



PAL News

The Prescription Access Litigation Project
A Community Catalyst Initiative

Weighing the Benefits and Costs of Drugs

PAL Director Alex Sugerman-Brozan interviews Jerry Avorn, MD, author of *Powerful Medicines: The Benefits, Risks and Costs of Prescription Drugs*

Alex Sugerman-Brozan: What are the prospects for drug reform within the next four years and what can we expect from Congress and the President?

Dr. Jerry Avorn: We are likely to see more of the same coming out of Washington from every branch of government for the next four years: greater friendliness towards the needs of the pharmaceutical industry, less willingness to be tough on them on either cost or safety issues, and a Medicare entitlement program that is broken before it even begins, which is going to be a very big

disappointment to the nation's seniors when it starts in 2006. The focus is going to have to shift to the state and institutional level.

ASB: What kinds of changes should the states be trying to enact?

JA: There is one exciting innovation which Harvard Medical School is participating in: Pennsylvania will be consolidating all its state-paid drug benefits programs under one administrative roof: their state Medicaid program, the state's pharmaceutical assistance for the elderly, the state employee and state retiree drug bills, which together



Jerry Avorn, MD, author of *Powerful Medicines: The Benefits, Risks and Costs of Prescription Drugs* (Knopf, 2004)

combine for \$3 billion worth of medication spending directly paid by the state. The state recognized that it might be a neat idea to help doctors make more clinically appropriate and cost-effective decisions. So they asked us to create a statewide program of "academic detailing", which I helped develop in the 1980s, in which we will

continued on page 2

IN THIS ISSUE

- 3 Consumer Profile
- 4 Settlement News
- 5 News Briefs
- 7 Litigation Update
- 11 **New:** Ask Pharmie
- 12 Support PAL
- 12 PAL Bookshelf
- 13 PAL Participants by State



Alex Sugerman-Brozan, *Director*
Renée Markus Hodin, *Associate Director*
Julie Bizzotto, *Project Associate*
S. Stephen Rosenfeld, *Senior Legal Advisor*
Justin Keith, *Writer*
Robert Restuccia, *Executive Director*
Susan Sherry, *Deputy Director*
Jennifer Cande, *Production Coordinator*
Michael Gipstein, *Media Specialist*

30 Winter Street, Ste. 1010 / Boston, MA 02108
T: 617-275-2931 F: 617-451-5838
E: pal@communitycatalyst.org
http://www.prescriptionaccess.org
http://www.communitycatalyst.org

AFL-CIO Joins PAL and Takes Aim at Deceptive Advertising of Nexium

On October 18, the American Federation of Labor and Congress of Industrial Organizations (AFL-CIO), the federation of America's unions, joined the PAL coalition. As its first act as a PAL coalition member, the AFL-CIO joined with coalition members Congress of California Seniors and California Alliance for Retired Americans in a lawsuit against AstraZeneca, maker of the heartburn drug Nexium.

The suit claims that AstraZeneca ran a multi-million dollar advertising and marketing

campaign aimed at getting patients to switch from its earlier heartburn drug, Prilosec (the "purple pill"), to its new drug, Nexium (the "healing purple pill"). In 2000, Prilosec was the world's most prescribed drug and AstraZeneca's best seller with sales of \$6 billion. Prilosec's patent was due to expire in 2001. The company feared that when cheaper generic versions of Prilosec became available, their sales would suffer. Before Prilosec's patent expired, AstraZeneca introduced Nexium, which is nearly identical to Prilosec.

continued on page 5

help train pharmacists who will go out to doctor's offices to serve essentially as an "un-sales rep" to visit with doctors one-on-one as the drug sales reps do. To do so, not in the name of pushing one particular product and boosting its sales, but in the name of helping the doctors to learn about evidence-based practice and more appropriate prescribing. We and others have shown that this actually does improve prescribing and the program actually pays for itself. Programs of this kind have already been put into place in Australia and England and a number of Canadian provinces, so we in the U.S. are just catching up and implementing it in the home country of the guy who helped develop it.

ASB: Give an example of how academic detailing works, say, for a specific type of drug and what effects that has on prescribing patterns of physicians and the cost to patients.

JA: Over the last decade we have seen one class of drugs, the calcium channel blockers [for the management of hypertension,] really eclipse sales of the older category of drugs, for example the thiazide diuretics, even though the new drugs never really had any major clinical advantage for many patients. The older drugs were off-patent, had generics, were inexpensive, so nobody was out there pushing them the way that these very expensive and highly marketed drugs were being pushed. So throughout the 80s and 90s there was less and less use of the thiazides and more and more use of other classes of drugs. The reason for that is clearly not that these drugs were dramatically better for most people but because it was so worth it for the companies to promote them. So 20 years ago or more, the idea was

Mrs. R is doing fine... *without vasodilators*



An example of the "un-advertisements" produced by the Harvard Medical School, which Avorn had a part in producing.

developed that the reason that the companies were so much more successful than us academics in shaping prescribing practices was because they were more effective in selling their storyline to doctors than we were. One of the ways they do this very effectively is by putting a person in the doctor's office with him or her with very interactive and engagingly produced materials that capture the doctor's attention. In the 80s we wondered if it would be possible for the "good guys" to use the same very effective behavior-change strategies in the service of evidence-based cost-effective prescribing. In a series of studies in the late 70s and early 80s, my collaborators and I showed that if you put a smart educational outreach worker, usually a pharmacist, in a

doctor's office to talk to them one-on-one, it is quite possible to educate the doctor to make better prescribing choices, and those programs end up saving more than they cost. Most doctors know what they know about drugs from sales reps. The goal is to get out there before the sales reps do and to give doctors a far more balanced picture of whether these new drugs really do add a great deal. If they do, then let's use them. But if they don't, then let's use the old drugs that work just as well and are more affordable.

ASB: Most people would think that doctors are educated enough about drugs and their effects to make these decisions on their own. What is it about medical practice or medical

education that makes a program like this necessary?

