



# PAL News

The Prescription Access Litigation Project  
A Community Catalyst Initiative

## AARP Joins Forces with PAL on Three Lawsuits Targeting Companies that Blocked Generics

The Prescription Access Litigation (PAL) project and AARP, the 35-million member organization formerly known as the American Association of Retired Persons, announced May 29 at a press conference in Washington D.C. that AARP's Foundation Litigation (AFL) has joined PAL's class-action litigation campaign against companies that act illegally to prevent the American health care consumer from getting cheaper, generic versions of the drugs they need.

AARP attorneys will serve as co-counsel on three of the lawsuits PAL litigators filed in state and federal court in 2001: the **BuSpar** case charging Bristol-Myers Squibb with illegally extending its monopoly on manufacture and sale of the anti-anxiety drug; the **K-Dur 20** case charging that Schering-Plough, Upsher-Smith Laboratories, and American Home Products Corporation conspired to keep a generic version of the

potassium supplement off the market; and the **Tamoxifen** case charging that Astra-Zeneca and Barr Laboratories colluded illegally to keep a true generic version of the breast cancer drug off the market.

The new legal collaboration between the two consumer organizations was hailed at a press conference by Robert Restuccia, executive director of Community Catalyst, the Boston-based organization that created the PAL initiative.

"We welcome this decision by AARP to join PAL's litigation team on the fight to bring down the price of drugs," he said. "This additional legal firepower strengthens our capacity to fight back against drug company profiteering at the expense of American consumers."

AARP Executive Director Bill Novelli has said that the decision to join PAL's legal team on three of its class-action lawsuits is another approach to AARP's overriding public policy goal—the creation of a prescription drug benefit for Medicare recipients. AARP recently launched a \$10 million national public education campaign about generic drugs.

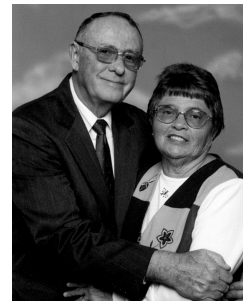
PAL Director Ahaviah Glaser also welcomed AARP's decision to join forces with PAL attorneys on three key cases.

"The consumer groups that make up the PAL coalition all believe concerted legal action is the only way to break through the public policy gridlock on drug prices. To do this, we must work with organizations that share our goals. We welcome AARP's decision to partner with us on key pieces of our litigation effort."

### PROFILE:

## Emma Ruth Smith Pittsboro, Indiana

Emma Ruth Smith and her 73-year-old husband had health insurance up until last February. That's when she lost her insurance com-



pany job and, grateful for a bit of income, took some part-time work at the local mortuary at \$7.50 an hour with no benefits. Her husband, who worked for Eastern Airlines for 30 years, had long since been forced to retire after his second heart attack. They're the kind of people PAL is fighting for.

Today, the combined cost of their medications for his heart condition and her rheumatoid arthritis runs them \$1082.34 a month, and Emma Ruth says they simply can't afford it. Not with what they live on, his combined pension and retirement checks, and her part-time income. And those costs may soon go up, because Emma Ruth's husband was recently diagnosed with prostate cancer.

"On top of dealing with all these health problems," she says, "it's tough having to worry about all these expensive drugs."

How do they manage? "Very carefully," she replies. Some doctors have given them free samples and she's applied to some of the drug company assistance programs. But she and her husband probably make too much to qualify. When she's not worrying about how they're going to get the medications they need, Emma Ruth thinks about the system—and how it's not working.

"We should be able to get the drugs we need, and still have a place to live, still be able to put food on our table," she says. "We don't have much. I suppose you could count our motor home. But it's 20 years old, and a person's got to have a little pleasure. But it seems like every last bit we've



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## PAL Files Three New Lawsuits in 2002

### **Neurontin® (Salowe-Kaye, et al., v. Pfizer, Inc. and Warner –Lambert Co.)**

Neurontin is a widely prescribed anti-convulsant for the treatment of epilepsy which Warner-Lambert Company has manufactured and sold since 1993. Neurontin has been extremely profitable for both Warner and its parent company Pfizer, generating in excess of \$1.3 billion in worldwide revenues in 2000. In April 2002, PAL filed a federal class action lawsuit in New Jersey alleging that Warner and Pfizer listed illegitimate secondary patents on the drugs in order to keep more affordable generic versions of Neurontin off the market. The lawsuit also alleges that in another effort to illegally prolong their monopoly on Neurontin sales, the companies filed baseless patent infringement lawsuits against potential generic competitors. As a result of these actions, consumers who take Neurontin have never had the opportunity to buy lower cost generic versions of Neurontin and have been paying an artificially inflated price for the drug.

