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**CENTER FOR JUSTICE
& DEMOCRACY
NEWS**

Dear Friend,

Attacks on the civil justice system hurt every American. Yet there is a shocking lack of public education and understanding of who is hurt and who benefits by these attacks. According to one poll, many members of the public perceive so-called "tort reform" to hurt only two groups: trial lawyers and people with "frivolous" lawsuits.

They falsely believe by "unclogging the courts," these laws will help people with legitimate lawsuits. In essence, the real impact of attacks on the civil justice system has been buried beneath a barrage of misinformation and outrageous lawyer-bashing.

Building a consumer organization dedicated solely to repairing and reversing the damage of "tort reform" is an unprecedented and historic undertaking. The Center for Justice & Democracy is up to this task - and we appreciate your support!

Thanks so much.

Joanne Doroshov
Executive Director

IN THIS ISSUE: INDEBTED POLITICIANS

A Deal for Drug Companies

What happens when lawmakers become so beholden to industry that they eliminate fundamental rights of their own constituents? Ask drug injury victims in Michigan.

In 1996, then Michigan Governor John Engler signed into law legislation granting drug companies immunity in civil suits - the only such law in the country, to date. The immunity extends to all suits relating to drugs that have killed or injured Michigan residents, so long as the drug in question had been approved by the Food & Drug Administration (FDA).

A lobbyist for the Michigan Manufacturers Association told the *Associated Press* in 2005 that that law was designed to protect the Michigan drug

company Upjohn (later taken over by Pfizer).

One of the most active groups seeking repeal of this extreme law is "DIIME" (Drug Industry Immunity Must End), a Michigan victims' rights



group associated with Michigan Citizen Action.

DIIME says: "This law has been disastrous for thousands of people like us-people who took drugs like Vioxx, Rezulin, Fen-Phen and Bextra, all of which

were approved by the U.S. Food and Drug Administration. These drugs, and others, were later pulled from the market due to their links to health problems like hypertension, stroke, liver failure and cardiac failure. Yet those of us who have been harmed by these dangerous drugs have no voice. We are excluded from taking action against the big pharmaceutical companies that marketed drugs they knew to be harmful and then made billions while we got sick."

A survey conducted by Public Citizen showed that in the late 1990's, there were at least 27 drugs approved by the agency over the objections of their own safety reviewers. Furthermore, ten different drugs were

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The Trouble With Not-So Blind Trusts

In June of 2005 Senate Majority Leader Bill Frist (R-TN) sold away his entire stock holdings in the Nashville-based for-profit hospital chain HCA Inc., which was founded and formally operated by his family. The value of this stock sale was estimated to be between \$2 million and \$6 million. The sale came just a week before the release of a weak earnings report, triggering a nearly 10 percent drop in the value of HCA's stock,

prompting an investigation by the Securities and Exchange Commission (SEC) and the Justice Department into possible insider trading.

Sen. Frist has maintained his innocence, claiming that he was unaware of the exact amount of his HCA holdings due to his having entered into a "blind trust"-the financial arrangements that shield legislators from knowledge of their stock holdings while in office.

These trusts are designed to guard against any perception of legislators voting in favor of their own interests. However, further investigation of this episode and other transactions has served to highlight the deeply flawed federal ethics laws governing "blind trusts," exposing a system that raises growing questions about the integrity of the congressional process.

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A Deal for Drug Companies *continued...*

removed from the marketplace in just the two years following the passage of



Michigan's immunity law, according to the *Washington Monthly*.

Now more than ten years later, while agency officials and legislators should be undertaking efforts to strengthen regulation at the FDA and undo harmful immunity laws, just the opposite is being done.

After attempts by the drug industry to push legislation similar to Michigan's were rebuffed by in the U.S. Senate, the FDA itself has taken drastic steps to subvert state laws regarding dangerous drugs through deregulation, thus endangering the safety of millions of Americans.

'Silent Tort Reform'

In January of this year, the FDA released a new set of rules governing the labels affixed to drug packaging. The rule changes, according to the FDA, were designed to provide consumers with a clearer understanding of the risks and side effects associated with certain drugs. However, inserted in the preamble to the new rule was language that provided drug manufacturers with blanket immunity from liability in court.

This rule change is part of a larger effort on the part of federal agencies under the Bush Administration, so-called "silent

tort reform," to immunize the very industries they should be regulating.

Another angle the FDA is using is to "preempt" consumers' legal rights by intervening in lawsuits. Like they do in their new labeling rule, the FDA argues in its briefs that the agency "knows best" and that injured consumers should not be allowed to sue drug makers for marketing unsafe drugs.

This aggressive intervention by agencies was a recurring

theme under Daniel Troy's 2001-2004 tenure as Chief Counsel. Troy came to the FDA after a career representing pharmaceutical and tobacco companies in

cases against the agency. Soon after Troy's appointment, the FDA made an abrupt shift in legal strategy and began filing intervening briefs on behalf of these companies when they were involved in litigation.

In May 2006, the drug industry finally convinced a court to agree with it. In *Colacicco v. Apotex, Inc., al.*, (E.D. Pa. May 26, 2006), the court ruled that the FDA's new preamble preempted state tort claims in this failure-to-warn case involving a Paxil.

The Loss of Dual Protection Against Unsafe Drugs

While the Michigan immunity law has been devastating to individual Michigan families affected by harmful drugs, the impact of the FDA's new rule will be catastrophic to the health and safety of all

Americans, not just those who have suffered directly.

