CENTER FOR JUSTICE & DEMOCRACY
CJ&D

IMPACT

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...news, views and reviews from the Center for Justice & Democracy

CENTER FOR JUSTICE & DEMOCRACY **NEWS**

Dear Friend,

Here are a few examples of CJ&D's activities just since January 1, 2005:

- Rapid On-the-Ground Response to President Bush when he went to southern Illinois on January 5.
- Brought 50 families from 26 states to Washington before Congress had even held their first hearing on medical malpractice.
- Opened our first state office in Illinois.
- Testified in Congress and moderated U.S. House briefing.
- Created Civil Justice Resource Group, legal scholars to defend the civil justice system.

Plus, we published several breakthrough reports and continue as frequently-requested commentators on news shows.

We have big, exciting plans and we hope you can join us! See page. 4 for more information.

Sincerely,

Joanne Doroshow
Executive Director

IN THIS ISSUE: DRUG COMPANIES

Overview: The Failure of Government Regulation

Appearing on ABC's *This Week* in late December 2004, White House Press Secretary Andrew Card said the Food and Drug Administration (FDA) is doing a "spectacular job" and should "continue to do the job they do."

Spectacular? Untold numbers of patients have been injured or killed by Vioxx, a paikiller that the FDA knew significantly increased the risk of heart attack, stroke and sudden death. The agency's own drug safety reviewer, Dr. David Graham, testified that his superiors delayed publication of a study that connected Vioxx to heart problems and even pressured him to change the report's conclusions.

"Today, in 2004, you, we, are faced with what may be the single greatest drug safety catastrophe in the history of this country or in the history of the world," Graham told the Senate Finance Committee in November 2004. "We are talking about a catastrophe that I strongly believe could have, should have been largely or completely avoided. But it wasn't, and over 100,000 Americans have paid dearly for this failure. In my opinion, the FDA has let the American people down, and sadly, betrayed a public trust."

This story sounds all too familiar. Time and again, the FDA has failed to safe-

(continued on page 2)

The Move to Protect Drug Companies From Liability

Most Americans would agree that companies that disregard their responsibilities as corporate citizens should not be rewarded. Yet that is exactly what might happen for the pharmaceutical industry. Not satisfied with just weakening safety laws, drug manufacturers and their lobbyists are swarming Congress, asking for special treatment in the courts.

Their efforts to shield themselves from legal liability have already met with some success. Despite strong opposition from the National Conference of State Legislatures, the Conference of Chief Justices, the Federal Judicial Conference and the Chief Justice of the U.S. Supreme Court, in February 2005, Congress passed and George W. Bush signed the so-called "Class Action Fairness Act of 2005."

The law, among other things, allows "mass tort" actions involving dangerous drugs, consolidated by state courts for efficiency purposes, to be moved into the already overcrowded federal courts. According to Senator Patrick Leahy (D-VT), who fought the legislation, "Federalizing these individual cases would delay, and possibly deny, justice for victims suffering real physical injuries - such as the people injured by taking Vioxx."

Congress is now considering two other bills that would minimize drug companies' legal responsibility to those they've injured.

(continued on page 3)

Overview: The Failure of Gov't Regulation continued . . .

guard the public's health, quickly approving questionable drugs and leaving them on the market despite unequivocal evidence that they are dangerous or deadly, taking action only after tragedy strikes.

For example, the FDA knew as early as 1997 that the diabetes drug Rezulin caused severe liver toxicity but did not ban it until nearly three years later, after 63 liver deaths, seven liver transplants and hundreds of cases of liver damage. Similarly, by the time the FDA took the anti-cholesterol drug Baycol off the market in 2001, there were nearly 1,900 cases of rhabdomyolysis, an often-fatal destruction of muscle. Many of those patients would not have suffered had the FDA acted on data it was aware of one year earlier.

And according to FDA whistleblower Dr. David Graham, in addition to Vioxx, the FDA has recently mishandled safety problems with six other widely used drugs: Meridia, a weight-loss drug linked to higher blood pressure and strokes; Crestor, an anti-cholesterol drug associated with high rates of kidney failure; Accutane, an acne drug linked to birth defects; Bextra, a painkiller that increases the risk of heart attack and stroke; Serevent, an asthma medication shown to cause death; and Mobic, an arthritis painkiller associated with an increased risk of heart attacks.

Such public health disasters point to the FDA's systemic failure to protect the public from hazardous drugs, a failure confirmed by Dr. Sandra Kweder, deputy director of the FDA's Office of New Drugs. In March 2005, Kweder told a Senate panel that the agency would welcome more authority from Congress to force drug label changes and to require drug makers to conduct tests if safety issues arose after drugs were on the market.

