (PBM).

If review is not sought in advance, the process for prior authorization is as follows:

In other words, if you need a refill for your ongoing treatment or you need a new medicine, but your doctor forgot to check with the PBM first...

1. The prescription is presented to the pharmacy.

2. When the pharmacy submits the prescription to the PBM, an on-line message tells the pharmacist that authorization is necessary.

Sorry, there's a problem. No information about getting an emergency supply. No warning of possible risks to your health from discontinuing or delaying a treatment.

The pharmacist is provided with the PBM's phone number to begin the authorization process.

That's if the pharmacist has the time or patience to wait on the phone. More likely he says, "Come back tomorrow." Or simply, "Sorry it was denied."

3. The member should ask their prescribing physician to contact the PBM to discuss the criteria for use and other clinical parameters.

The burden is on you. If you really want the drug you need to go back to your doctor and tell him he has to call the PBM with a good reason why you should have that medicine.

Or maybe you just give up after hearing, "Sorry, it was denied."

4. Coverage is decided and patient and physician receive notice of either approval or denial.

If they approve the prescription (and you're not in the hospital from complications), you can go back to the pharmacy and pick up your medicine.

Hopefully, no more than a week has gone by.

If they deny authorization, go back to your doctor and start all over again.

If coverage is denied, your physician can request an appeal. With an appeal, new information MUST be provided.

It's not enough to say that you really need this drug... your doctor has to come up with another reason why you should be treated the way he thinks is best.

Good luck!

Crude Attempts to Control

Florida initiated a system in 2000 that put a four-drug cap on the number of brand name medicines a person on Medicaid could receive without getting prior authorization. This meant that someone already taking two drugs could show up at a pharmacy with three new prescriptions for a newly diagnosed condition and be told they could only fill two of them since they were over their 4-drug limit. At this point the pharmacist is supposed to contact the doctor to see if one of the drugs could be changed to a medicine that didn't need PA. But according to a study of the program's impact on consumers conducted by the University of Florida, there were instances when patients simply thought that they had been denied access to a drug and went home without their medication. There was no good mechanism for following up with the doctor or for providing a temporary supply of the prescribed drug.

This study (widely distributed by the pharmaceutical lobby) also found hidden costs in Florida's poorly administered PA program. For example, if individuals' drugs are denied or interrupted, hospitalizations may increase or additional office visits may be needed to adjust doses or treat complications. A person with a well-managed medical condition who is receiving expensive drugs may actually consume fewer resources than someone with the same condition who requires frequent dose adjustments or more serious interventions that limit their ability to work and enjoy life normally. A Federal class-action lawsuit against Florida Medicaid has recently been filed on behalf of low-income patients who have been denied prescription drugs without proper notice.

New York Medicaid has begun its prior authorization program with a short list of the most expensive drugs. Serostim is a recombinant human growth hormone that can cost as much as $8,000 a month to use. The drug is approved to combat wasting syndrome in people with AIDS and may have other beneficial uses. It's also possible that abuse may be a problem. As one nurse who monitors patients on Serostim put it, "It makes you feel fifteen years younger." This is usually the first drug that state payers try to limit, not only for its exorbitant price, but because there is no evidence of benefit after the first 12 weeks of use. Because growth hormones are highly valued by bodybuilders for their ability to build lean muscle mass, Serostim prescriptions are also carefully scrutinized for fraud and diversion.

Serostim costs are a particular problem for New York State Medicaid since it is one of the program's top five most prescribed drugs. A policy requiring prior authorization for Serostim went into effect in New York on February 15 of this year. A local pharmacist reported to GMHC that before the new policy began she had twelve patients using the drug—one month later she had four. And of those four, two are having or have had significant problems obtaining authorization to receive Serostim. One patient's doctor insisted that he got authorization for a 28-day supply. However when the pharmacist entered the authorization number into the automated phone system, only a one-day supply of the drug was approved. The pharmacist spent a week with Medicaid trying to solve the problem before sending the case back to the doctor to straighten out.

The other patient had his authorization rejected by Medicaid after the pharmacist punched in the code provided by the doctor's office. Eventually it was discovered that the doctor had written down the wrong code number in the first place. Despite these many, obvious sources of error, the State insists that prior authorization in New York is a simple three-minute process that works well.