JA: There is remarkably little in most medical education that teaches doctors how to critically evaluate one drug's claims against another. We don't do a good enough job with teaching medical students about this, so they are ill-prepared when they go out to practice and have to make those kinds of comparisons. The second problem is that, even if the doctors were prepared to evaluate it, the FDA does not require that a new drug demonstrate that it is any better than old drugs. They just have to demonstrate that they're better than a sugar pill. So if I were, as a doctor, to look for a head-to-head study of four different drugs on the market to treat condition X, I would probably find that those studies had never been done. It is also no one's job to get that type of information out to doctors whereas it is certainly the job of the company sales reps to get the other view out there.

ASB: Ours is not the only way of testing and approving new drugs. Other countries do these types of comparisons. Can you tell us about those and how we might implement a system like that here?

JA: Both Australia and Canada require that a company proposing a drug to be added to the list of available drugs in those countries demonstrate not only that it works, but also how it relates to other drugs that are available and how cost-effective it is. A number of other countries, such as Great Britain, provide a forum for evaluating both new drugs and old drugs that is impartial and not connected to the drug-approval process. This is done by the National Institute for Clinical Excellence, which is supported by the government and run by an

continued on page 6

PROFILE

Margo Crosthwaite

Cloverdale, California

At nearly 74 years old, Margo Crosthwaite finds herself in a situation familiar to many seniors her age: "My medication expenses eat up everything I have!"

Margo suffers from a number of physical ailments, including excruciating back pain as a result of degenerative arthritis. A Medicare recipient, Margo buys an AARP drug discount card. Still, she spends an average of \$525 per month for only five prescription drugs.

Margo's doctor has just increased the dosage of one of her most vital medications, further increasing her already high monthly costs.

Margo's drug expenses might be even higher *if* she filled all of the prescriptions her doctor gave her. But, because her drug bill eats up so much of her limited income from Social Security and a small pension from her years working as a jeweler, Margo picks and chooses among prescriptions. She fills only those she believes will give her the most pain relief and goes without those that might improve her overall health.

Margo's drug bill leaves little room to pay for her other regular expenses. She is fortunate enough to have a secure and stable home. (Although her son bought her a house in a retirement community, she is, however, still responsible for paying for her home association fees.) Her son also bought her a car for errands and doctors' visits. But, with the high cost of gasoline, Margo rarely uses the car. As she says, "The cost of my medicines has short-changed everything I can do."



"The cost of my medicines has short-changed everything I can do."

When she can't make ends meet, Margo dips into the money from her late husband's life insurance policy—a practice that is becoming more and more frequent.

Despite her own physical and financial difficulties, Margo is dedicated to helping others who cannot afford health care. As a board member of the Alliance Medical Center, she helps provide medical care for workers without health insurance. According to Margo, the Alliance's clinic treats approximately 4000 people each month.

Committed to improving health-care access locally, Margo hopes that by telling others about her own experience with the high cost of prescription drugs, she will contribute to a broader effort toward making them more affordable. 🌱

Margo first learned about PAL when she read an article in *Sonoma Seniors Today* by PAL coalition member Council on Aging Services for Seniors. If you would like to share your story with PAL, please call us toll-free at (866) 208-9800 x2931.

New Settlement in Lupron Case; Augmentin and Relafen Settlements Move towards Final Stage

Lupron: In November, parties agreed to a \$150 million settlement in a case on the cancer drug Lupron. The plaintiffs claimed that the drug's distributors illegally inflated the price of Lupron and overcharged patients. \$40 million of the settlement is set aside to reimburse consumers who bought Lupron. Patients who used Lupron will receive at least \$100, no matter how little they paid for the drug. This is called a "minimum payment." PAL always pushes for "minimum payments" in drug cases, because they give consumers an incentive to go to the trouble to submit a claim from a class action settlement. Normally, very few people who could get back money that they overpaid actually take the time to fill out the paperwork to get a check from settlements like this. Setting a "minimum payment" helps increase the number of people who get money back, which helps ensure that these settlements actually benefit the people they were intended to benefit.

PAL has been involved in the case from the beginning. Recently, PAL founder and Senior Legal Advisor Stephen Rosenfeld was selected to represent consumers during settlement negotiations. He played a key role in one of the largest drug case settlements in PAL's history and helped make sure that it really benefits consumers. The settlement was recently given preliminary approval by Judge Stearns, of the U.S. District Court for the District of Massachusetts. Within a few months, Lupron consumers will be able to submit claims to get money back. Watch our website (www.prescriptionaccess.org) and www.lupronclaims.com for more information and instructions

on how to submit a claim.

In our Summer newsletter, PAL reported the settlement of two major cases concerning the drugs Augmentin and Relafen. Both of these settlements recently received further court approval.

Augmentin: Judge Morgan of the U.S. District Court for the Eastern District of Virginia recently gave final approval to the \$29 million Augmentin settlement. Consumers who bought Augmentin were able to submit claims to get reimbursed, until December 16, 2004. Consumers who sent in claims should get their money within a few months.

PAL coalition members **Tennessee Health Care Campaign, Congress of California Seniors, AFSCME, AFSCME District Council 47, and Maine Consumers for Affordable Health Care** and other plaintiffs sued GlaxoSmithKline (GSK), claiming that GSK kept cheaper generic versions of its antibiotic Augmentin off the market by filing illegal "double patents". PAL Director Alex Sugerman-Brozan testified at the Court's "Fairness Hearing" on October 28. PAL fought to ensure that the settlement provided real benefit and protection to consumers in the nationwide class of Augmentin purchasers. PAL negotiated an agreement with the various plaintiffs' lawyers in the case that ensures that more of the money that was set aside in the settlement for consumers will actually go to benefit consumers. Under the original settlement, money set aside for consumers that did not get claimed by them would have gone almost entirely to "third party payors" in the case (insurance companies and oth-

ers who paid for Augmentin used by others).

