



PAL News

The Prescription Access Litigation Project

Groundbreaking PAL Settlements Put Nail in the Coffin of Drug Pricing System – \$4 billion in savings expected

Two recent major settlements of lawsuits brought by PAL members and others are demonstrating just how easy it is for drug companies and others to manipulate the system that sets drug prices in the United States. This system involves a complex network of players and middlemen, and a long supply chain. Typically, drug manufacturers sell their drugs to a wholesaler. The wholesaler then sells the drug to a wide variety of customers, including retail and mail-order pharmacies, hospitals, nursing homes, community health clinics, etc. From there, the drug is dispensed to the consumer. At each point, there are opportunities for skimming and price manipulation. PAL and its members have been working to expose the problems with the system.

Wholesalers typically sell drugs to pharmacies based on a price called “Wholesale Acquisition Cost”

(WAC). Pharmacies then sell drugs to health plans, insurance companies and government health programs like Medicaid based on a figure called “Average Wholesale Price” (AWP). The difference between what the pharmacy pays the wholesaler (based on WAC) and what the pharmacy charges a health plan (based on AWP) is the pharmacy’s profit and is called the “spread” or the “markup.”

This October, PAL announced a groundbreaking settlement agreement with First Databank regarding its manipulation of this drug pricing system. First Databank is the leading publisher of prescription drug price information in the United States. Once approved by the court, the settlement is expected to save at least \$4 billion prescription drug costs in the first year alone.



A cartoon on the settlement from Public Employee Press, the newspaper of AFSCME DC 37.

First Databank Settlement

PAL members **New England Carpenters Health Benefits Fund and AFSCME District Council 37 Health and Security Plan** and others brought a lawsuit against First Databank and McKesson Corp., one of the largest three drug wholesalers in the U.S. The lawsuit claims that First Databank conspired with McKesson to increase the markup on hundreds of drugs from 20% to 25%. In other words, the case alleges that First Databank and McKesson agreed to increase the AWP figures published in First Databank’s pricing guide by an additional 5%.

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Alex Sugerman-Brozan, Director
Renée Markus Hodin, Associate Director
S. Stephen Rosenfeld, Senior Legal Advisor
Mark Snyder, Project Associate
Carolyn Blake, Writer

30 Winter St., Ste. 1010/Boston MA 02108
 T: 617.275.2931 F: 617.451.5838
 E: pal@communitycatalyst.org
 www.prescriptionaccess.org

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PAL Members File New Suits Attacking Illegal Drug Company Tactics

Provigil

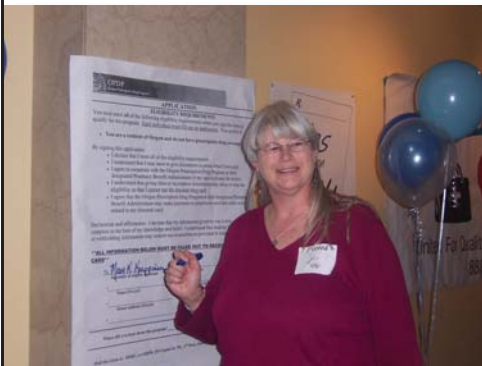
In October, PAL member **AFSCME District Council 37 Health & Security Plan** joined a lawsuit against brand-name drugmaker Cephalon and generic drugmakers Teva, Ranbaxy, Barr and Mylan. The case claims that the companies illegally prevented a generic version of Provigil from entering the market. Provigil is a drug approved to treat certain sleep disorders but is also commonly prescribed for unapproved uses such as to treat fatigue, depression, attention deficit hyperactivity disorder, and sleepiness caused by other prescription medications. The lawsuit alleges that Cephalon paid the four generic companies in excess of \$136 million for their agreement to keep

their generic versions of Provigil off the market until 2011 or 2012. Payments like this are all too common and are a cynical ploy by brand-name drug companies to increase their profits by keeping generic drugs out of consumers’ hands. PAL members have been in the forefront of challenging these payments through consumer class action lawsuits.

Zyprexa

In November, PAL member **Sergeants Benevolent Association Health & Welfare Fund** filed a lawsuit against Eli Lilly. The lawsuit claims that the company illegally marketed Zyprexa

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Kathy Karppinen || *Forest Grove, Oregon*

Kathy Karppinen knows first-hand what it's like to not be able to afford prescription drugs...and to do something about it.