There are signs that a major expansion of prior authorization for New York State Medicaid recipients will begin by including the therapeutic class of Cox-2 inhibitors used for arthritis pain management. New York's draft plan is typical in requiring a doctor to call and answer a long list of questions before receiving an authorization number. The patient would then take the authorized prescription to a pharmacy where the pharmacist confirms the PA by telephone. The cycle would be repeated after every two refills or after 60 tablets had been dispensed, which ever comes first. This elementary draft of a plan is sure to cause inconvenience and pain for affected patients unless strong consumer protections are added.

Consumers Resist

A letter written to state legislators by New York's StateWide Senior Action Council detailed some of the problems patients can expect if this system is implemented. The group is particularly concerned that stifling prescribing will make it impossible for many individuals who need medications to obtain them. Furthermore, StateWide anticipates that physicians already at the tipping point of their willingness to participate in Medicaid due to low reimbursement rates will simply refuse to treat Medicaid patients if the burden becomes unreasonable. "The plan will erect bureaucratic hurdles so high that most physicians will be unable to obtain prior authoriza-

tion. Contemporary medical practice puts doctors under extreme time and economic pressure to abbreviate each patient contact, leaving them without time to make the telephone calls. Further, the telephone questions will be considered professionally demeaning, with doctors' professional judgement subject to second-guessing by an automated interactive phone system."

Dr. Robert Witzburg, chief of community medicine at Boston Medical Center echoed these fears to the Boston Globe, "It's a tremendous hassle. Prior approval saves money in the short term because doctors and patients just give up. But in the end you just substitute other high-cost interventions because the drugs were unavailable. It's a disaster."

New York's StateWide group also believes that doctors will inevitably avoid prescribing medications requiring PA, even it means compromising the best interests of the patient. Since the harmful outcomes are apparent to anyone who has experience with the realities of medical care, the group wonders about New York's true agenda: "Some... suggest that the state is simply proposing prior authorization to force pharmaceutical manufacturers into paying higher Medicaid rebates. They suggest that the state would drop the prior authorization if the manufacturers cough up more money. StateWide certainly hopes that this is not true since it would mean that the plan was intended, in effect, to hold hostage the medical needs of patients in order to procure money."

A Kinder System?

Theoretically, the problems with PA arise from poor implementation, not necessarily from the concept itself. There are proposals to use sophisticated networked computer systems to manage drug authorizations without creating undue burdens for the participants. Ideally, the transaction between a doctor, the PA plan's administration and the pharmacist would be swiftly and transparently handled so that patients are never confused or inconvenienced by delays, denials, or the need to make multiple trips to pick up their medicines. While the technology exists to make a pain-free system possible, ultimately the rules adopted by legislatures and administrators will determine how successful a PA program will be.

A national pharmaceutical benefits management company (PBM), First Health Services, is the vendor for Michigan's controversial PA plan as well as for a more conventional plan in New Jersey. The company would also like to bid to operate a proposed Medicaid PA plan in New York State. In its marketing efforts, First Health places the emphasis on safety. There are certainly important public health gains to be made from reducing prescribing errors, drug interactions and preventable side effects by using a central authorization system. Computerized review could detect potentially deadly drug combinations before they were dispensed. The patients likely to bear the greatest burden from PA, those who use medications the most, are also the patients most likely to have drug interaction problems and could benefit most from a system that analyzed their entire pharmaceutical usage in one place.

Another worthy goal of prior authorization is to educate providers. The aim is to alter physicians' prescribing patterns by asking them to think twice before requesting the latest and most expensive drug when an earlier, far less costly, drug performs just as well. The difficulty is to accomplish this without imposing frustrating barriers that compromise appropriate patient care. Some advocates are proposing other ways to encourage doctors to prescribe responsibly, such as counter-marketing programs designed to offset the millions of dollars industry spends influencing physicians' prescribing habits.

It's clear that safeguards must be put in place to insure that cost cutting does not come at the expense of beneficiaries' health. One idea is to exempt entire classes of patients from PA based on their diagnosis. For example, it is understood

We can do better

The bottom line for any fair prior authorization (PA) system should be that no patient is denied medicine simply because arbitrary procedures haven't been followed.

The patient shows up at the pharmacy with a prescription. The script is entered into the pharmacist's computer, which communicates with the PBM. The PBM computer recognizes that the script is for a listed drug but the doctor hasn't obtained PA. At this point the PBM computer should:

1) Approve a 30 day supply of the drug for the patient;

2) Inform the pharmacist that a temporary exemption has been issued and print out a written notification to the patient;

3) Send a written notice to the doctor that this drug requires PA and tell the doctor how to request authorization. Follow up with phone calls to the doctor;

4) Insure that all problems are resolved before the patient returns for a refill.