The agreement that PAL negotiated ensures that a minimum of \$2 million will be absolutely protected for consumer classmembers, no matter how few consumers submit claims. PAL plans to work with the plaintiffs' lawyers in the case to ask the Court to give any leftover money in the \$2 million to organizations working to increase access to prescription drugs for people who can't afford them.

Relafen: Judge Young of the U.S. District Court for the District of Massachusetts recently gave "preliminary approval" to the \$75 million settlement. PAL coalition members **Health Care for All, Wisconsin Citizen Action** and others brought the case against GSK, claiming that GSK kept cheaper generic versions of its anti-inflammatory drug Relafen off the market by unfairly and illegally getting "double patents" for the drug.

PAL lawyers came up with a truly innovative and exciting new way to get checks to consumers who overpaid for Relafen. We expect this will greatly increase the number of consumers who receive money from the settlement. In drug cases, most consumers who find out about a settlement do so by chance - they see an ad in a magazine, or a notice on a website. Then they have to request a claim form, fill it out and send it in. All these steps mean that usually very few consumers (often less than





10% who are eligible) get a settlement payment. In this case, the lawyers will work with several large pharmacy chains to send checks directly to consumers. Pharmacies have records showing which customers bought particular drugs. Checks will be sent directly to consumers based on those records. Consumers will also be able to submit claims forms directly, and notices will still be printed in magazines and online. Under the settlement, \$500,000 has been set aside for charities in certain states. PAL will work with its lawyers and coalition members in those states to submit funding proposals to the Court. Watch PAL's website www.prescriptionaccess.org and www.relafensettlement.com for more information and instructions on how to submit a claim. ☺

More info on these and other drug price settlements are at our web site at <http://www.prescriptionaccess.org/settlements.htm>

New Member Organizations

PAL welcomes nine new member organizations to our coalition: **ABCD Health Services (MA)**, **AFL-CIO (National)**, **ASEA/AFSCME Local 52 Health Benefits Trust (AK)**, **California Alliance for Retired Americans (CA)**, **California Citizens for Health Freedom (CA)**, **Commonwealth Care Alliance (MA)**, **District of Columbia Primary Care Association (DC)**, **The Greenlining Institute (CA)** and the **Philadelphia Unemployment Project (PA)**.

Regional Meetings

On September 28, PAL Associate Director **Renée Markus Hodin** met with representatives from PAL member groups **Action Alliance for Seniors**, **Pennsylvania Alliance for Retired Americans**, and **PennPIRG** in Philadelphia, Pennsylvania. Also in attendance was the **Philadelphia**

Unemployment Project, a new PAL member, as well as representatives from other organizations including the **Mental Health Association of Southeastern Pennsylvania**. Thanks to **Pennsylvania Alliance for Retired Americans** for hosting the event!

Staff Changes

This October **Julie Bizzotto** joined the PAL team as the new Program Associate. She previously worked for **MASSPIRG**, a member of the PAL coalition, and brings organizing and advocacy experience with her to PAL.

Join PAL at Families USA Conference

PAL staff and members will present a panel on drug price lawsuits at the annual Families USA conference, in Washington DC on January 27, 2005. For more information, visit <http://www.familiesusa.org/>

AFL-CIO
continued from page 1

Nexium costs much more than Prilosec, which is now available in both a generic and over-the-counter form. PAL's lawsuit claims AstraZeneca misled consumers into thinking the drug was an improvement over Prilosec, even though clinical studies show that Nexium is no more effective than Prilosec. Academics, physicians and policymakers alike—including Dr. Jerry Avorn (see interview, p. 1) and former director of the Centers for Medicare and Medicaid Services Tom Scully—have criticized AstraZeneca's actions.

The AFL-CIO, whose 13 million members represent more than 80 percent of America's unionized workers, understands the importance of affordable drugs. According to the AFL-CIO's director of governmental affairs, Gerry Shea, "More and more workers cannot get the health care they need, and out-of-control drug prices are a huge factor." The AFL-CIO's partnership with PAL demonstrates both groups' commitment to ensuring access to affordable medicine for all Americans. The pharmaceutical industry's efforts to market "me-too" drugs to consumers at inflated prices are a major part of the problem. According to Gerry Shea, "The AFL-

CIO joined PAL and the Nexium suit because it's high time that drug companies were held accountable for deceiving American consumers into buying 'new' drugs they don't need at prices they can't afford."

The Nexium case is a good example of drug-industry practices that PAL is fighting to change. Every day, consumers are bombarded with ads for prescription drugs that claim to educate but often deceive. It is PAL's hope that through the leadership of its coalition members, the issues in the Nexium case will take center stage in the ongoing national debate over prescription drug prices. ☺

independent group of physicians and consumers and other stakeholders. They simply pull together the best available scientific evidence about the worth of various products and decide if it's a good product and would be an addition everyone in the United Kingdom should be able to obtain. If it's not, it's not covered by the National Health Service.

ASB: Let's talk about the recent recall of Vioxx. Vioxx didn't just threaten patients' health, it also threatened their wallets. Millions of patients took Vioxx when most of them would have done just as well on an over-the-counter drug—at a fraction of the price. If they had known the cardiac risks, many would not have been so willing to pay such a high price. What is the relationship between a drug's perceived benefits and risks and the price?

JA: The first thing we have to do is look at efficacy and risk. Because if the drug has poor efficacy or unacceptable risk, it doesn't matter what the cost is. It shouldn't be used. Oddly enough, that would have stopped Vioxx in its tracks if we knew at the time of marketing what we know now. When you do, however, have a drug that works well or is safer than another drug, then the tough question is what we should be willing to pay for it. What I see all around is drugs which may be effective but are horrendously overpriced compared to their alternatives. The "purple pill" comes to mind: Nexium and its cousins. They're being used lavishly even though we don't seem to have enough money to get people the medications that they desperately need. We have a tremendous mismatch and I would say that there

are easily tens of billions of dollars a year that are wasted on drugs that are either overpriced or have no virtue beyond what is already out there at a lower cost.

ASB: How do we get people the right drug at the right price? Assuming we have a drug with good efficacy and acceptable risks, how do we ensure that people can get it at a price they can afford?

