



PAL News

The Prescription Access Litigation Project
A Community Catalyst Initiative

Telling the Truth about the Drug Companies

PAL Director Alex Sugerman-Brozan interviews Marcia Angell, M.D., author of *The Truth about the Drug Companies*

Alex Sugerman-Brozan: The hottest issue around prescription drugs in the public right now is the issue of reimportation, with millions of seniors getting their drugs from Canada. This seems to be where the public outrage over drug prices is being channeled. But even if we imported the entire Canadian drug supply, it would meet only a small portion of demand that Americans have. So is reimportation a red herring?

Marcia Angell: It's not a red herring, but it's not a solution either. It's the symptom of the problem, and the problem is price gouging in the United States. So as

you suggest, it's not going to be a solution. Canada isn't big enough, and they need some drugs for themselves. It's not going to be a solution, but it may stimulate the United States to come to a solution. And it seems to me that the solution is going to have to be importing not the drugs, but a system for stopping the upward spiraling of prices, similar to the system Canada has.

ASB: The pharmaceutical industry has been on a wild public relations campaign recently to convince the American public that the high prices we pay for drugs are funding innovation, that the next blockbuster lifesaving drug is



Marcia Angell M.D. is the author of the recently released *The Truth about the Drug Companies: How They Deceive Us and What to Do About It* (Random House, 2004)

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PAL Settles Two Cases in Two Months

Early this summer, PAL settled two very important cases, Relafen and Augmentin. Both cases were filed against GlaxoSmithKline (GSK), one of the largest drug companies in the United States. Settlements like these show the powerful role litigation can play in the fight to lower the cost of prescription drugs. Since PAL formed three years ago, it has successfully settled three of its twenty lawsuits. Because drug-price lawsuits move very slowly, winning three settlements in such a short time is a tremendous success.

Each new settlement sends a

warning signal to drug companies that consumers will not stand for illegal actions that make drugs more expensive. Settlements like these force drug companies to pay millions of dollars to reimburse the consumers hurt by their unlawful practices. The hope is that settlements like these will have a deterrent effect on drug companies. The prospect of paying a multimillion-dollar settlement should make drug companies think twice before engaging in illegal conduct that raises the price of drugs.

PAL's first settlement came in 2003, in a case against Bristol-Myers

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around the corner, that the rest of the world is free-riding on American research and development (R&D). These are all myths that you and others have conclusively refuted. But there is that old saying that a lie repeated enough becomes true. How can we refute those messages in a way that sticks given the resources we are up against on the other side?

MA: I am not so sure that it is not sticking, at least somewhat. I think people are realizing that although the US is the major profit center for the big drug companies, the drug companies have consistently made more in profits than they spend on R&D. They spend two to two and a half times what they spend on R&D on something they call "marketing and administration." So what we are supporting is, yes, R&D but even more so profits and marketing and administration. I think the public is catching on to that.

It is very hard to make the case that we have to worry about price constraints cutting into R&D when drug company profits are higher than R&D. This is consistently one of the most profitable industries in the United States. It's not a risky business and it is not a business that is just eking out a living, that can barely afford its R&D. It could pay for its R&D out of its profits if it wanted to.

ASB: Marketing is one of the main drivers of the demand which enables them to charge the prices which they do, including direct-to-consumer advertising (DTCA). I've heard industry representatives argue that the ads on TV, for example, are a good thing because they encourage a dialogue between the doctor and the patient about whether the drug is



Publishers Weekly says...
Angell mounts a powerful case (and offers specific suggestions) for reform of this essential industry—a case worth bearing in mind as "big pharma" continues to oppose importing cheaper drugs from Canada.

really needed. Do you think that is really taking place or do you think that frequently besieged doctors who are extraordinarily busy will prescribe the drug even if they think it's not absolutely needed?

MA: I think it's ridiculous for drug companies to suggest that they're educating consumers in any way. They're selling drugs - they know that. And most of these drugs that are advertised are not especially innovative or effective drugs that patients may never have heard of or that treat conditions that are very subtle and hard to diagnose. They are the same old blockbusters over and over again. So I don't think that

this fosters a dialogue that somehow the doctors and patients are too shy to have had.

The consumer ads are just a waste of money. They're added onto the price of drugs. They set up a situation in which a patient comes to a doctor thinking that a drug that he or she just saw on television might be exactly what they need. The doctor finds it too easy to just write a prescription for that drug or reach into his cabinet for free samples of that drug rather than taking extra time to explain why that drug shouldn't be used, why it's too expensive, why it's not worth it. It's just easier to write the prescription.