As it stands now, Americans are able to rely on more than just the troubled FDA for keeping unsafe drugs out of the marketplace. As Dr. Henry Greenspan, a professor of social psychology and social ethics at the University of Michigan, who has been at the forefront of the effort to repeal the drug immunity law in Michigan described it this way, "Consumers have had two distinct but complimentary

"Consumers have had two distinct but complimentary protections against dangerous drugs, those being the FDA and the civil justice system."

protections against dangerous drugs, those being the FDA and the civil justice system."

The threat of civil actions has long been a safeguard against industry miscon-

duct, and the drug industry is no exception. Dr. Greenspan pointed out in an op-ed he published in the *Ann Arbor News*, the one-time chief counsel for the FDA, Margaret Porter, had even stated that the "FDA's view is that FDA product approval and state tort liability usually operate independently, each providing a significant, yet distinct, layer of consumer protection."

With the new rule shielding drug companies from state court actions, the necessary level of protection provided by the threat of civil suits has been eroded. Only with tougher drug safety regulations, as well as the repeal of laws like the one in Michigan, will we avoid the type of situation we are now seeing with so many unsafe drugs on the market.



90 Broad Street
Suite 401 New York, NY 10004
Phone: 212.267.2801
Fax: 212.459.0919
E-mail: centerjd@centerjd.org
Web: <http://centerjd.org>

IMPACT

Editor:
Daniel Albanese

Contributor:
Patrick Buckley

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The Trouble With Not-So Blind Trusts *continued...*

The Current Status of Blind Trusts

“Blind trusts,” while widely employed by federal lawmakers, are undertaken on a voluntary basis and regulated by the congressional ethics committees. Under the law, the beneficiary or lawmaker in this case must be notified when any of the original stocks they placed in the trust are sold. They are also provided with annual reports detailing the status of their overall holdings. Additionally, beneficiaries entering into these trusts can at any point request that a particular stock be liquidated, under the guise of ensuring they avoid any conflict of interest.

In other words, blind trusts are never completely “blind,” or beyond the knowledge and control of the member of Congress. This has led to a situation in which legislators can knowingly vote on laws in which they have a vested interest, while still being able to claim that their holdings are in a federally sanctioned blind trust.

Frist Looks Out for His Own Interests

Since being elected to the Senate in 1994, Sen. Frist has been one Congress’ strongest advocates for legislation that would, among other things, significantly limit the liability of hospitals and insurance companies in medical malpractice cases. Such laws would benefit HCA, presumably increasing its stock price, as well as one of the country’s largest medical malpractice insurance companies that it owns, HCI. Yet while the

Senator has stood to gain from such legislation, which he pushed to the Senate floor for votes and in fact voted on several times, he has been able to deflect questions about the apparent conflict of interest by stating that his stock portfolio was in a “blind trust.” Frist has also fought “patients bill of rights”

legislation that would have allowed patients to sue their HMOs, currently prohibited under federal law.

As he told CNBC in 2003, “as far as I know, I own no HCA stock.” However, records show that over the years he received 15 or so letters telling him about the companies in which he held shares in blind trust. Frist claims he did not pay attention to these letters but that matter continues to be under investigation, although he has twice been cleared of Senate Ethics violations, although new requests for further Ethics Committee investigations are pending. And Public Citizen has now called for additional investigations by both the Senate Ethics Committee and the S.E.C. after the disclosure of documents showing that Senator Frist’s family also founded and had interests in another company, American Retirement Corporation.

A Widespread Phenomenon

As has been reported in the press, a large number of con-

gressmen and senators have substantial personal wealth as well as stock holdings. According to published reports in 2004, fully one in three Senators, as well as one in four House Members, were considered to be millionaires.

As for stock holdings, the Foundation for Taxpayer and Consumer Rights released a 2005 report showing that in the health care sector alone - an industry that is substantially affected by the actions of Congress - “42 senators - 27 Republicans and 15 Democrats -

held pharmaceutical stock worth between \$8.1 and \$16 million in 2004. Senators earned an additional \$2.5 to \$7.2 million in capital gains and dividends, and two senators’ spouses also earned salaries from pharmaceuticals.”

The New York Times reported in 2005 that “32 senators have disclosed stakes in pharmaceutical or medical device companies, 24 in companies that sell malpractice insurance and 27 in hospital companies or health care providers.”

Under Senate rules, Senators are prohibited from “aiding the progress” of legislation with “a principal purpose” of benefiting their family financially. Despite this fact, in session after session, the Senate has engaged in votes that affect this industry and senators who have a demonstrated vested interest take part.

For example, a report released in 2006 by Public Citizen exposed just how much deference the drug industry is shown by members of Congress in the present environment. The report shows

how drug industry lobbyists were at the eleventh-hour able to insert their own language, verbatim, into a Defense appropriations bill granting drug manufacturers total immunity from prosecution in instances when their drugs were utilized to fight pandemics.

The Elimination of Vested Interests

As it stands now, Senators and Congressmen are participating in votes that they know will directly affect their pocketbooks. As the above statistics show, a large portion of Senators and Congressmen can be expected to continue voting in favor of the drug industry and against protecting Americans, even when it serves them personally. Until there is real, substantial reform of the ethics laws governing “blind trusts,” making them both mandatory and completely in the hands of a third party, lawmakers personal stock holdings will continue to be a corrupting influence in our federal government.



Blind trusts are never completely “blind,” or beyond the knowledge and control of the member of Congress.



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