



PAL News

The Prescription Access Litigation Project
A Community Catalyst Initiative

California Consumers and Drug Industry Go Head-to-Head on Drug Discounts *Special Election is 2005 Drug Policy Battleground*

California Governor Arnold Schwarzenegger has called a special election to take place on November 8, 2005. In this special election, Californians will vote on a number of ballot measures, on issues such as teacher tenure and the use of public employees' union dues for political contributions.

Two of the measures offer competing programs to give discounts on prescription drugs to people without drug coverage. The drug industry is behind one of these and consumer groups are behind the other.

Prop. 78 - Cal. Rx

Proposition 78 (called "Cal Rx") is backed by the pharmaceutical

industry. Under Cal Rx, the state would negotiate discounts with drug companies that voluntarily choose to participate. These discounts would help low-income uninsured Californians who earn no more than \$28,000 a year, or \$56,000 for a family of four. The backers claim that the discounts will be between 15 and 40 percent less than retail drug prices. Cal Rx includes provisions to protect drug companies. The biggest is that drug companies would not be required to offer discounts. Only those drugs made by companies that voluntarily choose to participate would be discounted. A similar, earlier program in 2001, called Golden Bear State Pharmacy saw only



"Pharminator" graphic from the Prop.79 web site.

fourteen out of five hundred drug companies voluntarily participate. There would be no penalties for drug companies that don't offer discounts in the Cal Rx program.

Prop. 79 - Cal Rx PLUS

Proposition 79 (called "Cal Rx PLUS") would require drug companies to offer discounts. A drug company that refused to provide discounts would face restrictions on its drugs being used in Medi-Cal, the California state Medicaid program. Supporters of Cal Rx PLUS, including the Department of Health Services, labor groups, and consumer and healthcare organizations, estimate

continued on page 6

IN THIS ISSUE

- 2 Ask Pharmie: Generic Drugs
- 3 Profile
- 4 News Briefs
- 6 Litigation Updates
- 8 How to Support PAL
- 11 PAL Participants



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Interview: Hawking Drugs to Doctors

PAL Director Alex Sugerman-Brozan interviews Kathleen Slattery-Moschkau, writer and director of *Sides Effects*, a new independent feature film about a young pharmaceutical sales representative struggling with the ethics of her profession.

Alex Sugerman-Brozan: *Side Effects*

calls attention to a phenomenon almost no consumers are aware of: the daily activities of approximately one hundred thousand pharmaceutical sales people who descend on doctors' offices to market their drugs. Pharmaceutical companies spend



Kathleen Slattery-Moschkau, Director of *Side Effects*

four times as much money marketing to doctors as they do to consumers, but the public is much more aware of, and angry about, television ads for drug. Why aren't consumers more up in arms about this?

continued on page 4



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

askpharmie@communitycatalyst.org

What is a generic drug?

First, we have to understand what a "brand-name" drug is. When a new drug becomes available, it is usually (but not always) protected by a patent that forbids anyone else from making or selling that particular drug. A drug company has a monopoly on that drug as long as the patent is in effect. Patents expire after a certain number of years. Once the patent expires, other companies can usually make and sell "generic" versions of the same drug. A generic drug is one that is the same as a brand-name drug, in dosage, safety, strength, how it is taken, quality, how well it works, and what conditions it can be used to treat. Generic drugs are made with the same "active ingredients" (the same chemicals that work to treat the particular condition). Generic drugs have the same effects in the body as the brand-name drugs of which they are copies. Federal law requires that each generic drug be tested to make sure the same amount of drug will be absorbed into the body.

What's the difference between a generic drug and a brand-name drug?

The color and/or shape of the generic drug is usually different. Generic drugs may also have different "inactive ingredients" (fillers, coatings, etc.), which do not effect how the drug works. The most important difference is that generic drugs are much cheaper. Today, almost half of all prescriptions are filled with generic drugs.

Are generic drugs as safe as brand-name drugs?

Yes. Since generic drugs use the same active ingredients and are tested to ensure that they work the same way in the body, they have the same risks and benefits as the brand-name drug.

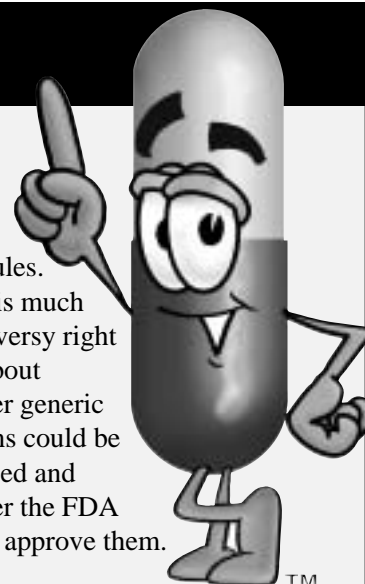
Why are generic drugs less expensive?