JA: Given the election, I think it is important not to spend a lot of energy trying to design price controls that are probably not going to be implemented by this administration or this Congress. An enormous amount of good could be done if we simply had more intelligent prescribing by doctors and drug consuming by patients. We clearly could save tens of billions of dollars if doctors simply always prescribed the most cost-effective alternative that's available. Mike Fischer and I had a paper in the *Journal of the American Medical Association* earlier this year in which we looked at what would have happened in Pennsylvania in the state programs if doctors were always prescribing the most appropriate drug both in terms of evidence and cost effectiveness. It would have saved, if we projected annually across the nation, the equivalent of \$1.2 billion dollars a year just for managing one condition in sixty five.

I think we need to create a climate in which patients are willing to say to their doctor when he or she prescribes a new product, is there a generic alternative? Is this more costly than other drugs on the market that are as good as it is? As well as asking a lot of tough questions about side effects and how to take the drug. Many patients are reluctant to talk back to the doctor and try to second guess their

prescribing decision. Frankly, if I'm asking a patient to put a chemical in their body three times a day and change their physiological function, I think they have the right to ask me a few questions about whether it's the right one for them. Particularly when we know that so many people can't afford to take the medicines that we prescribe. The Consumers Union is launching a new program later this year called *Best Buy Drugs*. [ed: Now online at bestbuydrugs.org] It's going to do for drugs what *Consumer Reports* has been doing for years with refrigerators and cars. I will be on their advisory board and working with physicians and pharmacists around the country evaluating, let's say, the whole class of statin drugs for cholesterol, whole classes of drugs for high blood pressure, and making recommendations to readers about which drugs are the "best buys" currently.

ASB: It seems lately that the industry has been its own worst enemy. The revelations around Vioxx and Paxil are examples of the worsening of its public image which is rapidly approaching that of big tobacco. There is also the drying up of its pipeline of blockbuster "me-too" drugs that really seems to spell a dangerous few years for the industry. If you had the ear of the industry's biggest CEOs, what would you be saying to them about what they need to do?

JA: I would say that it looks to me that they are bearing a terrible resemblance to the dot-coms of the 90s and the NASDAQ at the 5000 level which then fell off its perch when people starting asking "where's the beef?" I think the pharmaceutical industry, even

though it has been the most profitable industry of any in the U.S. for many years, is about to face some very critical "where's the beef?" questions. Their capacity to produce new drugs has really not been borne out in actual products in the numbers that we saw coming out of the industry in earlier decades. It's going to be a very difficult few years for them in both the financial and public relations way and eventually in a political way, and they should go back to their roots. These companies are worthy companies in both the social and financial sense only to the extent that they really are developing important and affordable new products. To the extent that they continue to resemble vast marketing machines that are peddling drugs of minimal, incremental worth, have very large advertising budgets and very high prices, they are very vulnerable to a rapid comedown that may make the dot-coms pale in comparison. They are going to have to face that their revenues and stock prices are probably never going to be as good as they once were. Still, there will be room for companies who are truly doing innovation and are making important products, just as a number of creative high tech companies survived the dot-com bust because they had useful products that worked and people wanted to buy. ♻️

The full interview with Dr. Avorn is available on PAL's web site. www.prescriptionaccess.org/newsletters.htm. To learn more about Dr. Avorn's book, visit www.powerfulmedicines.org. To learn more about Dr. Avorn's work in academic detailing, visit www.drugepi.org.

Update on Previously Filed Litigation

Adalat

Background: In July 2002, PAL filed suit against Elan Pharmaceuticals, Inc. and Biovail Corporation, two generic drug manufacturers of Adalat, a prescription drug used to treat hypertension and other cardiac conditions. The complaint alleges that these companies illegally agreed to divide the market for 30 and 60 mg doses between them. Under this agreement, Biovail paid Elan approximately \$45 million in return for a share of Elan's profits. This agreement significantly harmed consumers by keeping the price of these dosages artificially high.

Update: All Adalat cases were centralized in one court. On October 15, 2003, Elan and Biovail filed a motion to dismiss. Unfortunately, on September 1, 2004, the judge granted this motion, dismissing the case in whole.

Court: U.S. District Court for the District of Columbia (Judge Leon)

Augmentin

Background: In June 2002, PAL filed suit against GlaxoSmithKline (GSK), manufacturer of the widely prescribed antibiotic Augmentin. The suit charged that GSK illegally extended its monopoly over Augmentin by filing duplicative patents with the Food and Drug Administration (FDA). As a result of its "double patenting," GSK was able to keep cheaper generic forms of Augmentin off the market and force consumers to pay for the more expensive, brand-name product.

Update: On July 9, 2004, the indirect-purchaser class action, which covers consumers and insurers, was settled for \$29 million. Consumers who purchased Augmentin between January 4, 2000, and April 30, 2004, may be eligible for a refund from the Class Action Settlement

fund. Notices telling consumers how to file claims were published in a variety of national newspapers and magazines. (See article on p. 4.) The deadline for submitting claims was December 16, 2004.

Court: U.S. District Court for the Eastern District of Virginia (Judge Morgan)

Average Wholesale Price

Background: In December 2001, PAL filed suit against a large number of drug companies for manipulating the "Average Wholesale Price" (AWP) of their drugs. This lawsuit alleges that there has been an industry-wide scheme since 1991 to defraud consumers by listing inflated prices for prescription medications.

Update: On June 12, 2003, the plaintiffs filed an amended complaint, to which the defendants responded with a motion to dismiss. Judge Saris denied that motion for the most part and placed five defendants on a fast track for document production and depositions, which are currently underway. In early September 2004, plaintiffs submitted a motion to certify a national plaintiff class with respect to the five "fast-track" defendants. Expert depositions on the issue of class certification are ongoing. A hearing on the certification motion is scheduled for February 20, 2005.