The ads that the drug companies sometimes say are educational—look at them: they mainly show very nice-looking people out in a field of flowers. And the message is you too can be this beautiful and get out in fields of flowers. That's not educational.

ASB: DTCA is overshadowed by the massive amount of marketing directed at the physicians. Doctors often claim that they aren't affected by the marketing, that they are able to see through it and rise above it. But drug companies are in business to make money and they wouldn't go to these expenditures if they didn't think it was effective. What do you say to those doctors who say they are unaffected by it?

MA: Well I think that's what doctors have to say to themselves to make it OK in their minds. But doctors are not exempt from human nature. If people come bearing gifts, you come to feel warmly towards them, and that's exactly what's going on. The

studies that have been done in fact show that doctors do change their behavior after they've come to a dinner meeting with a drug representative or they've gone to a company sponsored event. It works, otherwise drug companies wouldn't do it. If they kept doing it and it didn't work, then heads would roll in the executive suites. Incidentally, if you ask a doctor whether he or she is influenced by drug companies, he or she will say no. But then if you ask the doctors if their colleagues are influenced, they say yes.

ASB: Drug companies are publicly traded companies and their fates are tied to those of their shareholders. Shareholders are looking for profitability and an increase in stock price. The norm is to seek rapacious profits and charge the highest prices the market will bear. There seems to be a fundamental tension between the needs of the patients and the public on the one hand and the demands of investors on the other. How do we break this stranglehold?

MA: Yes, what you say is absolutely true. The founder of Merck, George W. Merck, said "*We try never to forget that medicine is for the people. It is not for the profits. The profits follow, and if we have remembered that, they have never failed to appear.*" That was then, and now businesses are much more competitive and their investors are much more insistent on short-range profits.

You have to look at the wisdom of entrusting something as important as life saving drugs to for-profit businesses that are beholden only to their investors and not really to the public. That's a much, much bigger issue, and you could talk about the whole health care system in that way. We're the only industrialized nation

PROFILE

Cheryl Read

Seattle, Washington

As a single mother and self-employed development consultant for struggling nonprofit organizations, fifty-two-year-old Cheryl Read is accustomed to juggling many responsibilities and challenges at once. However, paying for her lifesaving medications was one ball she never thought would be so difficult to keep in the air.

Once an active weight lifter and runner, Cheryl's life changed dramatically three years ago when she learned that she suffers from congenital cervical spinal stenosis, a narrowing of the spinal column that causes excruciating pain and makes it difficult to function. After discovering she was allergic to many common pain-relief medications, Cheryl's doctor finally prescribed OxyContin. Because of the drug's controversial reputation, Cheryl has had to endure probing questions, dirty stares and the invasion of her privacy. "It's been so humiliating," she says, relating stories of how pharmacists questioned her truthfulness and fellow customers referred to her as a "junkie."

Cheryl has also had to endure the exorbitant cost of the painkiller. The monthly cost for her OxyContin alone is over \$800! She had full health-care benefits when she was married; but since her divorce in 2001, Cheryl has been forced to purchase a

variety of partial insurance plans. Unfortunately, they do not cover the cost of OxyContin. Aside from OxyContin, Cheryl must also take a number of prescription medications for diabetes, with which she was diagnosed just this past year. All told, her monthly drug costs are nearly \$950.

These costs would be hard for anyone to manage, but they pose a particular hardship for Cheryl, who is currently unemployed. With only her meager savings and \$500 each month in child support to rely upon, there isn't much left for her other expenses. Unable to keep up with her mortgage payments, she almost lost her home last year. Her home was saved only through a last-minute refinancing and some help from her sister.

Cheryl contacted PAL recently after learning about its OxyContin lawsuit through internet research. An activist at heart, she hopes to return to work soon to help nonprofit advocacy organizations like those in the PAL coalition. She hopes to connect with others facing spinal stenosis in order to form a support and advocacy group. In the meantime, she is eager to share her story, "especially if it helps others and brings attention to the issues so many of us face." ♣



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PAL challenges Abbott on 400 % AIDS-Drug Price Hike

On May 20, 2004, PAL brought a national consumer class-action suit in Illinois state court against Abbott Laboratories for a sudden and unprecedented price increase for its anti-AIDS drug, Norvir. The suit claims that the Norvir price increase violates the Illinois Consumer Fraud and Deceptive Business Practices Act. It argues that Abbott's price hike is so enormous and unjustifiable that it constitutes an illegally unfair practice. The use of state consumer-protection laws presents an important new strategy to challenge unconscionable price hikes by drug companies.