New drugs are protected by a patent for up to twenty years. Until the patent expires, no other company can produce the same drug, and the drug company can charge whatever it wants. When the drug patent expires, other companies can begin to make the drug as a generic. The competition between companies brings the price down. Generics usually cost 30-75 percent less than a brand-name drug. In 2004, the average price of a generic drug was \$28.74. The average price of a brand-name drug was \$96.01. Generic drugs save consumers approximately \$8-10 billion each year. A recent study showed that consumers could save an additional \$8.8 billion each year by using generic drugs whenever available.

Why do some drugs have generics and others do not?

There are several reasons a drug might not be available as a generic, including:

- 1.) The brand-name drug is still protected by a patent.
- 2.) No one else has figured out how to copy the brand-name drug. (This was the case for many years with certain hormone-replacement-therapy drugs-their patents had long since expired, but since no other company could figure out how to make a copy, there were no generics.)
- 3.) The drug is a "biotech" drug. These are drugs derived from living organisms or from manipulation of genes. They are very complex



molecules. There is much controversy right now about whether generic versions could be produced and whether the FDA should approve them.

Why aren't generic drugs advertised like brand-name drugs?

Drug companies heavily advertise brand-name drugs so that consumers will recognize the drug's name and ask their doctors about the drug. Drug advertising makes sense as long as only one company is making the drug. Once a drug's patent expires, many companies usually make generic versions. An ad for that drug would not make good financial sense, since there would be no way to ensure that a consumer would purchase a particular company's generic version.

In addition, generic drug companies don't have the same large amounts of money to spend on advertising as brand-name companies. Generic drugs go by their chemical names, not a catchy brand name, making it difficult to design an effective ad campaign. Imagine a drug ad that said, "Ask your doctor aboutesomeprazole magnesium," instead of one that said, "Ask your doctor about Nexium, the healing purple pill."

Unfortunately, drug advertising creates the impression that brand-name drugs are a breakthrough and an improvement over what's already available. Because generics are not advertised, many people believe them to be inferior to brand-name

continued on page 3

Judy Bachman

Bellingham, WA



Photo © Rachel Bayne, The Bellingham Herald

Sixty-six-year-old Judy Bachman has spent her career teaching others how to improve health and the delivery of health care services to patients. Since becoming disabled, however, she has gotten quite an education herself on how hard it is to find affordable prescription drugs.

Living with Sjögren's syndrome, Judy suffers from severe osteoarthritis. She has had fourteen separate orthopedic surgeries. In 1994, Judy became disabled and qualified for Medicare and Social Security Disability Income (SSDI). Since then, Judy has regularly paid for five to eight prescriptions each month, mostly to treat pain. Because she didn't have prescription drug coverage, these drugs cost her \$300-\$500, a hefty sum for someone on a limited income. So, in 2001, Judy began to drive over the border to Canada to get her prescriptions filled. "I cut my drug bill by 60 to 75 percent each month," Judy said.

In 2004, Judy joined the Pfizer for Living Share Program to get a

discount on one of her pain medications. She then switched to the U-Share Card, a Medicare-approved prescription drug discount card offered by five drug companies. As a low-income senior, Judy qualified for a \$600 credit. She thought this would be a major benefit, but was shocked when she ran through the \$600 credit in only six weeks! She soon learned that the prices she was paying under the Medicare discount card were much higher than what she paid before. They were even higher than when she paid completely out-of-pocket. When she asked the Centers for Medicare and Medicaid Services (which runs the Medicare program) about the prices and how she could run through her credit so quickly, the only explanation they gave her was that Medicare has no control over what the drug companies charge. Under the Medicare drug discount card plan, patients were locked into a card once they chose it, but the cards could change their prices and what drugs they covered as frequently as every week. Judy calls the drug prices "a moving target" and says she has come to realize "there is no accountability."

Like the other Medicare drug discount cards, the U-Share Card is being phased out at the end of 2005.

GENERIC DRUGS

continued from page 2

drugs. People may not even know that there are generic options for the drugs that they are taking.

How can I find out if a cheaper generic drug is available?