Court: U.S. District Court for the District of Massachusetts (Judge Saris)

Estratest

Background: In August 2003, PAL filed suit against Solvay Pharmaceuticals, Inc., and Solvay America, Inc., alleging that these firms illegally and fraudulently marketed the drug Estratest (a hormone replacement therapy) for hot flashes, an

unapproved use. In fact, Estratest has *never* received FDA approval for *any* use.

Update: The plaintiffs filed their second amended complaint on March 1, 2004, and the defendants filed another demurrer (similar to a motion to dismiss). Judge Hess overruled their demurrer in May 2004 and the defendants filed an answer to the second amended complaint on June 11, 2004. The case is now proceeding with discovery. On September 27, 2004, the parties presented a joint discovery plan to the court at a case-management conference. A status conference will be held on January 10, 2005.

Court: Superior Court of California for the County of Los Angeles (Judge Hess)

K-Dur 20

Background: In June 2001, PAL filed suit against Schering-Plough Corporation, Upsher-Smith Laboratories, Inc., and American Home Products Corporation, alleging that they illegally agreed to keep generic versions of K-Dur off the market. K-Dur is a potassium supplement often prescribed with high-blood-pressure medication, and it is the fourth most frequently prescribed drug for the elderly.

Update: Judge Greenaway approved consolidation of K-Dur cases in February 2004 and later denied the defendants' motions for reconsideration. On October 29, 2004, Defendants filed a motion to strike the class allegations, and the plaintiffs have opposed it. On November 5, 2004, the plaintiffs filed a motion for leave to file an amended consolidated class-action complaint. A hearing on that motion will be held on December 13, 2004. In the meantime, plaintiffs filed a motion for class certification on November 30, 2004.

Court: U.S. District Court for the District of New Jersey (Judge Greenaway)

Lupron

Background: In September 2001, PAL filed suit against Abbott Laboratories, Takeda Chemical Industries, Ltd., and their joint venture company, TAP Pharmaceutical Products Inc. The complaint alleges that they implemented a fraudulent marketing scheme to increase sales of Lupron, a prostate cancer treatment, and reap unlawful profits at the expense of Medicare patients. In October 2001, TAP agreed to settle a criminal case brought against it by the federal government, pleading guilty and agreeing to pay \$875 million. This was the largest health-care fraud settlement in history.

Update: On November 15, 2004, after more than three years of hard-fought litigation and months of negotiation with the defendants, the parties entered into a proposed settlement agreement and jointly moved that the court certify a class of purchasers of Lupron for purposes of settlement. The defendants agreed to pay a total of \$150 million to settle this litigation. After a payment of \$55 million to private health insurers who had brought suit separately against the defendants, the remaining \$95 million will be made available for distribution to the class—\$40 million has been allocated to satisfy consumer claims and \$55 million to satisfy the claims of third-party payors. On November 24, 2004, the court granted preliminary approval of the settlement. See article on p. 4.

Court: U.S. District Court for the District of Massachusetts (Judge Stearns)

Neurontin

(Patent-Related Litigation)

Background: In April 2002, PAL filed suit against Pfizer Inc. and its subsidiary, Warner-Lambert, alleging that they submitted illegitimate secondary patents on Neurontin in order to keep more affordable generic versions off the market. The complaint also accuses these drug com-

panies of filing baseless patent-infringement lawsuits against generic competitors. As a result, Neurontin, a widely prescribed anticonvulsant for the treatment of epilepsy, has been extremely profitable for both companies.

Update: In March 2003, all patent-related Neurontin cases were consolidated, but further proceedings have been suspended until the underlying patent litigation between Pfizer and generic manufacturers has been resolved. To date, many of the generic manufacturers have overcome motions for summary judgment, but there are a few outstanding motions awaiting the Judge's decision.

Court: U.S. District Court for the District of New Jersey (Judge Lifland)

Neurontin

(Off-Label Promotion)

Background: In February 2003, PAL filed suit against Pfizer Inc. and its subsidiary, Parke-Davis, accusing the companies of circumventing Food and Drug Administration (FDA) regulations by promoting scientifically unproven "off-label" uses of Neurontin, a drug approved for the treatment of epilepsy. Only 10 percent of Neurontin prescriptions are for its FDA-approved use for epilepsy. Specifically, the complaint alleges that Parke-Davis implemented an illegal promotional campaign to increase the number of patients taking Neurontin. Disguised as "medical education" for doctors or "consulting" for the company, the Parke-Davis gave illegal cash kickbacks to physicians, in addition to other promotional schemes, to boost Neurontin sales for off-label uses.

Update: The plaintiffs filed a first amended complaint on March 19, 2004, and the defendants renewed their demurrer (similar to a motion to dismiss) and special motion to strike against the first amended complaint. Judge Mohr denied the demurrer and the special motion to strike on

August 27, 2004. Since that time, the parties have been proceeding with discovery on a statute-of-limitations issue. The plaintiffs expect to file a second amended complaint on March 18, 2005, at which time the parties will participate in a status conference. In a related matter, on October 26, 2004, the Judicial Panel on Multidistrict Litigation consolidated nearly all Neurontin off-label promotions cases in the U.S. District Court for the District of Massachusetts. The PAL case, however, remains in California.

Court: Superior Court of California, County of Los Angeles (Judge Mohr)

Nexium

Background: In October 2004, PAL filed suit against AstraZeneca, manufacturer of the blockbuster heartburn drug Nexium (advertised as "the healing purple pill"). Plaintiffs allege that in order to maintain the profits it was reaping through its earlier drug, Prilosec, AstraZeneca engaged in an extensive and deceptive marketing campaign aimed at switching Prilosec users to Nexium before the patent on Prilosec expired. The lawsuit contends that AstraZeneca misled consumers into believing that Nexium was a major improvement over Prilosec, basing these claims on clinical studies that compared 40 mg of Nexium to 20 mg of Prilosec instead of comparing comparable doses of each drug. See article on p. 1.