In cases when the doctor has correctly obtained PA, the patient should present the script to the pharmacist whose computer will confirm the authorization and approve dispensing the drug. No special action is required of the patient or pharmacist and the confirmation is handled transparently. Once authorized, PA should remain in effect for one year.

In cases when PA is denied but the doctor states the drug is medically necessary for the patient, PA must be granted and the drug must be dispensed.

at the outset that people with HIV on treatment will require multiple brand name medications, therefore an HIV diagnosis should be sufficient to justify a blanket PA. Another approach would be to exempt patients based on individual clinical necessity. A doctor should be able to make one phone call that would justify authorization of prescriptions for an entire year if a person has complicated treatment needs. These may be fair and humane solutions, but for budget hawks, one overarching question looms larger: If everyone who needs medication is able to obtain their drugs without barriers, will there be any room left to realize significant savings? And if the state can't save money without harming patients, then are plans to limit utilization merely papering over the crisis? It may all come back to prices.

Changes need to be made, and it's clear that the current system cannot continue to support the growing burden indefinitely. Most critically, the pharmaceutical industry needs to accept discipline over its pricing and marketing practices. As for the states, better provider education, a focus on waste and inappropriate prescribing, and measures to improve drug safety are all potentially positive outcomes of prior authorization plans. But crudely implemented schemes to limit utilization will only cause additional pain and suffering while simply shifting costs elsewhere.

Many thanks to Susan Dooha, David Wunch, Gregg Gonsalves, Anne Donnelly and Lei Chou for help in preparing this article.

ADAP Strapped

By Lei Chou and Anne Donnelly

ADAP stands for AIDS Drug Assistance Program, although some states have different names for similar programs. ADAP provides life-sustaining and life-prolonging medications to low income individuals with HIV who have no other source of payment for these drugs.

In June of 2001, ADAP served roughly 77,000 people and national ADAP enrollments have been growing consistently at about 600 people per month.

Although an average of 80 percent of ADAP funding comes from the Federal government, individual ADAPs are administered by the states and require some additional amount of state funding if they are to offer more than bare bones drug coverage. The list of medications provided by the ADAPs varies considerably from state to state, ranging from excellent programs in California and New York to very problematic programs in much of the Southeast and other areas.

Federal ADAP funding was increased by $50 million this year – well short of the $130 million estimated need. Recent pharmaceutical price increases may push this estimated shortfall up by an additional 50 percent during 2002. This means that most, if not all, ADAPs will run out of money towards the end of this year.

Pressure on ADAP is expected to increase as new drugs such as pegylated interferon and T-20 become available next year. Access to these newer products will probably require prior authorization. Additional pressure will likely come from rising unemployment and loss of insurance; a steady level of new HIV infections and a possible rise in AIDS cases; the emergenge of long-term drug side-effects; and the tightening of state Medicaid programs.

For 2003, the President has proposed flat funding ADAP (no increases). Advocates for ADAP say a push in Congress for an Emergency Supplemental Request to increase federal funding is needed right away. If no supplemental funding is received this year, then next year's shortfall could rise to $161 million or about 14 percent of the total ADAP budget.

With the Federal shortfall, the States (already under budgetary pressure from Medicaid and other health programs) will need to contribute additional money to avoid resorting to waiting lists or other restrictions. Six ADAPs currently have waiting lists representing about 700 people who are going without treatment. This number is expected to grow. Several states currently have restrictive eligibility criteria and several more are likely to introduce new restrictions later this year. Most states will soon begin to debate increasing their own contributions to ADAP funding, but few can afford to fill the gap.

All of this means that ADAPs – and the people with HIV who depend on them — are in deep trouble.

The 2002 National ADAP Monitoring Report will be released soon by the Kaiser Family Foundation. This report will be available at www.kff.org.

