

Consumers Can No Longer Sue Drug Companies For The Harm Caused By Any FDA-Approved Drug

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The lawlessness of the FDA, Big Pharma immunity, and crimes against humanity (opinion)

June 30, 2006 is a day that will be long remembered as a dark milestone in the history of FDA and its campaign against health consumers. On June 30, an FDA "Final Rule" goes into effect, establishing a regulatory power grab of such scale and scope that it attempts to bypass all laws, the will of Congress and fundamental protections for consumers. This "Final Rule," which may as well be called a "Final Solution" for drug consumers, claims that consumers can no longer sue drug companies for the harm caused by any FDA-approved drug, even if the drug's manufacturer intentionally misled the FDA by hiding or fabricating clinical trial data.

In one blatantly illegal act, the FDA is attempting to pull off the greatest Big Pharma coup of all: The outright elimination of any responsibility whatsoever for the suffering and death caused by deadly pharmaceuticals.

In the preamble of the FDA's new "Final Rule" to take effect on June 30, the agency asserts that FDA approval of prescription drugs -- and their implied safety -- may no longer be second-guessed by consumers or organizations of any kind. The FDA's stamp of approval, the agency claims, is an absolute declaration of safety of all such drugs, for any use whatsoever, including off-label use (the use of drugs on health conditions that were never tested in clinical trials).

But such a position has no basis in law. During a June 6, 2006 hearing, a New Jersey state court judge Carol E. Higbee characterized the FDA's preamble as, "a political statement by the FDA" and explained that the ploy has, "...nothing to do with science. ...It is contrary to the U.S. Supreme Court's decisions. It is contrary to all the law on preemption. ... In addition to being contrary to the law of the land, it is also contrary to the Constitution of the United States."

The FDA is dangerous to America

That this outrageous assertion by the FDA would take place at a time when so many Americans are routinely killed by the harmful side effects of prescription drugs only contributes to the arrogance and absurdity of this rogue agency that has now become the No. 1 threat to the health and safety of the American people. Even a terrorist nuclear attack on a major U.S. city would not equal the number of Americans who have already been killed by the negligent actions of the FDA.

FDA-approved prescription drugs injure 2.2 million and kill approximately 100,000 Americans each year, according to peer-reviewed published studies, and more realistic estimates put the number of deaths at over 200,000 people annually in the United States alone (see Death By

Medicine for detailed statistics). Vioxx, according to senior FDA drug safety researcher Dr. David Graham, appears responsible for the deaths of over 60,000 Americans, and further deaths due to beta blockers, antidepressant drugs, statins and other medications continue to mount by the hour.

The resulting FDA body count of American casualties makes the casualties of war look small in comparison. The Vietnam War claimed the lives of approximately 50,000 Americans (plus many more Vietnamese), and a memorial in Washington D.C. honors those who died. But FDA-approved prescription drugs have killed well over a million Americans, yet no memorial will be built, no honors bestowed, and now the FDA would deny the families of those victims their legal right to fight for any sort of compensation.

It's not like these consumers were killed by enemy gunfire in a foreign land; they were killed by American companies, on American soil, with the full permission and approval of an American regulatory agency! The enemy from within is, indeed, far more dangerous than any foreign threat to the lives of American citizens. Not since World War II have so many Americans died from a single, common, preventable cause, and it almost seems that the FDA has declared war on the American people and is using chemical weapons to win that war.

The scourge of dangerous prescription drugs, combined with willful collusion at the FDA, has now created a chemical holocaust on U.S. soil that will continue to claim the lives of mothers, fathers, daughters and sons until the American people demand that justice be served and that the FDA / pharmaceutical industrial complex be dismantled and condemned through some modern-day equivalent of the Nuremberg Trials. How many millions more have to die from this chemical holocaust before this reign of medical terror is brought to an end?

The ramifications of the FDA's Final Rule

The FDA's new "Final Rule" would allow drug companies to operate with impunity, shouldering absolutely no responsibility for the harmful (even fatal) side effects of their prescription drugs, many of which we are now learning were only approved under highly suspicious circumstances that smack of fraud, corruption and outright criminal intent. Consumers harmed or killed by toxic prescription drugs -- even drugs that their manufacturers knew were extremely dangerous -- would have no recourse whatsoever.

If such a rule were to go unchallenged, the degree of profiteering by Big Pharma would be unprecedented. Free to charge monopoly prices thanks to the FDA-enforced domestic drug racket that outlaws international competition, and unburdened by the financial risk of lawsuits from consumers harmed by their drugs, Big Pharma would be emboldened to unleash a dystopian era of unprecedented disease mongering, bribery of doctors, false advertising and the mass drugging of children, adults and seniors alike... with absolutely nothing to hold them in check.