Court: Superior Court of California for the County of Los Angeles (Judge McCoy)

Norvir

Background: In May 2004, PAL filed suit against Abbott Laboratories, manufacturer of Norvir which is a critical drug for many HIV/AIDS patients. In 2004, PAL filed suit in CA federal court. The plaintiffs

assert that Abbott unfairly increased the price of Norvir by approximately 400 percent, knowing it was vital to most HIV/AIDS patients.

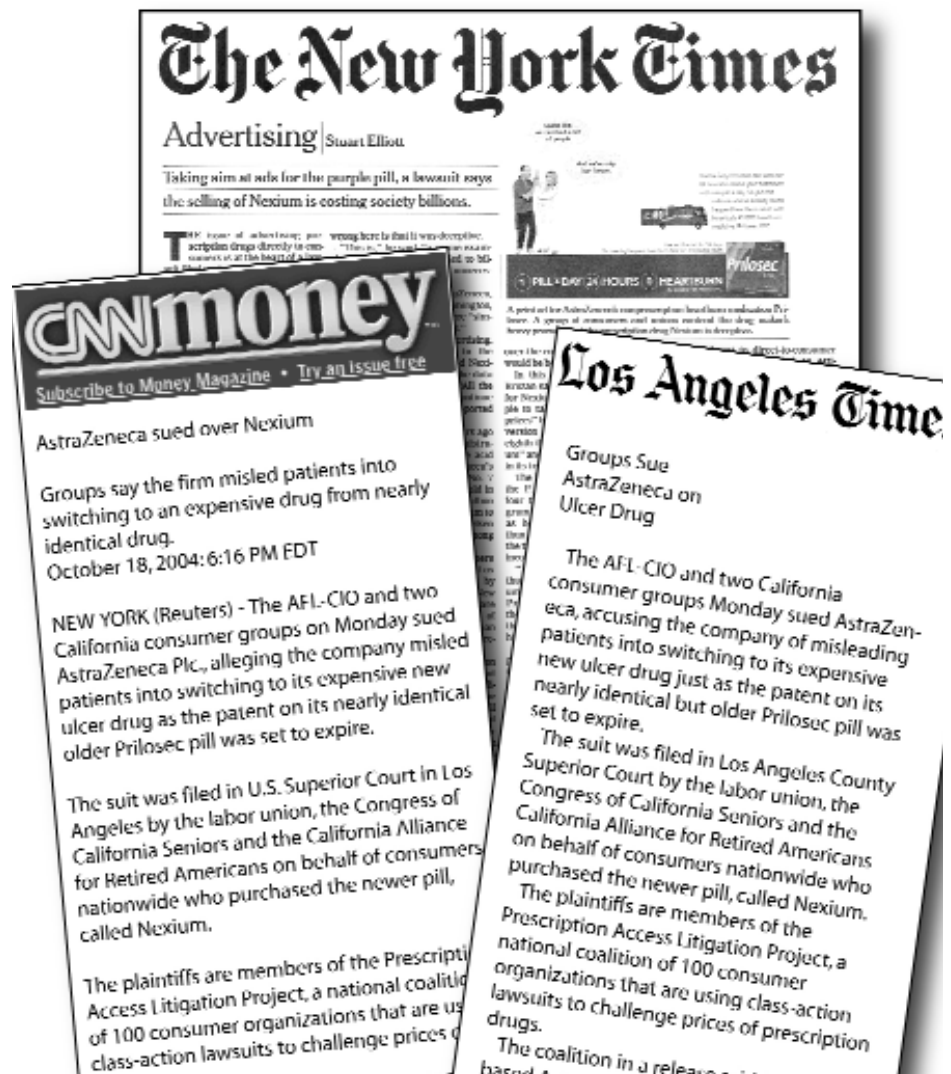
Update: In May 2004, PAL filed suit in Illinois state court against Abbott Laboratories, manufacturer of Norvir, which is a critical drug for many HIV/AIDS patients. Plaintiffs assert that Abbott unfairly increased the price of Norvir by approximately 400 percent, knowing it was vital to most HIV/AIDS patients. In October 2004, PAL filed a similar suit in federal court in California on behalf of a union health and welfare fund.

Courts: Circuit Court of Cook County, Illinois, Chancery Division (Judge Jaffe), U.S. District Court for the Northern District of California (Judge Wilken)

OxyContin

Background: In January 2004, PAL filed suit in Illinois state court against Purdue Pharma, LLP, manufacturer of the widely-prescribed pain medication, OxyContin. The complaint alleges that Purdue Pharma reaped billions in unlawful profits from consumers of OxyContin through fraudulent patents and sham lawsuits that blocked generic alternatives from coming to the market. The lawsuit claims that to win its patents, Purdue Pharma told the patent office that OxyContin was unique because of its effectiveness at very low dosages, despite the lack of evidence supporting this assertion. In a trial on the underlying patent suit, the court ruled in favor of generic manufacturers who had tried to bring a generic version of OxyContin to market, finding the patent invalid because of Purdue Pharma's material

The Prescription Access Litigation Project in the News



misrepresentations to the patent office.

Update: In early July 2004, the case was officially consolidated with other OxyContin cases in U.S. District Court for the Southern District of New York, where the underlying patent litigation was heard.

Court: U.S. District Court for the Southern District of New York (Judge Stein)

Pharmacy Benefit Managers

Background: In March 2003, PAL brought suit against the nation's four largest pharmacy benefit managers (PBMs), AdvancePCS, Caremark Inc., Express Scripts, Inc., and Medco Health Solutions, Inc. The suit claims they illegally contribute to escalating drug costs by failing to pass along rebates and other discounts negotiated with drug companies to their client health plans. PBMs act as intermediaries between drug manufacturers and health plans and administer consumers' health-plan prescription-drug benefits. Contracting with a range of clients, including health plans and employers, PBMs negotiate rebates with drug manufacturers, who in turn hope to secure favorable placement on PBM formularies or preferred-drug lists.

Update: In January 2004, Judge Lichtman denied the defendants' demurrer (similar to a motion to dismiss) and motion to strike, and discovery is now moving forward. The next status conference is on December 8, 2004.