For detailed information on each state's individual ADAP, contact the AIDS Treatment Data Network / The Access Project.: www.aidsinfonyc.org/network/access

Fighting Back Against Pharmaceutical Company Greed

By George M. Carter

The high price of drugs is destroying what there is of the dismal U.S. public healthcare system. AIDS Drug Assistance Programs (ADAP) have been crippled nationwide and the formularies of state Medicaid programs are under enormous strain. The pharmaceutical industry protests that they run a risky business and that their prices are fair. There's nothing wrong with drug makers earning a fair and decent profit, nor, certainly, with researchers bringing home good pay for doing good work. But with government subsidies, tax write-offs and the numerous incentives industry receives in the form of corporate welfare, the profit from bringing a drug to market dramatically outweighs the cost.

It appears that industry operates on the model that says, "Greed drives the engine of discovery." While this idea may be partly true, it has many pitfalls—and millions of human lives tumble into these pits each year. Examples were sharply highlighted at a meeting on neglected diseases sponsored by the humanitarian group, Doctors Without Borders held in New York City, March 14, 2002. There is little or no research occurring on better treatments for malaria or tuberculosis, despite their impact on millions of people. Compound this neglect with the fact that legal controls over certain drugs allow companies such as GlaxoSmithKline to actually block countries from obtaining fairly priced generic medications. If industry invested a fraction of the energy they spend for public relations and legal battles in finding new ways to help people afford treatment, they could be part of a win-win situation, be better positioned to negotiate reasonable tiered pricing strategies, have a vastly improved public image—and quite frankly, not be guilty of committing what many believe to be a criminal act of enormous proportions—an economic form of genocide.

The failure to study potentially useful products that have little profit potential stands as a further indictment of a broken system. Once a drug's patents have expired it is almost never clinically evaluated to see if it has therapeutic value for neglected or commercially unimportant diseases. A nearly complete absence of studies on the dietary supplements used by large numbers of people to help manage chronic diseases makes the data vacuum even worse.

How can activists respond in a meaningful way? Many are seeking new ways to inject competition into the equation, which may be the only way to gain genuine leverage against an industry that is out of control. One avenue being sought and strongly supported by activists, physicians and people with HIV/AIDS around the world is the use of certain legal means, recognized as valid by the World Trade Organization. While these are generally thought to apply to developing economies, could they also be invoked by struggling state health programs in the U.S.? Here's a few proposals.

A large pharmaceutical purchaser, say a state Medicaid formulary, could obtain expensive medications through a parallel import program. This would allow the state to buy drugs identical to the expensive domestic versions, but licensed only for distribution in other countries where they are sold for less. This idea drives the industry crazy. Another approach might be for a state to issue a compulsory license permitting local manufacturers of generic drugs to make copies at reasonable prices. Admittedly, these radical solutions might need significant litigation to realize, but perhaps an attorney general from a state at the end of its budgetary rope might be the first one to try.

Still another proposal might be for states to build on the personal use importation exception that permits a person to import a three-month supply of drugs from another country. In the early 1990s, the PWA Health Group buyer's club in New York exploited this rule to import as-yet unapproved drugs to the United States, which were distributed to its members. Nowadays most available AIDS drugs are approved, but there are generic formulations made by companies such as CIPLA in India that could be brought in. Some of these are convenient three-in-one combinations using drugs from multiple manufacturers that could never be produced otherwise. An organization such as a state Medicaid formulary or a separately constituted NGO could serve as a broker to undertake this activity. In the meantime, more and more Americans everyday fall hostage to the greed of Big Pharma. The need for relief is dramatic and growing. Must seniors, the disabled and people with AIDS gather before the gates of corporate headquarters and state legislatures to demand change? Or will the drug industry wise up—and drop their prices substantially?

Can We Reform the Drug Industry?
An Online Discussion

This is an edited email discussion that took place between participants in the AIDS Treatment Activists Coalition (ATAC). George Carter is an activist interested in patent reform and researching complementary therapies; Eric Goldman is a patent attorney.

For more on ATAC, see www.atac.org

George M. Carter wrote:

I think we should reform the patent system so pharmaceutical companies only get three years of exclusive profits on a patented drug instead of the twenty years they currently enjoy. After that, put price controls on them. Slash the salaries of the executives and increase the salaries of the people doing the real work—the bench workers and the study nurses.

Eric Goldman: Believe it or not, this is an issue of constitutional proportions. Today's patent laws are derived from Article I, Section 8 of the Constitution. Thus, today, in order to encourage drug companies to share the research and development information behind their drug development efforts, we grant them patent protection to ensure that disclosing that information will not kill their profits.

George: Patents may be constitutional, but we still need reforms.

