

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

CENTER FOR JUSTICE & DEMOCRACY
****NEWS****

Dear Friends,

We're having a party!

That's right, among a host of crazy things happening this year, it's the Center for Justice & Democracy's 10th Anniversary and we're having a cocktail reception in Philadelphia this summer to celebrate!

You can join us at the University of the Arts (next to the Kimmel Center) on Sunday July 13 from 5-7 pm.

Over the last 10 years, we are proud of all we have accomplished. Starting from scratch in 1998, we created the first national consumer rights organization exclusively dedicated to protecting the tort system, fighting attempts to weaken it and trying to reverse the damage done to the legal system by the tort "reform" movement. We've come a long way since then, and have every intention of continuing our efforts for years to come.

And we think it's time to celebrate! So do join us. See the back page for more details.

Thank you!

Sincerely,

Joanne Doroshov
Executive Director

IN THIS ISSUE: NEW IMMUNITIES

FDA PROBLEMS CONTINUE

On November 8, 2007, actor Dennis Quaid and his wife Kimberly celebrated the arrival of healthy twins Thomas Boone and Zoe Grace. Twelve days later, the new parents were wondering whether their babies would survive. The infants had received life-threatening overdoses of blood-thinning medication while in the hospital to treat a staph infection. The nurse was supposed to clean their IV lines with 10 units of Hep-Lock, an anti-clotting medication that contained a very small dose of heparin. Instead the newborns were injected with 10,000 units of heparin, 1,000 times the dose they should have been given. This mistake was made twice.

The massive overdoses turned the twins' blood into the consistency of water, causing it to flow from every place they had been poked or prodded. As a result, for over a day, the babies bled

profusely and suffered severe bruises from internal bleeding, all the while screaming in pain. Their blood's inability to clot literally remained off the charts all day and into the night. It took more than 40 hours for the newborns' clotting levels to drop into the measurable scale, eventually falling back within normal range.

Soon after this near-fatal tragedy, the Quaid's learned that a bottle of 10-unit Hep-Lock and a bottle of 10,000-unit heparin - both manufactured by Baxter Healthcare - were virtually indistinguishable in terms of their labels and shape. The Quaid's also discovered that only 14 months earlier, in September 2006, three babies had died and three were severely injured after receiving overdoses at an Indianapolis hospital because of the similar labels.



(continued on page 2)

MILITARY MADNESS

In October 2003, 25-year-old Staff Sgt. Dean Witt underwent routine surgery for acute appendicitis at the Travis Air Force Base hospital. Minutes after the procedure was over, when Witt was being moved to a recovery room, he gasped and stopped breathing. When a student nurse failed to resuscitate him, Witt's gurney was wheeled into a pediatric area where staff attempted to revive the 175-pound Witt using lifesaving devices meant for children. The errors continued, as Witt was mistakenly given double doses of a powerful stimulant and hooked up to a breathing tube that pumped air into his stom-

ach. By the time a breathing tube was inserted correctly, Witt had suffered severe brain damage. Three months later, he was removed from life support and died, leaving behind a wife and two children, including a 4-month-old son.

In March 2007, 21-year-old Petty Officer Nate Hafterson was admitted to the Naval Hospital Jacksonville after passing out in his barracks from low blood sugar. After being treated for that condition, Hafterson's breathing didn't immediately return to normal, so

(continued on page 3)

Although Baxter was aware of the incidents in Indianapolis, it took more than four months for the company to send hospitals a warning about the potential for deadly mix-ups of its Hep-Lock and heparin products. And it wasn't until August 2007 - seven months after it had issued a warning - that Baxter submitted changes in the labeling of its 10,000-unit heparin to the FDA. Since FDA regulations didn't require prior agency approval to revise the label, Baxter started using its new heparin labels in October 2007. Yet the company never recalled the older heparin bottles that were still on the market and in hospitals, like Los Angeles's Cedars-Sinai where Thomas Boone and Zoe Grace were being treated.

When the Quaid's filed a lawsuit against Baxter in California state court, the manufacturer filed a motion to dismiss, arguing that it could not be sued since

the drug had been approved by the FDA. The Supreme Court is set to rule on a case next term that may decide that very issue, potentially affecting the lives of all Americans.

Every year there are over 2 million serious adverse drug reactions (ADRs). Of this total, an estimated 100,000 people die from ADRs, making it one of the leading causes of death in the United States. The FDA is charged with ensuring the safety and efficacy of new prescription drugs, helping speed innovations that make medicines more effective and safer and ensuring the public gets the information they need to use medicines effectively. Clearly, the FDA is not doing its job. Why?