### **Relafen® (A.F. of L – AGC Building Trade, et al., v. SmithKline Beecham, Corp., et al)**

Relafen is a widely-used anti-inflammatory drug. In February 2002, PAL filed a lawsuit in federal court in Massachusetts against GlaxoSmithKline Corporation and its predecessors (collectively "Glaxo") alleging that Glaxo fraudulently obtained a patent on Relafen in order to prevent a generic version of Relafen from coming to market. Internal documents from Glaxo reflect that Glaxo knew that a patent should not be issued. Three generic drug manufacturers later filed applications for a generic Relafen, certifying that the Relafen patent was invalid and unenforceable. In response, Glaxo sued the generic manufacturers. In a non-jury trial on the suit, Federal District Court Judge Lindsay ruled in favor of the generic manufacturers finding that Glaxo made material misrepresentations to the Patent Office and that the Relafen patent was invalid and unenforceable. As a result of Glaxo's conduct, consumers have been forced to pay an artificially inflated price for Relafen for several years while a lesser expensive generic version of the drug was kept off the market.

### **Remicade® (New Jersey Citizen Action, et al., v. Johnson & Johnson, et al.)**

Remicade is a prescription drug used in treating Crohn's disease and moderate to severe rheumatoid arthritis. It is an expensive infusion drug that may only be taken under the supervision of a medical professional. Remicade is manufactured and marketed by Centocor, Inc., a wholly owned subsidiary of Johnson and Johnson, Inc. In April 2002, PAL filed a lawsuit in state court in New Jersey alleging that these companies have extracted millions in illegal profits by overcharging Medicare and Medicare patients who take Remicade. Specifically, the PAL lawsuit charges that Centocor has misrepresented the Average Wholesale Price (AWP), on which Medicare reimbursements and co-payments are based, in industry publications. The complaint further alleges that Centocor has given providers discounts that reduce the actual amount that they pay for the drug while simultaneously encouraging those providers to charge Medicare and patients for the full price based on the AWP and pocket the difference. As a result of these fraudulent marketing practices, Medicare and Medicaid consumers taking Remicade are being forced to pay artificially inflated prices for the drug.

## Updates on Previously Filed Litigation

### **Average Wholesale Price mega-lawsuit (Citizens for Consumer Justice et al. v. Abbott Laboratories, et al.)**

**Background:** In December 2001, PAL filed a lawsuit in federal court in Massachusetts on behalf of fourteen consumer groups against 28 drug companies for manipulating the "average wholesale price" (AWP). This lawsuit alleges that there is an industry-wide scheme to defraud the U.S. health care consumer by charging inflated prices for critically-needed medications. Specifically, the lawsuit charges that since 1993 the companies have engaged in "a pattern and practice" of selling drugs to physicians at prices well below the reimbursement cost charged to Medicare.

**Update** In March 2002, PAL attorneys filed an amended lawsuit in federal court in Massachusetts. In May, the joint panel on Multi-District Litigation issued a decision consolidating all Average Wholesale Price (AWP) litigation for pretrial proceedings,

and transferring all such litigation to the federal court in Massachusetts before Judge Saris.

### **BuSpar® (In Re: Buspirone Antitrust Litigation)**

**Background:** BuSpar is an anti-anxiety drug widely prescribed to the elderly and people with chronic illnesses. In April 2001, PAL filed 6 lawsuits against Bristol-Myers Squibb Co. alleging that the company has employed illegal tactics to artificially maintain a monopoly on the manufacturing, distribution and sales of BuSpar.

**Update** The BuSpar litigation was consolidated in federal court in the Southern District of New York before Judge Koeltl. In February 2002, Judge Koeltl issued an opinion denying the defendant's motion to dismiss the case and allowing the case to proceed. The Koeltl opinion included strong language indicating that pharmaceutical companies may not file invalid secondary patents to extend their patent monopoly on a drug without fear of legal attack.