Many health plans and states have rules that require pharmacists to fill your prescription with a generic if one is available for the drug you need. This is called "mandatory substitution." However, if your doctor writes "dispense as written" on your

Judy is still considering whether to join a Medicare prescription-drug plan when those plans begin in 2006. In the meantime, however, help has arrived, through Washington's Medically Needy Program. Through this program, Judy's prescriptions now cost only \$5 each after she pays a quarterly deductible.

An extraordinarily accomplished person, Judy has written five books, created a widely used curriculum for health-care providers, advised health-care facilities in creating consumer-friendly systems of care, set up rehabilitation centers, run a mental health agency for the homeless, and developed comprehensive drug programs for homeless teenagers. Yet even she, a savvy advocate who has spent her entire career in the health-care industry, struggles to afford life-saving medications. Hers is an all too familiar story. 🌟

Judy contacted the Prescription Access Litigation (PAL) Project after working with PAL member, Oregon Health Action Committee. If you would like to share your story with PAL, please call us toll-free at (866) 208-9800 ext. 2931, or e-mail pal@communitycatalyst.org.

prescription, then the pharmacist must fill your prescription with the brand-name drug. Doctors do this for many different reasons, so if your doctor writes this on your prescription, make sure to ask why. You should talk to your doctor or your pharmacist if you are interested in finding out if a generic option is available for a drug you are taking. 🌟

Learn more about generic drugs on the Internet:
theunadvertisedbrand.com
www.fda.gov/cder/consumerinfo/generics_q&a.htm

Kathleen Slattery-Moschkau: One of the motivations for me in making the film was an absolute lack of awareness of this particular marketing tactic by the industry. Most people have been in a doctor's office and seen a drug rep. Sometimes they even outnumber the patients in the waiting room. What I found when I would talk to people in the general public was that they couldn't believe that this went on. They didn't realize how this worked, how their doctors got the information about the drugs and where samples come from and that it is really all about marketing. It was this surprise that really made me realize that this is something people do need to be aware of.

ASB: You obviously know about this first-hand since you worked as a pharmaceutical salesperson for number of years. How long were you in that industry and what kind of drugs did you sell to doctors?

KSM: I was in the industry for almost a decade and I sold a wide variety of drugs, which is part of the humor of the situation. I sold everything from decongestants to heavy-duty psychiatric drugs to steroids and antibiotics. I had no expertise in any of these areas. That is the humorous and scary thing about the whole situation: one hour I would be in front of a psychiatrist selling a hard-hitting antipsychotic drug and then the next hour I would be in front of a pediatrician talking about bubble-gum-flavored antibiotic syrup. The film is closely based on the ten years of me working directly within the industry.

ASB: Tell us about the motivation of the individual detailers. Do they go into this with a sense of idealism, or

do they know what they are getting into?

KSM: I think that psychologically is a complex question and I tried to get into this in the film. I think most people come into the industry because its considered a really good job - you can make really good money, and get a company car and an expense account, and fly all over the country. I don't think people initially give much thought to what it is they're doing, in terms of if the work is ethical or not. Initially it is a kind of "stick your head in the sand" sort of mentality. Nobody questions the ethics initially and then over time a couple things happen: you start to make more money; even if you have doubts, the more money you make, the more you are buying into. The industry does a great job both with their employees and the general public in terms of spinning the PR perspective that the company is all about "research and development" and "if it wasn't for the benevolence of the pharmaceutical industry, where would we all be?" They pitch that to their employees. So as you're making more money, you find a way to rationalize it and cling to that brainwashing. I know that I personally did that and that was a motivation for me to make the film because I was constantly disgusted with myself. Every time I would think I would walk away, I would get a big raise or another company would come calling with a better position and I would find ways to rationalize it in my own mind.

ASB: In the film, we get to see Karly, the main character, learn how to pitch to doctors. Talk about the psychology



A scene in *Side Effects* shows drug representatives being taught the importance of "driving market share."

of persuasion at work. What kind of tactics do detailers use to sway physicians?

KSM: The companies spend so much money on developing the absolute perfect pitch. This is all very scientifically studied in terms of what exactly are the issues with the current drugs on the market: how the drug differentiates, how can we hammer that point home, how can we spin this in a way that does set us apart, (even though nine times out of ten it is a "me-too" drug that really isn't that much different,) and then that verbiage is used in the reps' training. Basically we're just told exactly what to say when we step foot into the office. It is a very well-rehearsed, preplanned pitch about that drug.