User fees. Federal legislation allows drug manufacturers to pay the FDA "user fees" to speed up review of their products. These "fees" are a huge portion of the agency's budget for regulating drugs. For example, "user fees" totaling \$380 million account for more than half of the FY 2009 budget for the Center for Drug Evaluation and Research, the FDA office that oversees drugs. Making the FDA financially beholden to the industry it's supposed to regulate has given drug companies and their lobbyists a great deal of influence over FDA decision-making and policy.

Biased drug advisory panels. FDA committees that recommend drugs for market often include several members with financial ties to the company whose drug is up for approval, creating clear conflicts of interest that jeopardize public health and safety. This was the finding of an April 2006 study by Public Citizen as well as a February 25, 2005 front-page article in the *New York Times*.

Culture of secrecy. Time and again, the FDA has failed to inform the public about the agency's drug review process, post-market safety concerns or issues surrounding a drug's effectiveness, making it difficult for Americans to make informed choices with their health care providers. And even when the FDA

believes a drug is risky, the agency has been unwilling to ask for strong warnings because companies typically oppose them and the FDA would rather avoid years of delay. As former FDA medical officer Dr. John Guerigan testified at a 2008 trial over the schizophrenia drug Zyprexa, "We at the FDA know what we can obtain and we cannot obtain. We have many, many problems, and we have a management system - what we can't obtain we will not ask."

More disturbing, however, is the fact that many FDA drug-safety officers have been punished or ignored after uncovering drug dangers. As reported in the June 11, 2007 *New York Times*, this happened to safety researchers reviewing the diabetes drug Avandia and a similar drug Actos, both of which were shown to cause heart failure; antidepressants that led some children to become suicidal; the antibiotic Ketek which caused serious illness and death in certain patients; and the painkiller Vioxx which significantly increased the risk of heart attack, stroke and sudden death.

Weak oversight. The FDA has no systematic way to monitor the safety of drugs once they've been approved. There are no regular public assessments or disclosures of post-market safety reviews, no clear timelines that force the FDA to act quickly on reports of drug problems and no requirements that the agency submit regular reports on its adherence to these goals. It often takes voluntary reports of injuries or deaths from doctors and patients for the FDA to undertake post-market study of a drug. Moreover, the agency does not have the money and infrastructure to run or commission its own drug trials. And although there is an FDA office charged with post-market surveillance, it lacks the funding, independence and authority to do its job effectively.

Inadequate policing. The FDA cannot, with few exceptions, force a manufacturer to conduct safety studies once a drug is on the market. It also lacks the

(continued on back page)



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MILITARY MADNESS continued...

doctors decided to insert a tube in his throat and prescribed a common muscle relaxant for the procedure. Within one minute of being given the medication, Hafterson's heart rate went up to 160 beats per minute and his body temperature spiked to 105 degrees. It took three phone calls before doctors found the medicine needed to revive him but it was too late. By the time they administered the antidote, several hours had passed since Hafterson's initial reaction and his muscles were now leaching potentially fatal levels of potassium into his bloodstream. He went into cardiac arrest and died before he could be moved to a civilian hospital to have the potassium taken out.

If Witt and Hafterson had been civilians and gone to non-military hospitals, their families would be able to sue for the negligence that caused their deaths. Yet because these men devoted their lives to the Armed Forces, there is no recourse. Under the Supreme Court's "Feres Doctrine," active-duty service members and their families cannot sue the military, even for non-combat-related deaths like medical malpractice.

Many have called the doctrine unconstitutional since its inception 57 years ago. Among the most significant opponents, Supreme Court Justice Antonin Scalia, who wrote in a 1987 dissent that "Feres was wrongly decided, and heartily deserves the 'widespread, almost universal criticism' it has received."


On May 19, 2008, Congressman Maurice Hinchey (D-NY) announced legislation that would reverse this injustice. The Carmelo Rodriguez Military Medical Accountability Act of 2008 (H.R. 6093) would allow active-duty service members and their families to sue the federal government for damages after death or injury resulting from negligence, the failure to act or wrongful acts in health care provided by the military. The bill is named for a 29-year-old U.S. Marine sergeant who died after military doctors repeatedly misdiagnosed his skin cancer.