### **Cipro® (In Re: Ciprofloxacin Hydrochloride Antitrust Litigation)**

**Background:** Cipro is the best selling antibiotic in the world and has been for eight consecutive years. In October 2001, PAL joined federal litigation against Bayer, the maker of Cipro, Barr Laboratories, and two other generic drug companies. The lawsuit alleges that Bayer Corporation has unlawfully agreed to pay three of its competitors – Barr Laboratories, Rugby, and Hoechst-Marion Roussel – a total of \$200 million to date to get them to abandon their efforts to bring cheaper generic versions of Cipro to the market, thereby manipulating both the price and supply of the drug.

**Update** The Cipro litigation has been consolidated in the Eastern District of New York. Defendants have filed a motion to dismiss. PAL attorneys have opposed defendants' motion to dismiss, and we expect that the Court will rule on the motion sometime this summer. In the meantime, discovery has begun and PAL lawyers are gathering documentation to support the allegations of the suit.

### **Claritin® (New Jersey Citizen Action, et al., v. Schering-Plough, et al.)**

**Background:** Claritin is both America's most widely prescribed and its most widely adver-

tised allergy drug. In 2000, Claritin was the seventh-ranked prescription drug, with sales of approximately \$1.7 billion. On August 9, 2001 PAL filed a class action lawsuit in New Jersey state court alleging that Schering-Plough has engaged in a campaign of misrepresentation that has artificially increased the demand and price for the drug, a drug that Schering-Plough's own studies have shown to be effective for only 50% of its users.

*Update* The Court heard arguments on Schering-Plough's motion to dismiss the suit in May 2002. The Court is expected to rule on this motion by the Fall.

### **K-Dur® (In Re: K-Dur Antitrust Litigation)**

*Background:* K-Dur is the fourth most frequently prescribed drug for the elderly. It is a potassium supplement that is often prescribed in conjunction with high blood pressure medication. In June 2001, PAL filed seven lawsuits in state and federal court alleging that that Schering-Plough Corp., maker of K-DUR, privately held Upsher-Smith Laboratories, and American Home Products Corp. illegally agreed to keep a generic version of K-Dur off the market, thereby depriving consumers of a lesser-expensive generic version of the drug.

*Update* PAL's K-Dur cases have been consolidated with other cases from around the country in the U.S. District Court in New Jersey before Judge Greenaway. In the consolidated case, PAL's attorneys have been appointed to two of four lead counsel positions on behalf of all indirect purchasers of K-Dur. Defendants have moved to dismiss the newly consolidated case, and PAL is opposing their motion. We expect a decision on defendants' motion to dismiss by the Fall. In the meantime, PAL attorneys are coordinating document review efforts in the case.

### **Lupron® (In Re: Lupron® Marketing and Sales Practices Litigation)**

*Background:* Lupron is a prescription drug that is manufactured, marketed, and sold by Abbott Laboratories, Takeda Chemical Industries, and TAP Pharmaceuticals (a wholly owned joint venture of Abbott and Takeda) as a treatment for prostate cancer. In September 2001, PAL filed a class action lawsuit in federal court in Illinois alleging that the Defendants

created and implemented a fraudulent marketing and sales scheme to substantially increase the sale of Lupron and reap unlawful profits at the expense of Medicare patients. The following month (October 2001) TAP pharmaceuticals 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 fraud settlement in history.

*Update* In March 2002, TAP Pharmaceuticals sent 300 boxes of documents to PAL's attorneys, the same documents produced by TAP during the federal government's criminal investigation of TAP billing practices and procedures. Since April, attorneys for PAL, in coordination with other plaintiffs' attorneys, have been reviewing these documents for information relevant to the lawsuit. Plaintiffs' attorneys also are preparing for depositions in that case. In April 2002, TAP, Takeda and Abbott moved to dismiss PAL's case. PAL attorneys are working to oppose this move by the defendants.

### **Tamoxifen (In re: Tamoxifen Citrate Antitrust Litigation)**

*Background:* Tamoxifen is the most commonly prescribed drug to treat women with breast cancer. In May 2001 PAL filed 8 lawsuits in state and federal courts against AstraZeneca, maker of Tamoxifen and Barr Laboratories, sole distributor of a generic form of Tamoxifen. The lawsuits allege that AstraZeneca and Barr are illegally colluding to keep the price of Tamoxifen high. The result of their collusive agreement is that women with breast cancer are being forced to pay very high prices for a drug that is crucial to their treatment.