Kathy has multiple chronic health conditions including diabetes, arthritis, carpal tunnel syndrome and sleep disorders. To treat these conditions, she takes seven different medications, and sometimes more.

In 2002, her worsening health required her to leave her job as a customer service representative for a health insurance company. Luckily, her husband still had good health insurance through his longtime job. However, in 2004, all that changed when her husband lost his job and, with it, their health coverage.

Kathy recalls, “[w]e used to both work, we made good money. We never thought this would happen to us. Never in our wildest dreams did we think we’d turn 50 and hit the skids.”

With no health insurance and little income, Kathy and her husband had to resort to a variety of ways to cope with their conditions. They didn’t go to see their doctors, even when they truly needed to. They stretched out their remaining pills by skipping doses or by not taking them at all. Kathy took a friend’s leftover medicine. She even signed up to

participate in a clinical study in order to get her cholesterol medication.

This went on until June 2005, when Kathy – who was deemed disabled in 2004 -- finally qualified for Medicare. She signed up for a Medicare Part D drug plan. Because her husband was still out of work, she qualified for “extra help.” This eliminated the usual \$250 deductible and lowered the co-payments for her prescription drugs. It also exempted her from the “donut hole,” the period of time during which Medicare beneficiaries are 100% responsible for the cost of their prescription drugs. Given the number and cost of Kathy’s prescriptions, she most certainly would have quickly reached the donut hole if not for the extra help. The cost of the drug she takes to treat her sleep disorder, for instance, is expensive...and ever-rising. The price of a 3-month supply was \$499 six months ago. It is now \$549 – a 10% increase. And, recently, the cholesterol drug clinical study she participated in was canceled because of safety concerns. This added the cost of her cholesterol medication to the equation.

Though contending with her own financial and health problems, Kathy knew she wasn’t alone in her struggle. She says, “there’s so many people without health coverage in this country it’s just criminal.” So she got to work. One day, she came across Oregonians for Health Security’s website (www.oregoniansforhealthsecurity.org) and sent in her story. The organization contacted her, and Kathy jumped right in to help. She immediately became involved in the effort to pass a law aimed at opening up the Oregon Prescription Drug Program (OPDP) to all uninsured Oregonians. The OPDP is a bulk purchasing pool that negotiates lower prices with the drug companies, and delivers savings as high as 60% to its beneficiaries. The OPDP, however, was only available to Oregon residents who were at least 54 years old, earned less than 185% of the federal

poverty level, and had been without private prescription drug coverage for six months.

To help with the effort to expand this program, Kathy testified before the Oregon Legislature on several occasions. When the law failed to pass, she leapt into action to help get the issue before Oregon voters. By her own estimation, she did “anything and everything” to gather the required number of signatures needed to put the issue on the ballot. The issue was eventually placed on the ballot as “Measure 44” and on November 7th Oregon voters overwhelmingly voted in favor of it. Beginning on December 8th, all uninsured Oregonians became eligible for the reduced prescription drug prices available under the OPDP.

The new law is welcome news for the more than one million Oregonians who are now eligible to join the program. And, Kathy is one of them. Kathy’s husband has recently landed a new job. With her husband’s new salary, Kathy no longer qualifies for the Medicare low-income subsidy “extra help” program. But this does not mean that they can easily afford the increased cost of her medications. Now, however, with the passage of Measure 44, she will be eligible to participate in the OPDP, which will provide assistance next year when she falls – as she inevitably will -- into the Medicare “donut hole.”

Kathy feels gratified by the ballot measure victory, but knows the real rewards will come to her and to those like her when they no longer have to make the hard choices between buying medication they can’t afford and simply hoping their illnesses don’t get worse.

Thanks to Oregonians for Health Security for putting us in contact with Kathy. If you would like to share your story with PAL, please call us toll-free at (866) 208-9800 x2931 or e-mail pal@communitycatalyst.org.



Contact the Prescription Access Litigation Project

PAL Program Associate

pal@communitycatalyst.org / (617) 275-2931

Ask Pharmie

In each issue, Pharmie, your guide to all things pharmaceutical, answers your questions about the drug industry. Questions may be sent to askpharmie@communitycatalyst.org.

Only one of my prescription drugs is available as a generic. Why does it take so long for generic drugs to become available?