Most reps can't get into an educated dialogue with a doctor about the drug. They're music majors, drama majors, history majors. They have no ability to get into the type of conversations that are necessary to truly educate a doctor. But what they can do is stand before them and look nice and rattle off all the benefits and the doctor is in a hurry. That is typically what the doctor takes away, the benefits of the drug. When it comes down to it, it is just sales. It is just like it is to sell any other item out there but the difference is that these are drugs that people are taking into their bodies and can mean the difference between life and death

in some cases, like we are finding out with Vioxx.

There is no educating going on. It is all about manipulation and spinning things in a way that is going to drive market share. It is never about what is in the patient's best interest. It is always about "what are the ways that we can get to this doctor to write more prescriptions for our drug?" That is how reps are compensated—they are not compensated by how knowledgeable they are and what a good job they do objectively educating physicians. They are specifically compensated by how much market share they drive.

ASB: Why did you decide to make a feature film instead of a documentary?

KSM: There's so much in the news lately about the greed of the pharmaceutical industry - Vioxx, Celebrex, etc. Even though there are all these articles being published on these topics, it's really hard to personally relate to it. After a while you start to tune it out: just another drug company who falsified their information on one of their drugs. I thought that I would make a movie that could be entertaining but that could get inside at the what this world looks like. It is one thing to read an article, but I think we need multilayered approaches; to see it on the screen it is a different way to reach people.

ASB: What do you want doctors who see your movie to do after leaving the theater?

KSM: For a physician, I would want them to now understand how this works and to question the information that is put before them, ideally in all forms, even if they read a study in a reputable medical journal, going back and questioning who funded the study—really questioning the motive of the information that is presented to them. Just the knowledge of how much they are being manipulated will help them to question the information more and overall make better prescribing choices for their patients. So for physicians, for them to come away with more awareness and then to apply that in a way to question everything they used to know about the industry and drug reps and samples.

continued on page 6



Prescription Access Litigation Project News Briefs

New Member Organizations

Please join PAL in welcoming the newest members to the coalition:

- **The Actors' Fund of America**
<http://www.actorsfund.org/>
- **Boston Building Service Employee Trust Fund (SEIU Local 615)**
http://www.seiu.org/building/security/allied_615.cfm
- **Breast Cancer Action**
<http://www.bcaction.org/>
<http://www.thinkbeforeyoupink.org/>
- **Center for Medical Consumers**
<http://www.medicalconsumers.org/>
- **New Hampshire Alliance for Retired Americans**
<http://www.retiredamericans.org/>
- **Public Patent Foundation**
<http://www.pubpat.org/>
- **SEIU Health and Welfare Fund**
<http://www.seiu.org/>
- **UnitedScripts Administrators**
<http://www.unitedscriptsrx.com/>

Meetings and Events

On June 14th, PAL Project Associate Julie Bizzotto spoke about PAL and its latest cases at the **Florida Alliance for Retired Americans' Annual Convention**. The convention was attended by seventy representatives of seniors' clubs throughout Florida.

On June 15th, PAL Director Alex Sugerman-Brozan spoke at "High Prescription Prices: Rx: How to Fight Back," which was cosponsored by the **Council on Aging Services for Seniors** (Sonoma County, California) and the United Way.

On June 15th, PAL Associate Director Renée Markus Hodin met with PAL member groups **Gay Men's Health Crisis, JPAC for Older Adults, Metro New York Health Care for All, and New York Statewide Senior Action Council** in New York City. Also in attendance were

representatives from the **Interfaith Center on Corporate Responsibility**. Thanks to JPAC for Older Adults for hosting the event!

On June 16th, Renée Markus Hodin spoke at the quarterly meeting of the **Association of Benefit Administrators (ABA)**. The ABA is an association of 225 members, including salaried administrators of union health and welfare funds, third-party administrators, and some service providers (such as attorneys).

On July 9, Alex Sugerman-Brozan represented a consumer perspective on why states need to regulate pharmacy benefits managers (PBMs) at the **National Conference of Insurance Legislators**.

that it would benefit 10 million low- and middle-income Californians. Cal Rx PLUS is similar to Maine's successful Maine Rx program, which the drug industry challenged all the way to the Supreme Court. Cal Rx PLUS would be open to many more people than Cal Rx, including individuals earning up to \$37,000 per year, families earning up to \$75,000 a year, and families with higher incomes whose medical expenses take up 5 percent of their total income. The drug discounts would be 50 percent or more off of retail prices.