The FDA has no systematic way to monitor the safety of drugs once they've been approved, leaving it to pharmaceutical manufacturers to report any injuries and side effects.

But under current law, the FDA has no power to order manufacturers to undertake post-approval studies. It can only suspend drug sales under extraordinary circumstances and lacks authority over how drugs are distributed and marketed to doctors and consumers. The pharmaceutical industry also has a say in all drug label changes. As Kweder testified, the agency sometimes negotiates for far too long over changes in drug labels. In the case of Vioxx, for example, it took over a year for Merck and the FDA to agree on language alerting physicians about the drug's heart risks.

Moreover, the FDA has no systematic way to monitor the safety of drugs once they've been approved, leaving it to pharmaceutical manufacturers to report any injuries and side effects. An internal FDA survey made public in December 2004 found that about two-thirds of agency scientists were less than fully confident in the agency's monitoring of the safety of prescription drugs now being sold. In addition, more than one-third of those scientists had doubts about the FDA's drug approval process.

So why, despite calls for accountability and reform, doesn't anything change?

One answer is that the FDA is too close to the industry it's supposed to regulate. The agency lost much of its independence in 1992 when Congress passed the Prescription Drug User Fee Act, which allows drug manufacturers to pay the FDA "user fees" to review their products.

These "user fees," paid to speed up the FDA's drug review process, constitute a huge portion of the agency's budget for regulating drugs, making the FDA financially beholden to the pharmaceutical industry. As a result, drug companies and their lobbyists have had a great deal of influence over FDA decision-making and policy.

During fiscal year 2003 alone, the agency collected $210 million in "user fees." To put this in perspective, the FDA's Center for Drug Evaluation and Research's operating cost for reviewing drugs in 2003 totaled almost $250 million. Moreover, researchers with ties to the pharmaceutical industry commonly serve on FDA drug review panels. Just look at the make-up of the recent FDA advisory committee which recommended that Merck's Vioxx and Pfizer's Celebrex be kept on the market, despite evidence that they both carry serious risks of heart attack and stroke. According to the February 25, 2005 *New York Times*, 10 of the 32 panel members have consulted in recent years for Merck, Pfizer or Novartis, which is applying to sell a very similar pill discussed by the panel.

As the *Times* reported, "If the 10 advisers had not cast their votes, the committee would

(continued on page 4)

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The Move to Protect Drug Companies From Liability continued . . .

Medical Malpractice Legislation (S. 354, H.R. 534)

This legislation, which is marketed to the public as a bill to protect doctors, also provides huge liability loopholes for drug companies. The bill puts an arbitrary ceiling - $250,000 - on the amount a patient hurt by a drug could receive in non-economic damages, no matter how devastating the injury. Non-economic damages compensate for intangible but real injuries like infertility, permanent disability, disfigurement, blindness, pain and suffering, loss of a limb or other physical impairment.

As Dr. Sidney Wolfe, Director of Public Citizen's Health Research Group, told a House Energy and Commerce committee in February 2005, the $250,000 cap "would affect patients with significant kidney damage from a drug such as Rezulin…or children who lost their young father from a heart attack induced by a CoX-2 pain reliever" like Vioxx.

The House medical malpractice bill also eliminates punitive damages against manufacturers of drugs approved by the FDA, even when the drug turns out to be harmful. Punitive damages may only be awarded against a drug maker if the plaintiff shows that the company committed fraud to get FDA approval or bribed an FDA official. And even if punitive damages are assessed, the bill limits them to two times the amount of economic damages or $250,000, whichever is greater.

Punitive damages are awarded by judges or juries to punish particularly outrageous, deliberate or harmful misconduct, and to deter the defendant and others from engaging in similar misconduct in the future. Capping or limiting punitive damages will allow pharmaceutical manufacturers to treat liability as a cost of doing business, weakening their deterrent impact.

The provision could dramatically affect the nearly 1,500 civil lawsuits filed against Merck over Vioxx. When Merck finally pulled Vioxx off the market on September 30, 2004, evidence had been accumulating for several years that the drug doubled the risk of heart attack or stroke. Internal emails at Merck suggest that the company kept this information to itself and sued a researcher who wrote about it. The threat of liability no doubt contributed to Merck's decision to voluntarily withdraw Vioxx when it did, knowing it could no longer hide the truth.

Imagine the signal that would be sent to other drug companies if the threat of financial liability were suddenly eliminated. The potential outcome is frightening: an environment in which unsafe products would proliferate, resulting in soaring rates of consumer deaths and injuries, and little chance of ever finding out why.