Generic drugs only become available when the original manufacturer's patent expires. Drug companies are granted "patents" on new drugs they discover or invent. A patent gives the company a monopoly for up to 20 years – during that time no one else can sell that drug. This does not mean, however, that drug companies actually get a full twenty years to sell the drug. They usually apply for a patent early in the process of developing a new drug. Only after the FDA has approved the drug can the company sell it. This usually takes at least a few years after the company has gotten its patent. So the real amount of time that a drug company can be the only one selling a new drug is less than 20 years.

These "patent monopolies" are extremely valuable. Most of the profits that a company will earn from a drug are earned while they have a patent and there is no competition. Once the patent expires (that is, the 20 years runs out), other drug companies can make "generic" versions of the drug. The competition drives the price of the drug down, and the original drug company makes much less money on that drug. This system, of giving drug companies a monopoly for a certain number of years, is intended to encourage them to invest in researching and developing new drugs by guaranteeing them a period when no one else can sell that drug and compete with them.

Unfortunately, this system also encourages drug companies to try to extend their patent monopoly, even if doing so hurts consumers or is illegal. Every year that there's no competition for a drug can mean literally billions in extra sales. So brand-name drug companies will often do everything they can to extend their patent monopoly.

PAL members have challenged the tactics used by drug companies to keep generics off the market. For example, in 2003, PAL members and state Attorneys General got Bristol Myers Squibb (BMS) to pay \$100 million to settle a case that alleged that BMS filed for a new patent for its prescription anti-anxiety medication, Buspar, just before their current one expired. In 2004 PAL members and others got GlaxoSmithKline (GSK) to settle two

lawsuits that alleged that GSK kept cheaper generic versions of their drugs Relafen and Augmentin off the market by fraudulently obtaining patents on those drugs. Those cases settled for a total of \$104 million.

This is just one of the many tactics that brand-name drug companies use to keep cheaper generics out of consumers' hands. Brand-name drug companies also pay generic drug companies to delay bringing their drugs to the market. PAL member Sergeants Benevolent Association are challenging such a payment in a case concerning the sleep disorders drug, Provigil (see article on p.1)

Another tactic drug companies use is to create a so-called Authorized Generics.

What are Authorized Generics?

When the patent for a brand name drug expires or is found invalid, generic drug manufacturers apply to the FDA to allow them to sell a generic version. The first generic drug manufacturer to do so successfully is granted 180 days (6 months) during which no other generic version will be sold. That 180 days is extremely important to generic drug manufacturers because it gives them some time to recoup their costs. Bringing a generic drug to market, while not as costly as developing a new drug, is expensive: generic drug companies often have to fend off a patent infringement lawsuit in court for several years, a process that can cost many millions. The 180 days gives generic drug companies an incentive to stick their necks out to make a cheaper generic available at the earliest possible time.

Unfortunately brand name companies have found a way to take advantage of a loophole. This loophole allows them to introduce "authorized generic" drugs to the market during the 180 days. These are really "fake generics" – they are just the original brand-name drug marketed and sold as a generic. Often, it is the exact same pill, made in the exact same factory, but with a different logo stamped on the pill.

Authorized generics are a problem because they further undermine the ability of generic drug companies to bring cheaper drugs to consumers. By decreasing the value of the 180 days when the generic company has no other generic competition, they add yet another obstacle in the way of generics becoming available as quickly as possible. Already generic drug companies face delays in getting their drugs approved (the FDA has a backlog of over 800 generic drugs awaiting approval) and

have to defend against patent infringement lawsuits.

Authorized generics just further tip the balance against the generic drug company and raises the possibility that fewer generic companies will take the risk and make the effort to bring new generics to market.



Unfortunately, the FDA ruled in 2004 that it does not consider authorized generics to violate federal law. But not all experts agree. Authorized generics certainly undermine the intent of the law that allows generics to come to market (called "the Hatch-Waxman Act"), if not the letter of that law as well.

The Prescription Access Litigation Project and our members have consistently spoken out against authorized generics and other tactics used to keep cheaper generics off the market. In addition to helping PAL members participate in lawsuits such as those described above, PAL submitted testimony this past summer to the Federal Trade Commission (FTC), on Authorized Generics. The FTC, the federal agency that is supposed to ensure that corporations don't undermine competition and harm consumers, is doing a study on the effects of authorized generics on prescription drug competition. PAL recommended that the federal government prohibit the marketing of authorized generics during the 180 day period, and prohibit and prosecute agreements between brand companies and traditional generic companies that keep generics off the market.