Norvir, a protease inhibitor (PI), is an essential ingredient for one of the three main types of drug regimens used to treat HIV and AIDS. Previously, Norvir was used as a standalone PI. Today, Norvir is used in low dosages together with another PI to make the primary PI more effective. Norvir is the only PI that can be used as such a "booster." Eight of the nine PIs on the market use Norvir as a booster. One of these is Kaletra, a combination product manufactured by Abbott that combines Norvir with Abbott's own PI, lopinavir.

In December 2003, Abbot raised the wholesale price of Norvir from \$205.74 to \$1,028.71 for 120 capsules, an increase of over 400 percent. However, Abbott did not increase the price of Kaletra. The result is that all the other PI regimens using Norvir are now much more expensive than Kaletra. PAL charges that Abbott has effectively raised the price of its competitors' products. The complaint claims Abbott is forcing patients either to pay much more for their lifesaving medications or to switch to Kaletra, which may not be

medically appropriate for them. The different PIs currently available are not interchangeable because each has its own properties and side effects.

Abbott's price increase has been widely criticized by HIV/AIDS patients, advocates, medical providers, and government officials. For example, a group of several hundred HIV/AIDS physicians has called for a boycott of Abbott, and several state attorneys general are investigating the price hike. Activists asked the National Institutes of Health (NIH) to invoke a never-before-used mechanism to force Abbott to allow a generic on the market (NIH refused). Also, the FDA

issued a warning letter to Abbott for distributing inaccurate information in materials put out to defend the price hike.

Abbott's Norvir price hike shows the control drug makers have over clinically important and lifesaving drugs. PAL's case directly challenges the idea that drug companies can put profits ahead of the health of chronically ill people like HIV/AIDS patients. Accordingly, the case seeks to roll back Norvir prices. The lawsuit alleges Abbott violated consumer protection laws when it took advantage of Norvir's unique properties, and the lawsuit is an important new front in the battle for affordable prescription drugs. ♻️

Research and Development Facts

Taxpayer dollars funded research which led to the development of Norvir. Because of this, the U.S. government has certain rights on the Norvir patent. For more information, visit the website of Essential Inventions, an organization that led the campaign to urge the U.S. government to use those rights to make more-affordable ritonavir available. Specific information on research funding for Norvir is at www.essentialinventions.org/media/norvirgovfunding.html; or visit Essential Invention's homepage at www.essentialinventions.org.

Many ground-breaking treatments are discovered directly or indirectly through federally funded research. In May 2000, the congressional Joint Economic Committee released a report titled, *The Benefits of Medical Research and the Role of the NIH*. This report found that "[o]f the 21 most important drugs introduced between 1965 and 1992, 15 [over 70%] were developed using knowledge and techniques from federally funded research."

In May 2002, the National Institute for Health Care Management, in a report titled, *Changing Patterns of Pharmaceutical Innovation*, suggested that many new drugs are really "me-too" drugs with little advantage over existing medications. This conclusion refutes the drug industry's claims that high prices are needed for research into important and innovative new drugs. Read the report online at www.nihcm.org/innovations.pdf.

Drug companies often spend more on marketing than they do on research and development into new drugs. The AFL-CIO's website has an interactive "game" to show how the production costs break down. Play it at lcio.org/familyfunresources/games/game_ospill.cfm.



Squibb (BMS) concerning the drug, BuSpar. That settlement resulted in a \$42 million fund to repay consumers. PAL helped notify consumers about this settlement and how to file claims for reimbursement, through its website and newsletter.

Relafen

PAL reached its second settlement in May 2004 in the Relafen case. PAL coalition members **Health Care for All** and **Wisconsin Citizen Action** sued GSK for keeping cheaper generic versions of the drug off the market by unfairly obtaining a duplicate patent for Relafen. The case against GSK was strengthened when a court in a separate patent lawsuit ruled that GSK had misled the patent office and invalidated GSK's patent on Relafen. This ruling basically meant that a cheaper generic had been illegally kept off the market for ten years and that consumers had been overpaying for Relafen for an entire decade. Consumers usually save 30-70% when generics are available. The ruling in the patent case helped pressure GSK to settle lawsuits, like PAL's, filed by consumers and insurers who overpaid for Relafen for years. In a settlement agreement filed with the court on May 20, 2004, GSK agreed to pay the Plaintiffs a total of \$75 million, with \$25 million slated to go to individual consumers. As is typical in such cases, GSK did not admit any wrongdoing. PAL expects the court will approve the settlement after a hearing on October 5, 2004.