Eric: Even if we eliminate or reduce the duration of the state monopoly created by a patent, one might predict that drug companies will begin to keep more and more of their research secret. What they cannot protect under patent laws, they will maintain as trade secrets. Once information is not freely shared, progress slows. There would be no more presentations at conferences about pending research.

George: But in genome research, proprietary claims and gene patents are stifling progress. Even university researchers have been prevented from investigating genes that are "owned" by someone else.

Eric: Anyway, I don't think gutting the patent laws will get us where we want to go. In my view, the best way to go is to track which drug patents were obtained in whole or in part with NIH money or money from another government source, and then seek to control the price of drugs so patented. There is already some legislation on the books (Bayh-Dole Act) to support this approach; it's just not being actively pursued by anyone.

George: Why are corporations able to profit from taxpayer-supported research?

Eric: Twenty years ago the government adopted a policy of granting exclusive licenses to let private industry conduct basic research on discoveries from government labs, rather than having the NIH conduct or fund such research directly. This was part of the whole "streamlining government" revolution. For example, the NIH holds patents on using blue-green algae as a topical and in-vivo microbicide, but is not doing the basic research. They've farmed it out to small companies under exclusive licenses.

George: And that development work should go forward with promising candidates investigated independently by the NIH, universities and hospitals. Then the cost of developing a drug could be assessed rationally and prices set accordingly. Until then, why shouldn't we be able to import fairly priced generic versions of life-saving drugs that are unaffordable here?

Eric: CIPLA in India and several other Israeli and Brazilian companies ignore patents to make generic versions of protected pharmaceuticals. But none of the outside-the-U.S. companies I am aware of have the infrastructure or expertise to develop drugs: they really ride on the coat tails of U.S. and European industry. They wait for Big Pharma to screen the drug, do the pharmacokinetics and toxicity stuff, do the full-scale clinical trials, and then get the drugs approved by the FDA.

George: Hmm. That sounds like the way Pharma treats the NIH.

Eric: If the U.S. and Europe start buying CIPLA knockoffs, or if we demand domestic pricing on parity with the lowest price developing nations pay, we would simultaneously remove virtually all incentive to develop AIDS drugs **and** we couldn't use the enormous inflated prices gouged out of U.S. customers to help subsidize lower rates in the developing world.

George: Nonsense. Paying lower prices here until the necessary reforms are in place would free up funds currently wasted on executive golden parachutes and the marketing departments of

Big Pharma. That money could be used to do other things like expand ADAP coverage.

Eric: This is a nation that functions on the profit motive. We have to accept that. Take away the profit motive, and investors in pharmaceutical companies will move their money someplace else. And, since we all seem to agree that the U.S. drug industry is the primary source of R&D, this prospect scares me.

George: The bottom line is, the industry is not going to settle for any situation where they don't make obscene profits.

Eric: I personally don't care how much profit drug companies make. I do care how much of that profit comes from me, either directly as a consumer or indirectly as a taxpayer; and I do care if their profit depends on restricting worldwide access to necessary drugs; and I do care that some of that profit be spent on basic research instead of stock dividends and advertising. I don't demonize profit, but I deplore a lack of progress in the name of profit.

George: Frankly, this is a campaign that other groups of pharmaceutical consumers are keenly interested in and the industry is frightened by that. Because a reform movement like this represents genuine leverage against their outrageous power and greed. Settling for the few crumbs they sweep from the table is a failed form of activism. It's time for a revolution.

Eric: And what will be the implications of that revolution? That we will force drug companies to produce better drugs for less money through legislation? Never gonna happen; they donate too much money to politicians. That we will get some form of socialized medicine, a federal drug plan? All the money for that plan just got spent on stealth bombers and a missile shield defense.

George: Yet the current situation is utterly intolerable.