This result may, in fact, have been the intention all along. This "Final Rule" appears to be little more than a thinly-veiled attempt to establish wide-ranging authority where none exists by burying it in the language of a drug labeling rule. A more detailed legal criticism is offered by Karen Barth Menzies, an attorney at Baum Hedlund in Los Angeles:

On Wednesday, Jan.18, 2006, the Food and Drug Administration issued new regulations

regarding the labeling of prescription drugs, including regulations aimed at providing doctors and patients with clearer information about the risks associated with prescription drugs. However, in the preamble to these new regulations, the FDA inserted conclusory and legally unsupported statements that tort lawsuits alleging a failure to warn of known or reasonably knowable safety risks are preempted by federal law. This attempted power-grab by the FDA wholly ignores the prerogative of Congress, contradicts both statutory and case law precedent, disregards the parallel but distinct roles played by FDA and tort liability law, fails to provide an avenue through which consumers may be compensated for drug-induced injury, neglects any federal replacement of applicable state policing and enforcement procedures, and shirks constitutionally established principles of federalism which protect the jurisdiction granted to states in matters involving public safety and health. By inserting preemption language into the Final Rule without an official consultation with state and local government groups concerning the preemption language, the FDA also violated Executive Order (E.O.) 13132. (When an Executive department or agency proposes to act through adjudication or rule-making to preempt State law, the department or agency shall provide all affected States notice and an opportunity for appropriate participation in the proceedings. Exec. Order No. 13132, [[4(e), 64 Fed.Reg. 43255, 43257 (1999). According to the National Conference of State Legislatures (NCSL), the preemption language inserted into the preamble of the Final Rule is a thinly veiled attempt on the part of FDA to confer upon itself authority it does not have by statute and does not have by way of judicial ruling. The NCSL called FDA's action an abuse of agency process and a complete disregard for our dual system of government.

The fallout of the FDA's "Final Solution"

The ramifications of this "Final Rule" action by the FDA cannot be overstated. If this rule is allowed to stand, it represents the end of health justice, the end of the power of Congress, and the surrender of absolute power to an agency of such arrogance and evil that it has conducted armed raids on vitamin clinics, organized the raid of a church, and even ordered the destruction of recipe books it didn't want to see published. (Supporting documents are available for all of these statements).

The FDA, through its willful negligence, is indirectly responsible for the deaths of more Americans than all terrorists, murderers and drunk drivers combined. As the deaths continue to mount, and drug companies become even more aggressive with outlandish disease mongering and advertising efforts, the FDA rears up to unleash a new wave of corporate terrorism upon the American people by emboldening drug companies to care even less about the safety of their synthetic chemical products, most of which cause harm by their very nature of being foreign to the human body.

As Menzies explains:

Pharmaceutical industry lobbying efforts and zealot tort reformers have sired a new wave of brazen attempts to shield drug manufacturers from tort liability. The preemption language in the preamble to the Final Rule is but the latest attempt. Preemption has become the argument du jour and politically appointed regulatory officials the mouthpieces. The crafty messages sound of consumer protection, but are just the opposite. Limiting the liability of drug companies will not improve public safety. The FDA's purported position on preemption assumes that the FDA is infallible and that negligent misconduct by pharmaceutical

companies should be the sole purview of FDA. Recent regulatory failures demonstrate that FDA is neither infallible nor does it have the capability of policing drug manufacturers negligent misconduct.

Want to see the real FDA at work? Read the story of Rezulin, and you'll be shocked to learn the truth about the real agenda that drives this rogue agency.

The end is near for the Big Pharma / FDA racket

Why would the FDA engage in such an obviously unlawful power grab? Because Big Pharma co-conspirators have realized that lawsuits threaten to bankrupt the drug companies. The products of these companies are so universally harmful, and their ability to hide this truth is slipping away so rapidly, that the financial burden of settling lawsuits (or defending them in court) threatens to crush the entire pharmaceutical empire.

Merck alone is defending itself against literally thousands of lawsuits from just one drug: Vioxx. As the truth emerges about the dangerous side effects from the long-term use of other widely-prescribed drugs, class action lawsuits will reach a momentum that will make the Big Tobacco settlements seem like a friendly game of Friday-night poker.

Truth be told, there is not enough money in the world to pay for all the pain, suffering and death that has already been caused by prescription drugs, and if drug companies are held responsible for even a small fraction of the patients their products have harmed and killed, they will rapidly fall from the most wealthy corporations in the world to the most bankrupt, both financially and morally.

And so the FDA is jumping in with one last, desperate attempt to cast a spell of immunity over all drug companies in order to preempt the coming flood of class action lawsuits. But even this effort will fail, as the truth about the dangers of prescription drugs can no longer be censored. Through a tidal wave of new books, documentaries and health websites, consumers are learning the shocking truth about Big Pharma and the FDA, and the beginning of the end of the age of chemical medicine is already under way.

Reading suggestions: *The Truth About the Drug Companies* by Marcia Angell, M.D., *Psyched Out* by Kelly Patricia O'Meara, or *Death by Prescription* by Ray Strand.

You see, the arrogance and greed of drug companies will ultimately be their downfall. They have pushed too hard, too far, and they have landed themselves in a realm of such obvious scientific fraud and criminal negligence that the backlash is inevitable. The rampant disease mongering, the mass drugging of schoolchildren with amphetamines, the false claims of drug ads, the bribery of doctors, the collusion at the FDA... it's all coming to the surface now, and by the time this house of cards comes tumbling down, the resulting criminal trials against drug company executives and FDA officials will make the Enron trials sound like a high school debate.

It is not only inevitable that drug company executives and FDA senior officials will do prison time for their crimes against humanity, it is important that they be loudly condemned via such punishments for knowingly defrauding, harming and ultimately killing countless Americans in

exchange for one thing: Corporate profits.

American medicine is now the shame of the world, and the conduct of senior officials at the FDA is nothing less than criminal. There is now no greater threat to the health and safety of the American people than the U.S. Food and Drug Administration.

"As currently configured, the FDA is not able to adequately protect the American public. It's more interested in protecting the interests of industry. It views industry as its client, and the client is someone whose interest you represent."

- Dr. David Graham, senior drug safety researcher at the Food and Drug Administration, and Vioxx whistleblower

Original story can be found here:

<http://www.newstarget.com/z019497.html>