Removing the obstacles to generics

Ultimately, ensuring that consumers have access to generics sooner requires closing the loopholes that allow brand-name drug companies to stifle generic competition. Brand-name drug companies must be prohibited from filing bogus patents, marketing fake generics, filing frivolous patent infringement lawsuits, and paying off generic companies not to bring generic drugs to market. The FDA must have enough funding to eliminate the backlog of over 800 generic drug applications. These changes will only be achieved when consumers demand them, and PAL will continue to do our part to call attention to these problems.

From Donuts to Dodgeball to Snake Oil: PAL Members Taking Action for Rx Drug Reform

PAL Coalition members across the country are working at the state and national level for affordable drug prices. Here are just some of their most recent activities:

Paying the Price

PIRG (Public Interest Research Group) affiliates in California, Illinois, Massachusetts, Michigan, North Carolina, Oregon, Vermont issued "Paying the Price: The High Cost of Prescription Drugs for Uninsured Americans" a report that highlights the wide disparity between what the uninsured pay for prescription drugs States and what the Veterans Administration (VA) pays.

Donut Hole Week

Numerous members of the PAL coalition have been working to educate their constituents and the public at large about the flaws of the Medicare Part D drug benefit and ways to fix the program. Many of them have focused on the so-called "donut-hole" – a gap in coverage during which Medicare Part D beneficiaries must pay the entire cost of their prescription drugs. The donut hole has been

perhaps the most widely criticized feature of the Medicare drug benefit, with some critics saying that there would be no donut hole if the government negotiated the drug prices Medicare Part D pays.

Groups across the country held events during the week of September 18-22, the week during which the average Medicare beneficiary would fall into the donut hole. Many PAL members delivered donuts to their congressional delegation, held community meetings or launched letter writing campaigns including: Action Alliance for Senior Citizens (PA), Alliance for Retired Americans, California Alliance for Retired Americans, Champaign County Health Care Consumers (IL), Citizen Action/Illinois, Citizen Action of New York, Congress of California Seniors, Gray Panthers Sacramento, Illinois Alliance for Retired Americans, Maine People's Alliance, Medicare Rights Center, Minnesota Senior Federation, SEIU Local 503 (OR), United Senior Action of Indiana, USAction, Wisconsin Citizen Action.

Defending DC's right to curb runaway drug prices

Earlier this year, the District of Columbia passed a law aimed at curbing excessive prescription drug prices. The pharmaceutical industry wasted no time in taking DC to court to block the law from taking effect. In November, a number of PAL members joined with PAL, the National Legislative Association on Prescription Drug Prices and Prescription Policy Choices to submit an amicus curiae ("friend of the court") brief. This brief argued that the new law should be upheld and allowed to go into effect. PAL members joining the brief were Action Alliance of Senior Citizens of Greater Philadelphia, AFSCME DC 37 Health & Security Plan, Alliance For Retired Americans, American Federation of State, County and Municipal Employees (AFSCME), Breast Cancer Action (CA), Council on Aging Services For Seniors (CA), Greenlining Institute (CA), Health Care For All (MA), Metro New York Health Care For All, Mon Valley Unemployed

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Prescription Access Litigation Project News Briefs

Welcome Mark!

Mark Snyder joined the PAL Team in September as our new Project Associate. Mark has a degree in Advertising and Public Relations from Emerson College, and previously worked as an office manager at the Boston Alliance of Gay & Lesbian Youth. We are excited to have him at PAL.

PAL In The News

On September 8th, Alex Sugerman-Brozan, Director of PAL, was a guest on the radio talk show, The Kathleen Show (www.thekathleenshow.com), to discuss why prescriptions are so expensive.

On November 8th, Alex was a guest on the AFSCME District Council 37 Radio Show to discuss the fight against high drug prices and our case against First Databank. To listen to the show go to www.dc37.net/news/radioshows/radioshows.html.

On December 19th, Alex was a featured panelist on the "Pharma Marketing Podcast," discussing "disease mongering," the phenomenon in which drug companies invent or exaggerate diseases to sell more prescription drugs. To listen, go to www.pharma-mkting.com/talk/show004.htm.