Court: Superior Court of California, County of Los Angeles (Judge Lichtman)

Relafen

Background: In February 2002, PAL filed suit against GlaxoSmithKline Corporation (GSK), alleging that GSK fraudulently obtained a patent on Relafen, a widely-used anti-inflammatory drug, in order to prevent a generic version from entering the market. In the underlying patent case,

Visit us online:

<http://www.prescriptionaccess.org/>



the Massachusetts federal District Court held in favor of the generic companies. It found that GSK made material misrepresentations to the patent office and, thus, the Relafen patent was unenforceable. As a result of GSK's conduct, consumers were forced to pay an artificially inflated price for Relafen for more than ten years, while a less expensive generic version was kept off the market.

Update: The parties filed a settlement agreement on May 20, 2004, and Judge Young granted preliminary approval on November 24, 2004. (See article on p. 4.)

Court: U.S. District Court for the District of Massachusetts (Judge Young)

Remicade

Background: In April 2002, PAL filed a lawsuit alleging that Centocor, Inc., Remicade's manufacturer, and its parent company, Johnson & Johnson, illegally overcharged Medicare and patients who take this drug by grossly overstating its average wholesale price (AWP). The plaintiffs assert that Centocor gave providers discounts on Remicade, which is used in the treatment of Crohn's disease and arthritis. The plaintiffs allege Centocor encouraged providers to charge Medicare and patients the full AWP-backed price and then pocket the difference between that price and

the discounted price they paid.

Update: This PAL lawsuit was consolidated with the AWP litigation in Massachusetts. (See AWP case update on p. 7.)

Court: U.S. District Court for the District of Massachusetts (Judge Saris)

Tamoxifen

Background: Tamoxifen is the most commonly prescribed drug to treat women with breast cancer. In May 2001, PAL filed suit against AstraZeneca, maker of Tamoxifen, and Barr Laboratories Inc., sole distributor of its generic form. The case alleges that these companies illegally colluded to keep the price of Tamoxifen high. When this unlawful agreement expired in February 2003, a cheaper generic finally became available.

Update: PAL attorneys appealed the May 2003 dismissal of the case and an argument hearing was held on July 12, 2004. The parties now await a ruling.

Court: Second Circuit Court of Appeals, on appeal from the U.S. District Court, Eastern District of New York (Judge Glasser)



"Ask Pharmie" is a new section of PAL News.

Each month, Pharmie, your guide to all things pharmaceutical, will answer your questions about the drug industry. Comments or questions may be sent to:

askpharmie@communitycatalyst.org.

Q: Why are there drug ads on TV that don't tell you what the drug is for?

A: This kind of ad is called a **"reminder ad"**---it only tells you the name of the drug and usually says something like, "Ask your doctor about..."

The Food and Drug Administration (FDA) monitors drug ads targeting consumers. The FDA allows three types of drug ads:

- **"product claims"** explaining how effective a drug is and what side effects it has;
- **"help-seeking advertisements"** describing symptoms and advising viewers to see a doctor, but which don't describe a particular drug; and
- **"reminder ads"** just giving the name of the drug with no details at all.

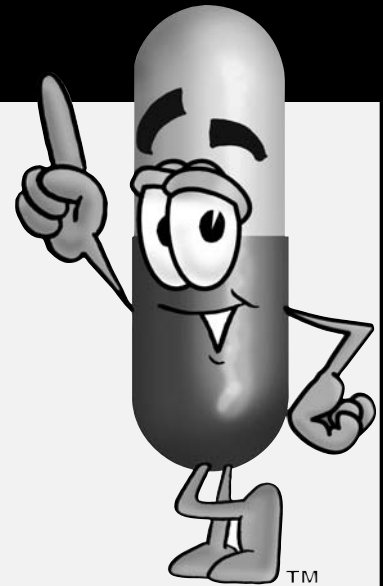
The FDA rules say that reminder ads may only "remind" people about a drug. They can't give any details about it or what it's used for. Reminder ads cannot even compare one drug to another. The rules don't just limit what you can say about the drug, but also how the ad looks and sounds. Reminder ads also have to tell you where you can learn more about the drug. This is why ads often say something like, "See our ad in X Magazine."

The FDA recently forced Pfizer to take a reminder ad for the popular impotence drug, Viagra, off the air. The ad showed a couple friskily shopping for lingerie. The ad said *"Remember that guy who used to be called 'Wild Thing'? The guy who wanted to spend the entire honeymoon indoors? Remember the one who couldn't resist a little mischief? Yeah, that guy. He's back."* It showed the blue "V" from the Viagra brand logo behind the man's head like a pair of devil horns. Even though it never specifically said what Viagra is for, this ad clearly suggested that Viagra is used for sex, breaking the rule that reminder ads cannot even imply a use for the drug.

The reason reminder ads can't mention what the drug is used for is that, under the FDA's rules, if you say anything about what the drug does or what it's for, you have to also talk about the risks and side effects. This is what "product claims" ads do. Reminder ads are OK because they don't say *anything* about the drug - if you don't talk about the good, you don't have to talk about the bad either.

Q: Why do drug companies use reminder ads if they can't say anything about the drug?

A: To create a buzz around a drug, companies will use a mix of all three types of ads. This way they build "name recognition" of a drug. Reminder ads just keep that name in peoples' minds. Unfortunately, all kinds of drug ads to consumers (called "Direct-to-Consumer Advertising," or DTCA) can lead people to believe that they need drugs that they don't really need, or that they need an expensive brand-name drug



when an older, cheaper generic or over-the-counter drug would work just as well. Over 20 million people took Vioxx, the drug that Merck recently pulled off the market after studies showed it increased the risk of heart attack. Merck aggressively marketed Vioxx, particularly with TV ads featuring former olympic skater Dorothy Hamill. But only about 4 percent of people were at risk for the type of stomach problems that Vioxx was designed to avoid. The other 96 percent could have taken a much cheaper but equally effective over-the-counter drug like Naproxen (Aleve.) The recent story with Vioxx shows how drug ads can lead people to take drugs that may be much more expensive than what they need. PAL's case against AstraZeneca on the drug Nexium also addresses the effects of drug ads on the prices consumers pay.