Augmentin

As it had with Relafen, GSK kept a generic version of Augmentin off the market for years. In the Augmentin case, PAL coalition members, including **Tennessee Health Care**

Campaign, Congress of California Seniors, AFSCME, AFSCME District Council 47, and Maine Consumers for Affordable Health Care, sued GSK for filing duplicate patents for Augmentin. Augmentin is an important antibiotic used to treat several different types of infections. The case claims that GSK filed "double patents" to keep an unlawful monopoly on the market for Augmentin. Because there was no generic competition, GSK could unfairly increase the price for this important medication.

GSK settled with the consumer and third-party-payor plaintiffs for \$29 million. As in the Relafen settlement, GSK refused to admit any wrongdoing. Attorneys submitted settlement papers on July 8, 2004, for court approval. Details on the settlement are being finalized, including how claims will be filed and how the settlement funds will be divided. Achieving these settlements shows the power consumer voices have in court to hold the drug industry accountable for dishonest pricing practices.

PAL will help notify the millions of consumers who were affected by

the Augmentin and Relafen price manipulations. PAL's website will have details on the final settlements and information on the claims process. Look for more information in PAL's next newsletter.

Given how long lawsuits like these take to finally resolve, these victories show that PAL is making progress in the fight to lower the costs of prescription drugs. Litigation has proven a useful tool for both consumers and advocates who are frustrated by the obstacles powerful drug makers pose to legislative reform on drug prices. In the courtroom, drug companies are less able to flex their political and financial muscle. As these settlements demonstrate, litigation helps level the playing field by allowing consumers to challenge unfair and illegal pricing while returning funds to consumers who have overpaid for necessary medications. Through these settlements, the PAL coalition's litigation strategy is gaining momentum and forging ahead in the movement for affordable prescription drugs. ♻️



Prescription Access Litigation Project News Briefs

New Member Organizations

PAL welcomes four new member organizations to the coalition: **The Annie Appleseed Project** (Florida); the **Council on Aging Services for Seniors** (Sonoma County, California); **Illinois PIRG**; and the **South Austin Coalition** (Illinois).

Regional Meetings

On July 16, PAL held its first **PAL Regional Meeting** with PAL-coalition members. PAL Project Director, Alex Sugerman-Brozan, met in Chicago with representatives from PAL member groups, **Citizen Action/Illinois** and **Campaign for Better Health Care**. Also in attendance were new PAL members, **Illinois PIRG** and **South Austin Coalition**, as well as

representatives from **Illinois Alliance for Retired Americans**. Thanks to Citizen Action/Illinois for hosting the event! Another regional gathering is scheduled for the end of August in Sacramento, California, and will be hosted by the **Congress of California Seniors**.

Staff Changes

At the end of August, **Kate Lowe**, PAL Project Associate, will leave PAL to begin graduate studies in community planning and development at Clark University. All of us at PAL are extremely grateful to Kate for her tireless dedication to the fight for affordable prescription drugs. We will miss her but know that she will continue working for a more just health care system.

that has a market-based health care system, and what markets do is distribute goods according to the ability to pay. They do not distribute goods according to need. So what can be said of the health care system as a whole can also be said about the pharmaceutical industry. Is this the way we want to distribute life saving drugs? If you do say yes, that there are offsetting advantages of the market, then it seems to me that you need to look at regulating the market some way. You have to demand of the pharmaceutical industry certain things in return for the great favors that they are given.

This industry, despite all the talk about the free market, is really totally dependant on government favors. First of all, many of their drugs, their most innovative drugs, are based on NIH-supported research. Second, government granted monopoly rights: patents, FDA-exclusive rights. And then they also get enormous tax deductions and credits. So this is a very blessed industry. The government takes good care of it. In return, I think we should be able to ask for certain things. We ought to be able to ask for moderation in prices; we ought to ask that drug companies work on drugs that may not be as profitable as some but are greatly needed. There are shortages now of some antibiotics and some important drugs because they don't pay. So there needs to be some kind of regulation if it's going to remain an investor-owned industry.