Opponents of Cal Rx PLUS, especially the drug companies, argue that it would cost too much for the drug companies, and that requiring them to offer discounts would be unfair. Drug companies have already pledged \$50 million to pass Prop. 78 and defeat Prop. 79. This comes on the heels of a recent report by the Center for Public Integrity showing that the drug industry spends more on lobbying than any other industry. With the drug industry having lost its legal battle to stop programs like this, it now fears that more and more states will pass laws requiring drug companies to give discounts to uninsured patients. This explains why the drug industry is investing so much money in California. Like it has many times in the past, California has become a national battleground for health-care debates such as how to pay for it, how to provide it for the uninsured, and who should have a say. 🌐

ASB: Should physicians refuse to see sales reps?

KSM: In my opinion, yes. At this point, with the system the way that it is, I can't imagine what benefit comes from them seeing a sales rep. The information that they are getting is only partial information typically, and only the positive information. As one physician once told me, "that's more dangerous than no information at all."

ASB: What do you want patients who see your movie to do after leaving the theater?

I want to get people thinking about what goes into the drugs that they take and the marketing to their doctors and hopefully how that filters down to direct-to-consumer advertising. I want them to really know that everything that they are seeing or doing is being driven by profits for those companies. So when they are getting free samples or a prescription, they need to question their doctors about their relationship to drug reps and how they make their prescribing choices. Raising that level of awareness will create patients who are better consumers of prescription drugs. 🌐

To learn more about Side Effects, including dates and locations of screenings, go to <http://www.sideeffectsthemovie.com/>.

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Nathan Cummings Foundation
Rockefeller Family Foundation
The George Gund Foundation
Atlantic Philanthropies

Update on Previously Filed Litigation

Augmentin

Background: In June 2002, PAL members filed suit against GlaxoSmithKline (GSK), maker 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: On July 9, 2004, the indirect-purchaser class action, which covers consumers and insurers, was settled for \$29 million. Consumers who purchased Augmentin between January 4, 2000, and April 30, 2004, were eligible for a refund from the settlement fund. The deadline for submitting claims was December 16, 2004. The court will soon consider a motion for distribution of the settlement funds.

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

Average Wholesale Price

Background: In December 2001, PAL members 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 February 10, 2005, the court held a hearing on the plaintiffs' motion to certify a national plaintiff class with respect to five "fast-track" defendant drug companies. The court

has taken the motion under advisement and has not yet issued a decision. Discovery against the five fast-track defendants is well underway and is expected to conclude on August 31, 2005.

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

Celebrex

Background: In February 2005, PAL members filed suits against Pfizer, Inc., Pharmacia Corporation, and GD Searle and Company in Massachusetts state court and federal court in California, alleging that these companies deceptively advertised and marketed Celebrex, a COX-2 inhibitor commonly used to treat pain associated with arthritis. The lawsuits claim that this advertising and marketing campaign hid the cardiovascular health risks associated with the drug while overstating the drug's effectiveness.

Update: Efforts are underway to consolidate all Celebrex cases into a federal multidistrict litigation (MDL) proceeding. The Judicial Panel on Multidistrict Litigation (JPML) held a hearing on July 28, 2005 to determine whether - and in what court - to consolidate the cases. The parties in the California case have agreed to delay the defendants' answer to the complaint until five days after the JPML ruling. In May 2005, the Massachusetts state court action was withdrawn in favor of a nationwide suit filed in federal court in Massachusetts. The Massachusetts federal case, like the California case, is on hold until the JPML issues a ruling on consolidation of all Celebrex cases. In the meantime, however, the defendants have filed a motion to dismiss the Massachusetts complaint and the plaintiffs filed their opposition in late July 2005.

Courts: U.S. District Court for the Northern District of California (Judge Breyer) U.S. District Court for the District of Massachusetts (Judge Woodlock)

Estratest

Background: In August 2003, PAL members 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: Following the passage of a state referendum that changed the requirements for bringing a case under California's consumer protection statute, the defendants filed a motion for judgment on the pleadings. On February 18, 2005, the court granted this motion, ruling that the referendum applies to cases previously filed in California state courts, and dismissing the case. However, the court also granted permission for the plaintiffs to file an amended complaint, which was filed on March 30, 2005. Based on the recently enacted Class Action Fairness Act (CAFA), the defendants removed the case to federal court and filed motions to stay and dismiss the case. The plaintiffs filed a motion to remand the case to state court, which the federal court granted on June 24, 2005. The federal court also dismissed the defendants' motions to stay and dismiss the case as moot based on the remand ruling. The next status conference is scheduled for October 3, 2005.

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

K-Dur 20

Background: In June 2001, PAL members filed suit against Schering-

Plough Corporation, Upsher-Smith Laboratories, Inc., and American Home Products Corporation, alleging that the companies illegally agreed to keep generic versions of K-Dur 20 off the market. K-Dur 20 is a potassium supplement often prescribed with high-blood-pressure medication and is the fourth most frequently prescribed drug for the elderly.