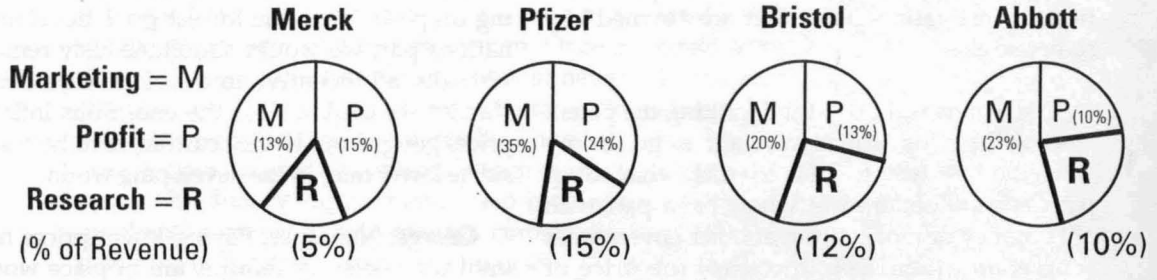
Eric: Or are you suggesting that we get into bed with AARP and the various State Attorneys General, the people who will be most interested in forming drug-buying collectives to drive down prices by using market forces? This seems more promising; to use the capitalist system to beat the capitalists by raising the market power of the consumers. Not as sexy as a revolution, but possibly more achievable.

PhRMA Speaks! And We All Listen

By Bob Huff

The marketing reach of the pharmaceutical industry is deep and pervasive. Among the top four U.S. drug makers, marketing expenses last year were at least double the amount spent for scientific research and development. Pharmaceutical marketing is a wide ranging set of activities that includes direct to consumer advertising (which has proliferated wildly since being deregulated in 1997); informative productions (such as those consumer health segments that fill space on local news broadcasts); or "issue awareness visits" with state and national elected officials (lobbying). Pharma money goes for the bagels and coffee consumed at a hospital's grand rounds session; an HIV community's "Meet the Doc" event at a nice hotel; and the slides and text

Pharma Phacts Industry Spending: Marketing vs. Profit vs. Research



Source: 2001 10K Reports—SEC Edgar Online www.sec.gov

preparation for a researcher's plenary talk at a major scientific conference. Drug company dollars also support hundreds of HIV outreach and educational programs for rural, urban or hard to reach populations, help float a raft of publications (including this one), and pay for meetings that bring treatment advocates together who would not otherwise meet. Arguably, the drug companies have kept the HIV treatment activist movement alive, not only through unrestricted educational grants and travel budgets, but by serving as a lightning rod to focus community interest over certain hot button issues. Whether for a product pitch at a resort destination or an adversarial meeting to criticize the pace of expanded access programs and negotiate lower prices, it all goes under the marketing budget.

It can be difficult to level criticism against pharmaceutical companies when your only point of contact is through a local representative. Drug reps are some of the nicest and most helpful people around; that's part of why they were hired. They provide an important conduit for channeling market information from the field to decision makers in the company and they bring life-giving grants and guidance to small non-profits. The clinical staff and researchers who work for big drug companies are usually great people, too. They are generally deeply dedicated to curing HIV/AIDS and often they have been personally affected by the epidemic. Yet these people are remote from the business strata of their companies, a world populated by individuals responsible for maximizing the profits of complex billion dollar enterprises. Practically speaking, the executives making multimillion-dollar salaries exist in an alien world; they don't necessarily share conventional humanitarian concerns, and it would be naïve to expect them to.

Recently several news stories have thrown a spotlight on the public relations activities of the Pharmaceutical Research and Manufacturers of America, (PhRMA) the drug industry's trade group and Washington representative. PhRMA is one of the most effective—and shameless—industry trade groups to cross the Beltway. With $154 billion spent on prescription drugs in the U.S. last year, the group's influence with politicians and media rivals that of the defense industry. One tried and not-so-true tactic rolled out in the emerging fight against state Medicaid prior authorization plans is the creation or co-optation of legitimate sounding grassroots consumer organizations that then are employed to influence politicians and produce sound bites for the media. These artificial grassroots groups are known as "astroturf" organizations.

The Baltimore Sun recently published a report about a fax campaign aimed at community leaders in Maryland. The fax was an urgent appeal from an organization called the Consumer Alliance. Recipients were urged to contact their state assembly members and demand free choice and affordable access to medicines for poor and disabled people. The campaign was actually organized by a Washington lobbying firm, Bonner & Associates, that specializes in generating ersatz grassroots outrage designed to sway impressionable politicians. Bonner's corporate clients select the issues and Bonner crafts the letters and chooses the targets. According to The Sun, "The fax, sent to dozens of community leaders, had the markings of a grassroots effort, including grammatical errors and a handwritten cover letter."

"This kind of politics is the most deceitful, underhanded brand of politics that can be practiced," Bishop Douglas I. Miles, pastor of Koinonia Baptist Church in Baltimore and one of those who received the fax told The Sun. The appeals, sent from a Washington office using Consumer Alliance letterhead, made no mention of the pharmaceutical industry, only of the need to protect "poor children, adults and seniors."