Look at a drug like Taxol which was developed almost entirely at the National Cancer Institute, and then handed over to Bristol-Myers Squibb as part of a cooperative research agreement with the NIH. That drug

cost Bristol-Myers Squibb relatively little and yet they put it on the market at something like ten to twenty thousand dollars for a year's supply and made nine billion dollars from the drug while they had exclusive marketing rights. That shouldn't be. In return for those special favors, they should have priced it more reasonably. And in fact, according to the law, they were supposed to make it available on reasonable terms. But that's not enforced.

ASB: One of the recommendations you make in your book is that new drugs be tested not just against placebos but against existing drugs. New drugs should have to show that they're more effective than what's already available, rather than just more effective than nothing. How would this affect the research that companies do?

MA: It would stop the "me-too" industry, which is where the drug companies focus most of their attention now. With many of these "me-too" families, the first drug is important and innovative. Many of those first drugs came on the market in the 1980s and were based on NIH-funded work. Since then, companies have strung the "me-too's" out. Sometimes the same company produces a minor variation in order to get another patent, so that the prices stay up. Sometimes it's just a matter of other companies wanting to get into the same lucrative market. They couldn't do that if "me-too" drugs had to be better in some significant way: more effective, safer, or markedly more convenient. If you required that then there would be far fewer "me-too" drugs on the market. All you know now, since they compare drugs with the placebos, is that they're better than nothing. But that isn't what a doctor wants to know. A doctor wants to know "Is this better than what I'm already



using?" And they don't know that. So it would pull the rug out from under the need to market.

What would the drug companies do? Well they could go in one of two directions. They could start to focus their energies on discovering and developing truly innovative drugs. That is a riskier proposition and takes longer, but they wouldn't have much choice. Or else they could explicitly say "We're not in the drug discovery business - we are in the drug development business, the manufacturing business, the distribution business. We don't do innovation." And that would be OK too. The problem now is that these companies are rewarded as though they were innovative, and they're not really. ☹

Marcia Angell, M.D., is the former editor-in-chief of the *New England Journal of Medicine* and a member of Harvard Medical School's Department of Social Medicine. She is the author of the recently released *The Truth about the Drug Companies: How They Deceive Us and What to Do About It* (Random House, 2004) The full interview with Dr. Angell is available on PAL's website, www.prescriptionaccess.org/newsletters.htm

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. The Plaintiffs filed an opposition to this motion on December 15, 2003, and are awaiting the judge's ruling.

Court: U.S. District Court, 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 generic forms of Augmentin off the market and force consumers to pay for the more-expensive, brand-name product.

Update: In the underlying patent case, the U.S. Court of Appeals affirmed that numerous GSK patents for Augmentin are invalid. As a result, all Augmentin cases, including PAL's, were consolidated in the Eastern District of Virginia on May 19, 2004. On July 9, the parties

announced that a settlement for \$29 million had been reached in the indirect-purchaser class action, which covers consumers and insurers.

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

Average Wholesale Price (AWP)

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 (Amended Master Consolidated 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. The plaintiffs are preparing to submit a motion to certify a national plaintiff class with respect to the five "fast-track" defendants.

Court: U.S. District Court, 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 demur-

rer (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. The parties are scheduled to present a joint discovery plan to the court on September 27, 2004, at a case management conference.

Court: Superior Court of California, 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. In May 2004, Judge Greenaway ordered that the last pretrial motions be filed by September 1, 2005, and that the last pretrial hearing take place on November 1, 2005.

Court: U.S. District Court, 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 the

sale 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: To date, Judge Stearns has declined to dismiss the Plaintiffs' case. In May 2004, he did dismiss the claim that the Defendants engaged physicians in their illegal schemes. Document discovery and depositions of all Defendants are underway. All discovery is scheduled to be completed in early September 2004.

Court: U.S. District Court, 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 companies 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, 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, 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. The hearing on these motions was held on August 12, 2004. At that hearing, Judge Mohr denied the Special Motion to Strike, but sustained the demurrer with leave to amend. The Second Amended Complaint will be filed on December 13, 2004.

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

Norvir

Background: In May 2004, PAL filed suit 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. (See article on p. 4.)

Update: Judge Jaffe has scheduled a case management conference for October

5, 2004, to determine a timeline for the proceedings.