On November 20th, PAL was featured in an article in the Boston Business Journal, titled "Hub advocacy group takes on big pharma in court." The article explained the work that PAL does and highlighted our recent settlement with First Databank. To read the article, go to www.bizjournals.com/boston/stories/2006/11/06/story6.html. PAL has also been featured recently in the Wall Street Journal, San Francisco Chronicle, San Jose Mercury News, San Francisco Bay Guardian, and Drug Topics.

Welcome New PAL Groups

Please join PAL in welcoming the

following organizations to the PAL Coalition.

- TeamstersCare (www.teamsterscare.com)
- Sergeants Benevolent Association Health & Welfare Fund (www.sbanyc.org)

We're pleased to have them aboard! This brings the number of coalitions in our organization to over 125. If you know of other organizations that are working on prescription drug issues and should be part of PAL, call Renée Markus Hodin at 617.275.2810 or e-mail her at hodin@communitycatalyst.org.

PAL Coalition

PAL is a coalition of over 125 non-profit organizations in 35 states, including labor, senior citizens, health advocacy, women's health, legal aid and other groups. For a full list of th emembers of the PAL coalition, visit prescriptionaccess.org and click on "Links to Members"

PAL SETTLEMENTS

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This alleged scheme caused virtually every health plan, insurance company and government health program in the country to pay more for these drugs. While the additional amount for each prescription drug may have been small, the combined effect was huge: The lawsuit claims that this resulted in over \$7 billion in additional drug costs.

First Databank agreed to settle the case against it, but McKesson has so far refused to do so. Under the settlement agreement, First Databank has agreed to roll back the “spread” from 25% to 20% on hundreds of drugs, including many additional ones that were not part of the original lawsuit complaint. These drugs represent 95% of retail branded drug sales in the United States. This reduction will mean a 4% reduction in the price that health plans and others pay pharmacies for these drugs. The savings from this rollback are estimated to be \$4 billion in the first year following approval of the settlement. It is expected to save consumers approximately \$400 million.

First Databank also agreed to stop publishing AWP data within two years. Because First Databank is the leading publisher of AWP data, the settlement may mean the end of the use of AWP to pay for drugs. Many critics believe that AWP is fundamentally flawed and needs to be replaced, but up to now, there has been no real pressure

to do away with it. Some government programs are already phasing out the use of AWP. But this settlement will force the private market to switch to a new pricing system, by making AWP data unavailable. Although the settlement does not include payment of money damages to health plans or individual consumers, the impact of the price rollback and end of AWP data will have a far greater impact than any monetary settlement could have.

The settlement awaits approval in the U.S. District Court in Massachusetts, where the case is still pending. McKesson is not a part of the settlement. The case against McKesson will continue.

GlaxoSmithKline \$70 million settlement

Since 2001, PAL members have been involved in another case about AWP, *In re Pharmaceutical Industry Average Wholesale Price Litigation*. This massive lawsuit alleges that dozens of pharmaceutical companies manipulated the AWP of drugs administered in doctor’s offices (such as cancer drugs) and paid for by Medicare Part B.

In August, PAL members and others reached the first settlement to date in this huge lawsuit. Under the agreement, GlaxoSmithKline (GSK) will pay \$70 million to health plans and cancer patients who were overcharged for the drugs Kytril and Zofran. These drugs

are commonly prescribed to reduce the side effects of cancer treatments.

The U.S. District Court in Massachusetts granted preliminary approval to this settlement on November 15, 2006. The first trial in this case also began in November, against four of the other defendants (AstraZeneca, Bristol-MeyersSquibb, Johnson & Johnson, and Schering-Plough). Notices about the settlement and how health plans and consumers can get reimbursement from it will begin being sent out in February, 2007. Details on the settlement and how to submit claims for reimbursement will be posted on PAL’s website at prescriptionaccess.org

Both of these settlements are major victories that expose the flaws in the AWP system. The First Databank settlement was national news, with front-page coverage in the *Wall Street Journal*, and stories in numerous other newspapers. PAL expects that this settlement will cause health plans across the country to demand greater transparency in drug prices and lead to major changes in the way drug prices are set in the U.S. The First Databank and GSK settlements bring the number of PAL cases that have been settled to five, and the total amount of money for reimbursement of consumers and health plans from those settlements to more than \$400 million.