Update: In February 2004, Judge Greenaway approved consolidation of several K-Dur 20 cases. The plaintiffs filed an amended consolidated complaint on November 1, 2004, and a motion for class certification on November 30, 2004. In the meantime, fact discovery is concluding and expert reports will be exchanged by May 2005.

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

Lupron

Background: In September 2001, attorneys affiliated with PAL filed suit against Abbott Laboratories, Takeda Chemical Industries, Ltd., and their joint venture company, TAP Pharmaceutical Products, Inc. The suit alleged that the companies 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. This suit is the consumer counterpart to a criminal case brought by the federal government against TAP. In October 2001, TAP agreed to settle that criminal case, pleading guilty and agreeing to pay \$875 million. This was the largest health care fraud settlement in history. The consumer suit seeks recovery for Medicare patients who paid coinsurance for the drug and non-Medicare patients who paid out-of-pocket.

Update: On November 15, 2004, the parties filed a settlement agreement.

The court granted preliminary approval on November 24, 2004. Consumers and third-party payors who purchased Lupron between January 1, 1985, and March 31, 2005, were eligible to get money back. The deadline for submitting claims was July 25, 2005. Following a two-day fairness hearing, the court granted final approval of the settlement and certified the class on May 12, 2005. However, the parties are currently attempting to resolve objections by certain state attorneys general so that a final judgment may be entered. The parties anticipate that the objections will be resolved and that the processing of claims and payment to consumers will take place before the end of 2005.

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

Neurontin

(Patent-Related Litigation)

Background: In April 2002, PAL members 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 is resolved. To date, many of the generic manufacturers have overcome motions for summary judgment, but a few outstanding motions await the judge's decision.

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

Neurontin

(Off-Label Promotion)

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

Update: Following the passage of a state referendum that changed the requirements for bringing a case under California's consumer-protection statute, the defendants filed a motion to dismiss the complaint. Unfortunately, on March 22, 2005, the court granted this motion, ruling that the referendum applies to cases previously filed in California state courts, and dismissed the case. On April 21, 2005, PAL attorneys filed a motion for leave to file a second amended complaint. However, based on the recently enacted Class Action Fairness Act (CAFA), which changed the ground rules for where class-action lawsuits may be filed, defendants removed the case to federal court. Following the submission of briefs on the issue of removal, the federal court remanded the case back to state court on June 24, 2005 (on the grounds that removal was premature). The Court will hold a hearing on Plaintiffs' motion for leave to file a second amended complaint on August 31, 2005.

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



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PAL Project

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Thank you very much for your support.

Nexium

Background: PAL members have filed numerous suits against AstraZeneca, manufacturer of the blockbuster heartburn drug Nexium (advertised as "the healing purple pill"). These cases allege that in order to maintain the profits the drug maker was reaping through its earlier drug, Prilosec, AstraZeneca engaged in an extensive and deceptive marketing campaign aimed at switching Prilosec users to Nexium before the patent on Prilosec expired. The lawsuits contend that AstraZeneca misled consumers into believing that Nexium is a major improvement over Prilosec, basing these claims on clinical studies that compared 40 mg of Nexium to 20 mg of Prilosec instead of comparing comparable doses of each drug.

Update: In the California state cases, the plaintiffs filed amended complaints in March 2005. Defendants filed their demurrers and motions to strike on June 10, 2005. Plaintiffs opposed these motions, and a hearing and status conference were held on August 11, 2005. In the Massachusetts case, the defendants removed the case to federal court, but after the plaintiffs opposed the removal, the defendants agreed to remand. The case was officially remanded back to state court on April 13, 2005. The plaintiffs filed an amended complaint on April 11, 2005. The defendants filed a motion to dismiss the complaint on May 27, 2005, and the plaintiffs have opposed the motion. A nationwide class-action suit was filed in federal court in Delaware in June 2005.

Courts: Superior Court of California, County of Los Angeles (Judge Chaney) Massachusetts Superior Court, Suffolk County (Judge van Gestel,) U.S. District Court for the District of Delaware (Judge Robinson)

Norvir

Background: In October 2004, PAL members filed suit against Abbott Laboratories, manufacturer of Norvir, a critical drug for many HIV/AIDS patients. The suit alleges that Abbott tried to monopolize the market for "protease inhibitors" (PIs), which are taken with Norvir, by leveraging its patent-protected monopoly on Norvir itself. In December 2003, Abbott increased the price of Norvir by approximately 400 percent while knowing the drug was vital to most HIV/AIDS patients, but did not increase the price of Kaletra, which contains its own PI in combination with Norvir.