"Joining the military should not mean that one has to give up his or her right to hold medical providers accountable," said Hinchey. The Act will "finally bring accountability into the military medical system and afford our service members and their families the same rights that the rest of us have when it comes to medical malpractice," explained Hinchey, adding that this bill "helps encourage the military to take the steps needed to improve its care so that no one else ever has to go through what the Rodriguez's have endured."


H.R. 6093 should become law. As General George Washington wrote in 1775, "When we assumed the Soldier, we did not lay aside the Citizen."





GOOD AND BAD: IMPACT PAGE 3 A BRIEF MED MAL UPDATE


New York. In May, Governor David Patterson proposed legislation that would authorize the state's Office of Professional Medical Conduct to, among other things, reveal the names of physicians who have been accused of malpractice and routinely monitor medical malpractice claims and payouts to see if a doctor should be investigated. The legislation would also require HMOs and other health plans to report when they have terminated a contract with a doctor because of impairment or misconduct. 

North Carolina. In June, the state medical board will vote whether to post doctors' malpractice information on its website. The site would disclose the existence of malpractice payments dating back to 2001 and whether the board had publicly disciplined the doctor. 

Oklahoma. In April, Governor Brad Henry vetoed legislation that would have required injured victims to first obtain certificates of legal merit from experts in order to sue a professional for negligence. 

Tennessee. In May, Governor Phil Bredesen signed into law a bill requiring a medical expert to validate the merits of a medical malpractice case within 90 days of filing suit. The legislation also mandated that patients give doctors 60 days' notice before filing a lawsuit. 

Oregon. In May, the state supreme court upheld a five-year statute of limitations on medical malpractice lawsuits involving minors. 

Virginia. The state's Birth-Related Neurological Injury Compensation Program continues to be a disaster. According to a March 6, 2008 article in the *Washington Post*, Virginia is still scrambling to find funds for the program, which remains the exclusive remedy for catastrophically injured newborns who are delivered in a participating hospital and/or by a participating physician. 

FDA PROBLEMS CONTINUE continued...

power to fine companies that fail to carry out promised post-approval safety studies, which allows drug companies to renege on such pledges without consequence. In addition, the FDA has little control over how drugs are distributed and marketed to doctors and consumers, nor can it fine drug makers for false or misleading drug advertisements. The pharmaceutical industry also has a say in all drug label changes, which can take far too long, as was the case with Vioxx. And as for taking drugs off the market, the FDA can only suspend drug sales under extraordinary circumstances and is slow to remove approved drugs from the shelves even when evidence shows them to be unsafe.

Given the state of today's FDA, it is extremely troubling that the Supreme Court is considering wiping out lawsuits over FDA-approved drugs. Banning such suits - a goal of pharmaceutical

companies and the Bush administration - would not only deny victims redress but also eliminate the last consumer mechanism standing in the way of unsafe drugs reaching the marketplace or the public's learning about them. As former FDA Commissioner David Kessler testified on May 14, 2008 before the House Oversight and Government Reform Committee, "My greatest concern with preemption [i.e. immunity] is that it would, I believe, dramatically reduce the incentives for manufacturers to act quickly and responsibly to detect, analyze, investigate, and take action on potentially serious and life-threatening adverse reactions once a drug is on the market."

Barring civil lawsuits would also remove one of the most effective tools for alerting the FDA about dangerous drugs. As reported on the front page of the April 6, 2008 *New York Times*, "For

years, top officials at the agency acknowledged that lawsuits could aid the agency's oversight of safety issues. In the last decade, suits over Zyprexa, the withdrawn pain pill Vioxx, the withdrawn diabetes medicine Rezulin, the withdrawn heartburn medicine Propulsid and several antidepressants have shown that companies played down the risks of their medicines and failed to disclose clinical trials to the public even as they have aggressively marketed their drugs."

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 drug industry if the Supreme Court gives them immunity from civil lawsuits. Hopefully Congress will step in and enact legislation that protects the rights of injured patients.



CENTER FOR JUSTICE & DEMOCRACY'S 10TH ANNIVERSARY

COCKTAIL RECEPTION

Please join us as we celebrate CJ&D's decade of service and honor the supporters who make our work possible.

Sunday, July 13, 2008
5pm - 7:30pm

The University of the Arts
320 S. Broad Street, Philadelphia
(Located next door to the Kimmel Center)

For more information or to RSVP:
212.267.2801 or daniel@centerjd.org

Purchase two tickets to receive a discounted CJ&D Associate Membership. Reception tickets are \$250. Contributions to CJ&D are tax-deductible.

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