NEW PAL CASES

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for uses not approved by the FDA (called “off-label” uses). Zyprexa is approved to treat schizophrenia and bipolar disorder, but is widely prescribed for treatment of dementia and Alzheimer’s in the elderly as well as treatment of children suffering from depression, anxiety and attention deficit disorders. The case claims that, among other things, Eli Lilly paid doctors to give talks promoting off-label uses of Zyprexa and to put their names on articles ghost-written by the company.

The lawsuit also asserts that the drugmaker deceptively advertised the drug as being more effective than other less-expensive similar drugs when the evidence fails to support those claims. While it is legal for a physician to prescribe a drug for an off-label use, it is illegal for a company to advertise or promote such uses. Off-label marketing puts consumers at risk by doing an end-run around the FDA’s review to ensure that drugs are safe and effective for particular conditions. Such marketing

also can increase costs by causing consumers and health plans to pay for drugs that may not be effective for the conditions they are prescribed for.

These two new cases are important additions to the PAL docket. They represent a continued push by our coalition members to remove barriers to cheaper generic drugs and to demand that drug marketing be honest and comply with the law.

PAL MEMBERS TAKING ACTION

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Committee (PA), Patients Not Patents, Public Patent Foundation, Senior Action Network (CA), United Senior Action of Indiana, and Wisconsin Citizen Action.

Individual PAL organizations' actions

AFSCME District Council 37 Health & Security Plan (dc37.net) recently joined a lawsuit against drugmaker Cephalon. See the article on p.1 concerning this case.

Center for Medical Consumers (NY) (medicalconsumers.org) published an article about the FDA and drug safety in the October 2006 edition of the prestigious Archives of Internal Medicine. The group also recently published a report entitled "Dodgeball: The Pharmaceutical Companies' Direct Marketing To Doctors and The Impact on Health Care Costs and Patient Safety."

The Coalition of Wisconsin Aging Groups (cwag.org) began holding Senior Issues Forums throughout Wisconsin this Fall at which staff members from its Prescription Drug Information Center provided one-on-one consultation to seniors about their medicines.

California Alliance for Retired Americans (californiaalliance.org), **CALPIRG** (calpirg.org), **Congress of California Seniors** (seniors.org), **Greenlining Institute** (greenlining.org), and **Senior Action Network** (senioractionnetwork.org), as members of the OURx Bill of Rights Coalition, were key sponsors of a newly enacted law that allows California to negotiate drug discounts for nearly 6 million low-income uninsured Californians. The law gives drug companies three years to voluntarily offer discounts. If, after three years, companies are not offering adequate discounts, the state is permitted to use the weight of its \$4 billion Medi-Cal (Medicaid) purchasing power to induce discounts.

In 2005, US Customs began seizing prescription drugs ordered by mail from Canada for personal use. **Congress of California Seniors** (seniors.org) and **California Alliance for Retired Americans** (californiaalliance.org) were among the key groups that opposed these seizures, which stopped nearly 40,000 packages sent to U.S. consumers seeking more affordable medications. As a result of this opposition, US Customs announced that as of October 9, 2006, it would halt the seizures.

Connecticut Citizen Action Group (ccag.net) co-released "Falling into the Doughnut Hole: How Congress and the Drug Industry

Created a Trap for American Seniors and People with Disabilities" with the Institute for America's Future.

The Council on Aging Services for Seniors (councilonaging.com) featured a front-page story on prescription drug issues in a recent edition of its newsletter "Sonoma Seniors Today."

J PAC for Older Adults (NY) (jpac.org) has launched a campaign to get New York seniors to send letters to their U.S. Senators in favor of several bills aimed at improving the drug safety system at the FDA.

Massachusetts Senior Action Council (masssenioraction.org) recently issued a new prescription drug guide called "Rx Information for Seniors in Massachusetts."

In October, the **New England Regional Council of Carpenters** (necarpenters.org) was highlighted in a front-page Wall Street Journal article about the settlement with First Databank (See article, p.1). **AFSCME District Council 37 Health & Security Plan** (dc37.net) also served as a plaintiff in the case.