Update: The defendants filed a motion to dismiss on November 15, 2004, but on March 2, 2005, the court denied the motion, allowing the case to proceed. A settlement conference is scheduled for July 26, 2005. On June 1, 2005, Abbott filed for summary judgment on two key issues in the case. The parties are working on a schedule for briefing. Discovery is nearly complete.

Court: U.S. District Court for the Northern District of California (Judge Wilken)

OxyContin

Background: In January 2004, PAL members filed suit against Purdue Pharma, LLP, 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 kept generic alternatives off the market. The lawsuit claims that to win its patents, Purdue told the U.S. Patent and Trademark Office that OxyContin was unique because of its effectiveness at very low dosages, despite the lack of evidence supporting this assertion. In the underlying patent suit, the court ruled in favor of generic

manufacturers who had sought to sell a generic version of OxyContin to market, invalidating the patent because of Purdue's material misrepresentations to the Patent Office.

Update: In early July 2004, the case was consolidated with other OxyContin cases in U.S. District Court for the Southern District of New York, where the underlying patent litigation was heard. On June 6, 2005, the Federal Circuit Court of Appeals, which specializes in patent cases, affirmed the federal district court's decision holding that the OxyContin patents at issue are unenforceable. In its opinion, the appellate court stated that Purdue failed to disclose material information to the patent office and that its conduct reflected "a clear pattern of misdirection throughout the prosecution" of its patents. This ruling allows the PAL case to proceed.

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

Pharmacy Benefit Managers

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

Update: Following the passage of a state referendum that changed the requirements for bringing a case under California's consumer-protection statute, the Judge issued an initial stay in the case to allow time for a decision from the California Supreme Court on whether the new law applies to cases, such as this one, that were filed before the law passed. Plaintiffs have filed their notice of appeal of this retroactivity issue and have filed a stipulation application to continue the stay pending the California Supreme Court decision.

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

Relafen

Background: In February 2002, PAL members filed suit against GlaxoSmithKline, alleging that it fraudulently obtained a patent on Relafen, a widely used anti-inflammatory drug, in order to prevent a cheaper generic version from entering the market. In the underlying patent case, the U.S. District Court for the District of Massachusetts held in favor of the generic companies. It found that GSK made material misrepresentations to the patent office, and thus the Relafen patent was unenforceable. As a result of GSK's conduct, consumers were forced to pay an artificially inflated price for Relafen for more than ten years, while a less expensive generic version was kept off the market.

Update: The parties filed a settlement agreement on May 20, 2004, and Judge Young granted preliminary approval on November 24, 2004. GSK has agreed to pay \$75 million to settle the claims of consumers and third-party payors. Consumers and third-party payors who purchased Relafen between September 1, 1998, and June 30, 2003, were eligible to get money back. The deadline for submitting claims was July

29, 2005. The court held a fairness hearing on May 4, 2005, but has not yet issued its order for final approval of the settlement agreement. The court is also considering a number of proposals for funds that were set aside in the settlement agreement for charities in various states.

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

Tamoxifen

Background: Tamoxifen is the most commonly prescribed drug to treat women with breast cancer. In May 2001, PAL members 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 became available.

Update: PAL attorneys appealed the May 2003 dismissal of the case and an appeal 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 for the Eastern District of New York (Judge Glasser)

Vioxx

Background: PAL members have filed suits against Merck, alleging that it deceptively advertised and marketed Vioxx, a COX-2 inhibitor commonly used to treat pain associated with arthritis. These lawsuits claim that Merck's advertising and marketing campaign hid the cardiovascular health risks associated with the drug while overstating the drug's effectiveness.

Update: The Massachusetts case was filed in February 2005. The defendants answered the complaint, removed the case to federal court, and are currently seeking to transfer the case to

Louisiana, where a multidistrict litigation proceeding has been established to coordinate all federal Vioxx litigation. In March 2005, PAL members filed a separate case in Louisiana, which has been consolidated in the multidistrict litigation proceeding.