Jack Bonner, who directs the firm orchestrating the campaign, was not sympathetic to criticisms that hiding behind legitimate sounding community organizations to disseminate PhRMA positions was fraudulent. "Welcome to the big leagues," he told The Sun. "The more people and organizations that come forward on your behalf, the better off you are in politics."

On the prior authorization issue, the offensive is well under way. The Boston Globe quoted a PhRMA spokesperson on the group's plans to influence public opinion: "We will launch a grass-roots education campaign, so they're aware of what the state's trying to do, before it's implemented."

As the rebellion against uncontrolled drug prices spreads to state legislatures throughout the country, look for a message from PhRMA in your fax machine soon.

treatment ISSUES

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Opinion

The Looming Crisis in Drug Pricing

By Martin Delaney

By any measure, the present system of paying for expensive anti-HIV therapies is on the verge of collapse. The AIDS Drug Assistance Program (ADAP) is failing to meet needs in many states, leading to lengthy waiting lists and reduced coverage. Nor can Medicaid keep up. Even people with private insurance programs are affected. More and more of them are reaching the life-time cap or limits on their prescription drug benefits, forcing them to join those already dependent on federal and state programs and hastening the day when these programs will become insolvent. And, as the drug prices go up, so too does the cost of private insurance. Every year, more and more people are priced out of the market for insurance and forced into the government programs, again increasing the demand on those programs. Even the wealthy few that were once able to purchase treatment for themselves cannot keep up with the upward price spiral.

To be fair, many factors contribute to this. Certainly, the increased number of people seeking treatment puts growing pressure on all payer programs. But there is simply nothing that can be done about that, other than to create better prevention programs, a vaccine or a real cure. In contrast, the upward spiral of drug prices is both unnecessary and something we should be able to change. The continual increase in the price of drugs seems to say that the pharmaceutical companies have put a higher priority on paying dividends to their stockholders than they do on saving human lives. They seem to believe that people with HIV will constantly create enough political pressure to force government and other payers to foot the bill.

In the last round of Federal negotiations over the ADAP program, the final amount agreed to by Congress and the Administration fell far short of what was needed just to keep up with the growing demand. To make matters worse—far worse—almost all of the pharmaceutical companies announced, without warning, sudden price increases in late 2001 and early 2002. As a consequence, roughly half the amount of new money allotted was consumed by price increases, further diminishing the number of people served. Though exact figures aren't available, a similar scenario almost certainly occurred for the Medicaid program.

Even if the needs of ADAP and Medicaid were being met (which they most certainly are not), allowing these annual price increases for private insurance and retail sales still ends up creating havoc. Each time the price goes up on the retail or wholesale level, that new price impacts on the federal price. It also pushes price thresholds higher for entire classes of drugs, and when a new drug comes out, pricing negotiations begin at record high levels. Onward and upward goes the spiral.

There is no economic justification for constantly increasing prices. The development costs of the new drugs are typically recovered within the first few years of sales. Not only are AIDS drugs already among the highest priced, but such drugs are used for a lifetime. Each new drug is a new and virtually permanent profit stream for industry and its stockholders.

That's fine for the shareholders and the companies, but unacceptable to the rest of us. It must stop. No one wants to deny industry a fair profit, nor does anyone want to drive companies away from working in AIDS. But surely there must be room for a compromise that places a higher value on human life. After years of quiet acceptance, the HIV community is rising up against drug pricing, just as it did in the early years of the epidemic.

In the last few weeks, one company, Pfizer, announced a "two year price hold" on prices for ADAP programs, while another, Bristol Meyers Squibb announced a one year hold. They didn't hear the applause they were seeking, however. Unless guarantees are built in that prevent them from simply postponing a large leap in prices until the end of the "hold," such offers are meaningless. Moreover, any offer which is limited to the price paid by a single program, such as ADAP, makes little or no difference to the larger problem in the long run.

The HIV community must unite in demanding an end to the price spiral for existing drugs and an end to increased price thresholds for new drugs. There is perhaps no more critical domestic battle around HIV than the fight to stabilize, if not reduce prices. Without it, our entire system of paying for medical care for people with HIV is in jeopardy, brought about by the companies that already profit most from the disease.