New Jersey Citizen Action (NJCA) (njcitizenaction.org) was instrumental in the passage of a new law in New Jersey creating the Prescription Drug Pricing Registry, a web site and toll-free number that will allow consumers to shop around for the most affordable prescription drugs. NJCA recently won another legislative victory when it successfully fought off burdensome prescription drug co-payments for Medicaid recipients.

New Jersey Public Interest Research Group (njpirg.org) has recently launched the Campaign for Safe Drugs. Following on its May 2006 report "Turning Medicine into Snake Oil," which highlighted the problem of widespread and poorly regulated deceptive prescription drug marketing, NJPIRG is actively backing a bill that would create a statewide clinical trial registry for all drugs sold in New Jersey.

Oregon Consumers League (orconsumer.org), **Oregon State Public Interest Research Group** (ospirg.org), **Oregon Health Action Campaign** (ohac.org), **SEIU Local 503** (seiu503.org) and **SEIU Local 49** (seiu49.org) were key supporters of ballot measure 44, which was overwhelmingly approved by Oregon voters on November 7th. This ballot measure opened the Oregon Prescription Drug Program to all one million Oregonians

lacking drug coverage. The program uses the power of bulk purchasing to negotiate lower prices with the drug companies, and delivers savings as high as 60%.

Patients Not Patents (patientsnotpatents.org) filed an amicus curiae ("friend of the court") brief in June in the case of *Aventis v. Barr Labs*. The brief encouraged the court not to allow drugmaker Aventis to block generic versions of Allegra after its original patent expired. Aventis had argued that its discovery that the drug is not harmful to a subset of patients already taking the drug warranted it having additional patent exclusivity. In November, the Court held that the new Aventis patent is likely invalid, allowing generic companies to continue selling the allergy medicine at reduced prices. A final decision in the case isn't expected until next year, but the finding by the appellate court that the generic company will probably win is a good sign.

In October, **Pennsylvania Alliance for Retired Americans** (retiredamericans.org) released the preliminary results of a research study, "The Impact of Medicare Part D on Pennsylvania Seniors." The researchers found that seniors who received their medications solely through Medicare Part D: (1) paid more in drug co-pays and monthly premiums; (2) faced significant coverage gaps; and (3) had significant restrictions on covered medications.

The Administrators of **Pipefitters Local 537 Trust Funds and IUOE Local 4 Health & Welfare Fund** (local4funds.org) testified in the opening days of the first trial in the Average Wholesale Price Litigation. The trial is against AstraZeneca, Bristol Squibb Meyers, Johnson & Johnson, and Schering-Plough. This is the first of PAL's cases to come to trial.

The Public Patent Foundation (pubpat.org) recently joined AARP and **Patients Not Patents** (patientsnotpatents.org) in submitting an amicus curiae ("friend of the court") brief filed in a case currently pending before the U.S. Supreme Court. In the brief, the groups argue that improperly granting patents to obvious combination drugs has the extremely harmful effect of delaying the availability of generic drugs to consumers.

The Sergeants Benevolent Association Health & Welfare Fund (sbanyc.org) recently joined a lawsuit against Eli Lilly. See the article on p.1 concerning this case.

PAL ONGOING LITIGATION UPDATE

Please visit the PAL website www.prescriptionaccess.org for more background information about each case listed below