Court: Circuit Court of Cook County, Illinois, Chancery Division (Judge Jaffe)

OxyContin

Background: In January 2004, PAL filed suit against Purdue Pharma L.P., manufacturer of the widely-prescribed pain medication, OxyContin. The complaint alleges that Purdue 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 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 non-jury 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, holding the patent invalid because of Purdue's material 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, 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'

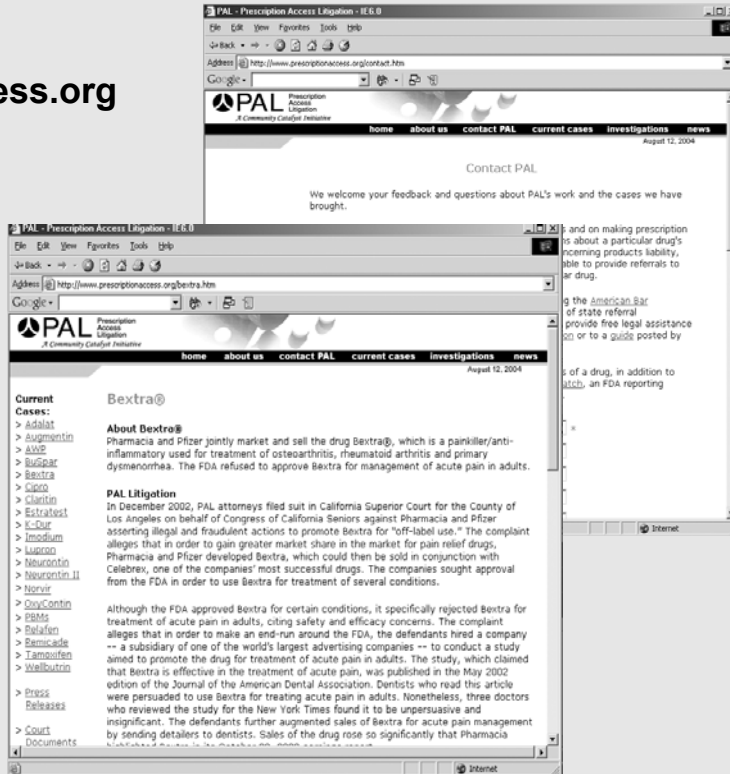
For information on all of PAL's cases:

<http://www.prescriptionaccess.org>

Also includes cases in which
PAL is no longer active:

**Bextra, BuSpar,
Cipro, Claritin,
Imodium
& Wellbutrin**

**Or contact us online
for more information
and to tell us your story.**



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

Court: U.S. District Court, 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)

Other Litigation Activities

On July 22, PAL submitted an amicus curiae ("friend of the court") brief along with AARP Foundation Litigation, the legal arm of AARP, and Legal Counsel for the Elderly in a case concerning a new law on the business practices of pharmacy benefit managers (PBMs). PAL filed a lawsuit last year against the nation's four largest PBMs (see PBMs case update) and closely tracks efforts to curb the abuses of the PBM industry.

PAL's amicus brief supports a recently enacted District of Columbia law that sets forth strict reporting and disclosure requirements for PBMs. This law aims to increase the accountability and transparency of the PBM industry. Earlier this

summer, the Pharmaceutical Care Management Association, the national association for PBMs, sued the District of Columbia, seeking to keep this very important law from being implemented.

On August 3, PAL submitted another amicus curiae brief with AARP Foundation Litigation. The brief concerns an appeal of the Federal Trade Commission's (FTC) ruling on agreements between Schering-Plough Corporation, Upsher-Smith Laboratories and American Home Products Corporation. The FTC determined these companies violated anti-trust laws in order to delay the entry generic competition for the drug K-Dur. PAL currently has a consumer class action on K-Dur concerning these same allegations that was filed in June 2001 (See K-Dur case update). The PAL/AARP brief argues that the FTC decision should be upheld and the manufacturer's appeal seeking to overturn that decision should be denied. 

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

Arizona

Arizona Citizen Action
Senior Disabled Arizona Protest

California

California PIRG
Congress of California Seniors
Council on Aging Services for Seniors (Sonoma County)
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

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

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 for Law in The Public Interest

New Hampshire

New Hampshire Citizens Alliance

New Jersey

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

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
AFSCME District Council 47 Health and Welfare Fund
Citizens for Consumer Justice
Consumer Health Coalition
Mon Valley Unemployed Committee
PennPIRG
Pennsylvania Alliance for Retired Americans

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

PAL Participants (cont.)

National Organizations

AIDS Action (Washington D.C.)
Alliance for Retired Americans
American Federation of State County and
Municipal Employees
Association of Community Affiliated Plans
Our Bodies Ourselves
Community Catalyst
Medicare Rights Center
National Health Law Program, Inc.
USAction

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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.



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