"The FDA exemption sets, in a way, a downward course," said Senator Dianne Feinstein (D-CA) during last year's debate on the legislation. "If a company has an FDA-approved product on the market and then learns of dangerous complications, the company must remove the product from the marketplace immediately. To provide an exemption for products with FDA approval may well be a disincentive to prompt removal from the shelf." And as Senate Minority Leader Harry Reid (D-NV) recently put it, "Congress should not be giving a free pass to big drug companies at a time when millions of Americans may have had their health put at risk by pharmaceutical giants."

Anti- Terrorism Bill (S. 3)

The anti-terrorism bill provides another direct gift to the pharmaceutical industry. If signed into law, S. 3 would allow civil lawsuits involving dangerous FDA-approved drugs and vaccines to proceed, in federal court, when drug makers acted "fraudulently or with willful misconduct" and, even in those cases, non-economic damages would be capped at $250,000 with no punitive damages allowed.

S. 3 is also the fifth piece of legislation championed by Senate Majority Leader Bill Frist (R-TN) that would shield Eli Lilly and other pharmaceutical giants from lawsuits over thimerosal, a mercury preservative in infant vaccines that has been connected with autism.

With regulatory oversight of drug industry practices virtually ground to a halt, limiting the public's ability to bring civil lawsuits, so-called "tort reform" is not the direction in which we should be going. Such laws protect drug manufacturers while stripping away patients' rights.

Lawsuits Save Lives

Untold numbers of Americans have suffered tremendously as a result of dangerous and deadly pharmaceuticals. Many of these drugs and devices were only made safer or removed from the market after victims and their families filed lawsuits against culpable manufacturers.

For example,

Dalkon Shield IUD
The Dalkon Shield IUD was a dangerous birth control device that caused pelvic infections, septic abortions, infertility and death. Although removed from the market in 1974, it took 11 punitive damages awards over a number of years before the company finally agreed in 1984 to urge doctors and women to remove the Dalkon Shield and offered to pay for the removal.

Extra-Strength Tylenol
In 1993, a man was in a coma, near death, and required an emergency liver transplant after mixing the drug with alcohol. After a jury verdict in his favor, the FDA decided to require stronger warnings on aspirin, ibuprofen and acetaminophen products for alcohol drinkers.

Ortho-Novum 1/80
A woman suffered life-threatening injuries after taking the oral contraceptive in the 1970s. As a result of this case, manufacturer Ortho Pharmaceutical Corp. lowered estrogen levels in the contraceptive.

Overview: The FDA Doesn't Do Its Job continued . . .

have voted 12 to 8 that Bextra should be withdrawn and 14 to 8 that Vioxx should not return to the market. The 10 advisers with company ties voted 9 to 1 to keep Bextra on the market and 9 to 1 for Vioxx's return….Of the 30 votes cast by the 10 panel members on whether Celebrex, Bextra and Vioxx should continue to be marketed, 28 favored the drugs. Among the 66 votes cast by the remaining 22 members of the panel, just 37 favored the drugs." In the end, the committee suggested that only severe warnings be put in black boxes on the drugs' packaging.

On April 7, Pfizer reluctantly withdrew Bextra from the market after the FDA asked the drug company to suspend its availability. In this case, the FDA chose to act against the recommendation of its advisors and remove the drug because of its risky side effects. The impact of this decision on future FDA actions remains to be seen.

Big federal campaign contributions from the drug industry may further explain why Congress hasn't taken steps to reform the FDA. Data from the Center for Responsive Politics show that since 2000 pharmaceutical manufacturers have given federal candidates over $50 million, the majority of which went to Republicans who now control both Chambers of Congress. Of that $50 million, the industry's main trade group, the Pharmaceutical Research and Manufacturers of America (PhRMA), contributed more than $4 million.

The drug industry has also used its vast resources to lobby Congress for legal protection. According to Public Citizen's June 2004 report *The Medicare Drug War*, the drug industry spent $108.6 million on lobbying activities and hired 824 individual lobbyists in 2003. The study also found that PhRMA spent more than $16 million on lobbying and hired 136 lobbyists in 2003.

Given that the FDA is, as Senator Charles Grassley (R-IA) put it, "too complacent" about safety and "too cozy" with drug companies, he and Senator Christopher Dodd (D-CT) introduced federal legislation--the "Food and Drug Administration Safety Act"-- that would create an independent drug safety office within the FDA. This is a step in the right direction.

Congress should put the health of the nation before the interests of the pharmaceutical industry and revamp the FDA's grossly inadequate drug-oversight system. If not, countless Americans will continue to be unnecessarily hurt or killed by dangerous drugs.

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