Drug/Issue	Defendant(s)	Case Type	Court	Status
Average Wholesale Price	39 different drug companies	Fraud (gaming the drug reimbursement system)	U.S. District Court for the District of Massachusetts (Judge Saris)	\$70 million settlement with GlaxoSmithKline filed 8/10/06 (see article page 1). Preliminary approval granted 11/15/06. Order denying both parties' motions for summary judgment issued 11/2/06. Trial regarding first set of defendants began 11/6/06. Trial on behalf of nationwide class of Medicare recipients who paid for Zoladex to begin in Spring 2007.
Celebrex	Pfizer	Deceptive advertising	U.S. District Court for the Northern District of California (Judge Breyer)	On 8/16/06, Court issued ruling allowing certain claims to proceed and dismissing others. On 9/22/06, Plaintiffs filed amended complaint. Defendants filed motion to dismiss amended complaint on 11/3/06. Plaintiffs have opposed the motion. A hearing is set for 1/26/07.
First DataBank	First DataBank; McKesson	Fraud (gaming the drug reimbursement system)	U.S. District Court for the District of Massachusetts (Judge Saris)	Settlement with First Databank filed 10/2/06 (see article page 1). Preliminary approval granted 11/17/06. Case against McKesson continues. Discovery is proceeding.
K-Dur 20	Schering-Plough; Upsher-Smith Laboratories; American Home Products	Suppressing generics	U.S. District Court for the District of New Jersey (Judge Greenaway)	On 6/19/06 a Special Master assigned to the case issued a decision on three pending discovery motions. Several motions remain to be decided. In the meantime, plaintiffs filed amended complaint to include claims against subsidiary of Schering-Plough. Defendants have filed motion to dismiss amended complaint. Plaintiffs have opposed that motion.
Lipitor	Pfizer	Deceptive advertising	U.S. District Court for the Southern District of Florida (Judge Jordan)	Hearing on Defendants' motion to dismiss held 12/1/06. Awaiting decision.
Neurontin (patent)	Pfizer; Warner-Lambert	Suppressing generics	U.S. District Court for the District of New Jersey (Judge Lifland)	Case has been stayed awaiting decisions in underlying patent litigation between Pfizer and generic manufacturers.
Neurontin (off-label Promotion)	Pfizer; Parke-Davis	Deceptive advertising	Superior Court of California, County of Los Angeles (Judge Mohr)	Case on hold pending decisions in two cases currently pending in the California Supreme Court that would impact the standing of plaintiffs in the case.
Nexium	AstraZeneca	Deceptive advertising	Superior Court of California, County of Los Angeles (Judge Chaney) Massachusetts Superior Court, Suffolk County (Judge van Gestel) Third Circuit Court of Appeals, on appeal from the U.S. District Court for the District of Delaware (Judge Robinson).	<u>California</u> : Class certification discovery is proceeding. <u>Massachusetts</u> : Discovery is proceeding. <u>Nationwide</u> : Appeal of dismissal fully briefed. Awaiting date for oral argument.
Norvir	Abbott Laboratories	Unfair competition	U.S. District Court for the Northern District of California (Judge Wilken)	Defendants' Motion for Summary Judgment denied on 7/6/06. Plaintiffs filed class certification motion on 10/26/06. Hearing scheduled for 3/30/07.
OxyContin	Purdue Pharma	Suppressing generics	U.S. District Court for the Southern District of New York (Judge Stein)	On 2/1/06, Federal Circuit Court of Appeals overruled lower court decision that OxyContin patents were unenforceable. Case on hold until lower court makes additional rulings.
Pharmacy Benefit Managers	Advance PCS, Express Scripts, Medco Health Solutions	Fraud (gaming the drug reimbursement system)	California Court of Appeals, Second Appellate Division, on appeal from the Superior Court of California, County of Los Angeles (Judge Lichtman)	Case dismissed after California Supreme Court's decision allowing Proposition 64 (which changed requirements for bringing a case under the state consumer protection statute) to apply to pending cases.
Provigil	Cephalon	Suppressing generics	U.S. District Court for the District of Pennsylvania	Complaint filed 10/10/06. Defendants filed motions to dismiss on 11/3/06 and plaintiffs have opposed those motions.
Serostim	Serono	Deceptive advertising	U.S. District Court for the District of Massachusetts	Hearing on Defendants' Motion to Dismiss held on 9/14/06. Awaiting decision. Third amended complaint filed 10/16/06. Litigation currently stayed to allow for settlement discussions.
Tamoxifen	AstraZeneca; Barr Laboratories	Suppressing generics	Second Circuit Court of Appeals, on appeal from the U.S. District Court for the Eastern District of New York (Judge Glasser)	Case dismissed 5/03. Court of Appeals affirmed dismissal 11/05. Re-hearing denied 9/06. Plaintiffs submitted a petition for a writ of certiorari to the U.S. Supreme Court in early 12/06.
Vioux	Merck	Deceptive advertising	U.S. District Court for the Eastern District of Louisiana (Judge Fallon); Superior Court of California, County of Los Angeles (Judge Chaney)	<u>Louisiana</u> Hearings on Defendants' motion to dismiss held 2/2/06. Awaiting decision. <u>California</u> Court denied Defendants' motion to dismiss on 7/19/06. Discovery is proceeding.
Zyprexa	Eli Lilly	Deceptive Advertising	U.S. District Court for the Southern District of New York.	Complaint filed 11/21/06.



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