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

U.S. District Court for the Eastern District of Louisiana (Judge Fallon)

Wellbutrin

Background: Wellbutrin is a drug used to treat depression. While the main ingredient of Wellbutrin has been off-patent for several years, its extended-release formula, Wellbutrin SR, is not. In July, 2002, PAL filed suit against GlaxoSmithKline (GSK), maker of Wellbutrin and Wellbutrin SR. The lawsuits allege that GSK filed baseless patent lawsuits against generic drug companies in order to delay the manufacture and sale of generic versions of Wellbutrin SR. The result of this misuse of the patent system is that people suffering from depression were forced to pay higher prices for extended-release versions of a medication vital to their mental health.

Update: The PAL case was voluntarily dismissed in 2003 following an adverse appeals court decision in the Andrx patent litigation. However, the case was refiled in December 2004 after subsequent positive appeals court decisions in patent cases involving two other generic competitors. The defendants filed a motion to dismiss on March 23, 2005. The plaintiffs have opposed this motion. The court will soon schedule a hearing.

Court: U.S. District Court for the Eastern District of Pennsylvania (Judge Kauffman)

PAL Participants

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.

Alaska

ASEA/AFSCME Local 52
Health Benefits Trust

California

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

Colorado

Colorado PIRG
Colorado Progressive Coalition

Connecticut

Connecticut Citizen Action Group

District of Columbia

District of Columbia Primary
Care Association

Florida

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

Idaho

Idaho Community Action Network
Living Independence Network Corporation (Idaho)

Illinois

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

Indiana

United Senior Action of Indiana

Kansas

Kansas Association for the Medically Underserved

Maine

Consumers for Affordable Health Care
Maine People's Alliance

Maryland

Maryland Citizens' Health Initiative

Massachusetts

ABCD Health Services
Boston Building Service Employee Trust Fund
(SEIU Local 615)*
Commonwealth Care Alliance
Health Care For All
Health Law Advocates
Lynn Health Task Force
Massachusetts Breast Cancer Coalition
MASSPIRG
Massachusetts Senior Action Council
New England Regional Council of Carpenters
SEIU 615
Women's Health Institute (Massachusetts)

Michigan

Public Interest Research Group in Michigan
(PIRGIM)

Minnesota

Minnesota COACT
Minnesota Senior Federation

Mississippi

Mississippi Human Services Coalition
Mississippi Health Advocacy Program

Nebraska

Nebraska Appleseed

New Hampshire

New Hampshire Citizens Alliance
New Hampshire Alliance for Retired Americans*

New Jersey

New Jersey Citizen Action
New Jersey Public Interest Research Group
Public Interest Law Center of New Jersey

New Mexico

Health Action New Mexico
Senior Citizens' Law Office

New York

BWICA Education Fund Inc.
CAIRE
Center for Medical Consumers*
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
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 for 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
Philadelphia Unemployment Project

Rhode Island

Health Care Organizing Project
Ocean State Action

South Carolina

South Carolina Appleseed Legal Justice Center

Tennessee

Tennessee Health Care Campaign

Texas

Texas Alliance for Human Needs

Utah

Utah Issues: Center for Poverty Research & Action

Vermont

Vermont PIRG

Virginia

Virginia Poverty Law Center

Washington

Washington Citizen Action
Washington Public Interest Research Group

West Virginia

West Virginia Citizen Action Group

Wisconsin

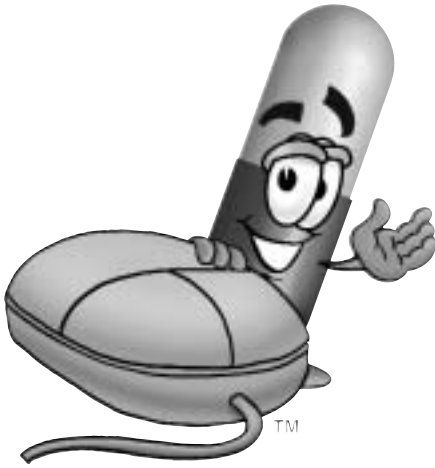
Wisconsin Citizen Action

National organizations

The Actors' Fund of America*
AIDS Action (Washington, DC)
Alliance for Retired Americans
AFL-CIO (American Federation of Labor-Congress
of Industrial Organizations)
AFSCME (American Federation of State County
and Municipal Employees)
Association for Community Affiliated Plans
Community Catalyst
Medicare Rights Center
Our Bodies Ourselves
Public Patent Foundation*
SEIU Health and Welfare Fund*
United Scripts Administrators*
USAction

*New member of the PAL coalition.

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



Visit us Online
www.prescriptionaccess.org

Contact the Prescription Access Litigation Project

Julie Bizzotto, PAL Program Associate
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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/>.

You may also contact the communications coordinator, Jennifer Pieroni, at (617) 275-2892 for more information.



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