*Update* Both the state court and the federal court Tamoxifen cases were consolidated in the United States District Court for the Eastern District of New York. Defendants have sought to return the state cases to state court (a "remand motion"), and PAL attorneys are awaiting the Court's decision on this motion. Defendants also have moved to dismiss the case in its entirety, and PAL attorneys have opposed this motion. A decision on defendants' motion to dismiss should come by summer's end. In the meantime, PAL attorneys are reviewing documents produced by the defendants in discovery.

## **PROFILE**

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got has to go for our medicines."

Emma Ruth is perhaps most angry with the drug companies, although she reserves some of her anger for Congress and her state lawmakers since she feels they ignore people like her.

"They just don't seem to care about people like my husband and me, the Republicans and the Democrats both," she says. "They won't put any caps on the drugs companies. And the drug companies are just getting rich off of us."

"I'm not looking for a free ride," she says. "I'm willing to pay something towards our drugs. And if they ever give us a drug benefit with Medicare, I know I'll have to pay a little. That's OK."

What really makes her mad is how much cheaper drugs are in Canada. A three-month supply of Lipitor costs \$329.19 at Kroeger's, her local pharmacy chain; but in Canada, the same supply costs only \$183.84.

Emma Ruth says some folks she knows get so desperate that they begin to ration their drugs. If the doctor prescribes two pills a day, they take one. If the dose is a single pill, they cut it in half. Anything to make their medicine go further.

"The pricing has just gone out of reason," she adds. "I'm not downgrading the drug companies. I don't know where we'd be without their drugs. We need the heart drugs, the cancer drugs, the arthritis drugs. I'm an American, I shouldn't have to go to Canada to buy the drugs we need."

But that seems her best hope right now. She says a friend from church is helping her order drugs from Canada. Meanwhile, the lifelong Indiana resident is doing what she can to fight back and change the system.

"Some people are just too ill or too old to get up on a soapbox the way I do," she said. "Sure I've got rheumatoid arthritis, but that's not going to keep me from calling people and writing letters. They've got to do something about this."

# 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.

## Arizona

Arizona Citizen Action  
Senior Disabled Arizona Protest

## California

California PIRG  
Congress of California Seniors  
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

Florida Alliance for Retired Americans  
Human Services Coalition of  
Miami-Dade County

## Idaho

Living Independence Network  
Corporation (Idaho)  
Idaho Community Action Network

## Illinois

Illinois Citizen Action  
Campaign for Better Health Care

## Indiana

United Senior Action of Indiana

## Kansas

Kansas Association for the  
Medically Underserved

## Maine

Consumers for Affordable Health Care  
Maine People's Alliance

## Massachusetts

Health Care For All  
Health Law Advocates  
Lynn Health Task Force  
Massachusetts Breast Cancer Coalition  
Massachusetts PIRG  
Massachusetts Senior Action Council  
Women's Health Institute (Massachusetts)

## Michigan

Public Interest Research Group in Michigan

## Minnesota

Minnesota COACT  
Minnesota Senior Federation

## Mississippi

Mississippi Human Services Coalition

## 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

Brooklyn-wide Interagency Council  
of the Aging  
CAIRE  
Citizen Action of New York  
JPAC for Older Adults  
Gay Men's Health Crisis  
Long Island Coalition for a  
National Health Plan  
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

## Oregon

Oregon Health Action Campaign  
Oregon State Public Interest  
Research Group

## Pennsylvania

Action Alliance  
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

## Vermont

Vermont PIRG

## Virginia

Virginia Poverty Law Center

## Washington

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 State County and  
Municipal Employees, AFL-CIO  
Boston Women's Health Book Collective  
Community Catalyst  
The Medicare Rights Center  
National Health Law Program

## PAL's Legal Team

The PAL plaintiffs are being represented by some of the country's most experienced class action litigators: Loeff, Cabraser, Heimann & Bernstein, LLP ([www.lchb.com](http://www.lchb.com)); Milberg Weiss Bershad Hynes & Lerach LLP ([www.milberg.com](http://www.milberg.com)); and Carey & Danis, LLC ([www.careydanis.com](http://www.careydanis.com)).

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**Send me more information about PAL!**

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