So when you see drug ads of any kind, look at them critically. Do your own research, talk to your doctor, and don't assume that just because a drug is new that it must be better.

Got a question for Pharmie? Email: askpharmie@communitycatalyst.org.

Prescription Access Litigation Project (PAL)

The Prescription Access Litigation (PAL) participants agree to work in a collaborative effort: (a) to achieve our shared mission of creating substantial economic value for consumers in order to remedy past unlawful practices of pharmaceutical companies; and (b) to achieve meaningful change in the way the pharmaceutical industry does business in order to increase access to affordable prescription and other drugs.

PAL Participants

Alaska

ASEA/AFSCME Local 52
Health Benefits Trust*

Arizona

Arizona Citizen Action
Senior Disabled Arizona
Protest

California

California Alliance for Retired
Americans (CARA)*
California Citizens for Health
Freedom*
California PIRG
Congress of California
Seniors
Council on Aging Services for
Seniors (Sonoma County)
Greenlining Institute*
Gray Panthers of Sacramento
Legal Assistance to the
Elderly
San Francisco Senior Action
Network

Colorado

Colorado PIRG
Colorado Progressive
Coalition

Connecticut

Connecticut Citizen Action
Group

District of Columbia

Nonprofit Clinic Consortium
District of Columbia Primary
Care Association
(DCPCA)*

Florida

The Annie Appleseed Project
Florida Alliance for Retired
Americans
Human Services Coalition of
Miami-Dade County

Idaho

Idaho Community Action
Network
Living Independence
Network Corporation

Illinois

Campaign for Better Health
Care
Champaign County Health
Care Consumers
Citizen Action/Illinois
Illinois Public Interest
Research Group
South Austin Coalition

Indiana

United Senior Action of
Indiana

Kansas

Kansas Association for the
Medically Underserved

Maine

Consumers for Affordable
Health Care
Maine People's Alliance

Maryland

Maryland Citizens' Health
Initiative

Massachusetts

ABCD Health Services*
Commonwealth Care Alliance*
Health Care For All
Health Law Advocates
Lynn Health Task Force
Massachusetts Breast Cancer
Coalition
MASSPIRG
Massachusetts Senior Action
Council
New England Regional
Council of Carpenters
Women's Health Institute

Michigan

Public Interest Research
Group in Michigan
(PIRGIM)

Minnesota

Minnesota COACT
Minnesota Senior Federation

Mississippi

Mississippi Human Services
Coalition
Mississippi Health Advocacy
Program

Nebraska

Nebraska Appleseed

New Hampshire

New Hampshire Citizens
Alliance

New Jersey

New Jersey Citizen Action
New Jersey PIRG
Public Interest Law Center of
New Jersey

New Mexico

Health Action New Mexico
Senior Citizens' Law Office

New York

BWICA Education Fund Inc.
CAIRE
Citizen Action of New York
JPAC for Older Adults
Gay Men's Health Crisis
Ithaca Breast Cancer Alliance
Long Island Coalition for a
National Health Plan
Long Island Progressive
Coalition
Metro New York Health Care
for All Campaign
New York Statewide Senior
Action Council
Rockland County Senior
Health Care Coalition
Utica Citizens in Action

North Carolina

North Carolina Fair Share
North Carolina Health Access
Coalition
North Carolina PIRG

Ohio

Universal Health Care Action
Network of Ohio
Working in Neighborhoods
Senior Action Coalition

Oregon

Oregon Consumers League
Oregon Health Action
Campaign
Oregon State Public Interest
Research Group
SEIU Local 503
SEIU Local 49

Pennsylvania

Action Alliance of Senior
Citizens
Citizens for Consumer Justice
Consumer Health Coalition
Mon Valley Unemployed
Committee
PennPIRG
Pennsylvania Alliance for
Retired Americans
Philadelphia Unemployment
Project*

Rhode Island

Health Care Organizing
Project
Ocean State Action

South Carolina

South Carolina Appleseed
Legal Justice Center

Tennessee

Tennessee Health Care
Campaign

Texas

Texas Alliance for Human
Needs

Utah

Utah Issues: Center for
Poverty Research & Action

Vermont

Vermont PIRG

Virginia

Virginia Poverty Law Center

Washington

Washington Citizen Action
Washington PIRG

West Virginia

West Virginia Citizen Action
Group

Wisconsin

Wisconsin Citizen Action

National Organizations

AIDS Action (Washington,
D.C.)
Alliance for Retired Americans
American Federation of
Labor and Congress of
Industrial Organizations
(AFL-CIO)
American Federation of State
County and Municipal
Employees (AFSCME)
Association for Community
Affiliated Plans
Our Bodies Ourselves
Community Catalyst
Medicare Rights Center
National Health Law Program,
USACTION

***New member of the PAL
coalition.**

**If your organization is interested
in joining the PAL coalition,
please contact Julie Bizzotto at
bizzotto@communitycatalyst.org
or (617) 275-2931.**



Contact the Prescription Access Litigation Project

Julie Bizzotto, PAL Program Associate
bizzotto@communitycatalyst.org / (617) 275-2931

Please direct all media inquiries to:

Michael Gipstein, Media Specialist
gipstein@communitycatalyst.org / (617) 275-2805

Learn More about Community Catalyst

Community Catalyst, home to the PAL Project, is a national advocacy organization that builds consumer and community participation in the shaping of our health system to ensure quality, affordable health care for all by providing legal, technical, and policy assistance to organizations that advocate on behalf of health-care consumers.

A full catalogue of our reports, newsletters, and other materials can be accessed at http://www.communitycatalyst.org/acrobat/Current_Catalogue.pdf.

You may also contact the production coordinator at (617) 275-2892 for more information.



30 Winter Street, 10th Floor
Boston, MA 02108

ADDRESS SERVICE REQUESTED

NON PROFIT US POSTAGE PAID BOSTON, MA PERMIT NO. 54076
--