

Testimony of Sidney M. Wolfe, MD
Director, Public Citizen's Health Research Group (HRG)
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Hearing on Current Issues Related to Medical Liability Reform
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Chairman Deal and Members of the Subcommittee, thank you for the opportunity to testify today. Under the most perfect circumstances, if the FDA were actually doing as good a job as possible at preventing the approval of drugs and other medical products whose benefits are known to be outweighed by their risks and, as expeditiously as possible, removing such products when such risks are discovered after approval, this legislation would still unfairly punish patients and their families.

I will focus on substantial evidence, based on our more than 33 years of oversight over the agency, demonstrating that the FDA is far from doing an adequate job protecting the public from such products, making the impact of this legislation even more disastrous to potential victims.

HRG Medical Officer Survey / FDA Study / Inspector General Study

In late 1998, prompted by many drugs with clear evidence of dangers not being adequately regulated, we surveyed FDA medical officers who were the primary reviewers in the Center for Drug Evaluation and Research (CDER) for new drug applications. The responses, from 53 FDA physicians, included 27 instances cited in which the FDA medical officer thought a drug too dangerous to be approved but approval occurred over their objection. Seventeen medical officers described the current standards of FDA review for safety and efficacy as "lower" or "much lower" compared to those in existence prior to 1995. And several medical officers said they had been instructed by their superiors to censor their reports or presentations.

A study in 2001 by the FDA itself, precipitated by high turnover rates among scientists and physicians in the agency, showed that about one-third of medical officers did not feel comfortable expressing differing scientific opinions, and a similar number felt that decisions adverse to a drug were stigmatized within the agency. A number of reviewers said that decisions should be based more on science and less on corporate wishes.

A subsequent study by the HHS Inspector General in 2003 confirmed that decisions concerning drug safety and effectiveness were being overturned. Eighteen percent of surveyed FDA physicians and scientists felt pressure to recommend that drugs be approved for sale despite their reservations about the drug's safety, efficacy or quality. The report concluded: "Overall, these findings present a significant warning signal."

Specific Examples of Dangerously Poor FDA Regulation

Rezulin (troglitazone-diabetes drug)

- March, 1997: U.S. Rezulin marketing begins
- Dec, 1997: drug withdrawn in UK after 130 cases of liver damage including six deaths, mainly in the US
- July, 1998: Health Research Group petitions FDA to ban Rezulin after 560 cases of liver damage, including 26 liver deaths
- March, 1999: FDA advisory committee meeting: now 43 liver deaths
- early, 2000: Some FDA physicians state drug should be banned
- March, 2000: Rezulin is withdrawn in the US; by then, 63 liver deaths, seven liver transplants

Trovan (trovafloxacin-antibiotic) Like two other drugs also approved in 1997, the painkiller Duract (bromfenac) and the diabetes drug Rezulin (troglitazone), (now both off the market) there was also clear evidence of liver damage caused by Trovan (in animals and in humans) before the drug was approved in December 1997. In one study prior to approval in which the drug was used to treat prostatitis, almost 10% of the men (14 out of 140) given the drug developed evidence of liver toxicity. With eight other drugs in the fluoroquinolone antibiotic family available in the U.S, as well as dozens of other safer and equally or more effective drugs for infections, the removal of Trovan from the market would not have deprived doctors or patients of a drug that could possibly be considered indispensable. Instead of banning Trovan as was done everywhere else in the world, the FDA chose to “limit” its use in the United States to patients who were either hospitalized or in nursing homes. At the time of our petition in 1999 to ban the drug, there were eight cases of liver failure, including five deaths and three liver transplants. There are now a total of 56 cases of liver failure, including 29 deaths and nine people requiring liver transplants.

Baycol (cerivastatin-cholesterol lowering) Approximately one year before Baycol was removed from the market in August 2001, its manufacturer Bayer, using FDA data on other statins found that Baycol had 20 times more reports of rhabdomyolysis (an often-fatal destruction of muscle) per million prescriptions than Lipitor. An FDA official, feebly excusing FDA’s belated ban, stated that “We weren’t aware at that point of the difference between Baycol, and the other similar [drugs]. Our expectation is when a company becomes aware of a specific problem with their drug, they come to us.” By the time Baycol was banned, there were 1,899 cases of rhabdomyolysis, a significant number having occurred between the time there was unequivocal evidence that FDA should have banned the drug and when it was actually banned a year later.

Crestor (rosuvastatin-cholesterol lowering) Despite the Baycol disaster, and some chemical similarity between Baycol and Crestor, the FDA approved Crestor in August 2003, knowing that prior to approval there had already been 7 cases of rhabdomyolysis in clinical trials, compared to none in

clinical trials prior to Baycol's approval (or that of any other statin). In addition to this risk, which AstraZeneca (Crestor's manufacturer) and the FDA wrote off as limited to the highest (80 mg) dose that was subsequently not approved, the drug also causes unique kidney toxicity, even in people who did not have rhabdomyolysis that can lead to secondary kidney damage. An FDA medical officer reviewing dozens of cases of blood and protein in the urine and several cases of renal insufficiency/renal failure in people using Crestor before approval said "if they [these findings] are the signals for the potential progression to renal failure in a small number of patients, this may represent an unacceptable risk since currently approved statins do not have similar renal effects." Since Crestor came on the market, there have been more than 100 cases of rhabdomyolysis reported to the FDA, a rate per million prescriptions that is higher than any of the other statins still on the market. In addition, there have been approximately 40 cases of renal failure in people without rhabdomyolysis, a rate approximately 75 times higher per million prescriptions than that of the other statins combined.

Vioxx (rofecoxib-NSAID) A study published more than four years ago showed a four to five-fold increase in heart attacks in people using Vioxx compared to those using naproxen. As a result, we asked FDA for a black box warning four years ago. Although such a warning would have greatly reduced the toll of tens of thousands of heart attacks occurring between then and Vioxx's withdrawal, the agency, to the pleasure of Merck, rejected a black box and chose not to adequately warn the public. Many lives were thus lost.

Bextra (valdecoxib-NSAID) When we learned almost two years ago that FDA had rejected Pfizer's application for a new pain indication for Bextra, the agency, in collaboration with Pfizer, denied our freedom of information request for the FDA review as to why the application had been rejected. We thus had to sue the FDA to obtain these data. The medical officer who reviewed the study stated that "The excess of serious cardiovascular thromboembolic [blood clots] in the valdecoxib arm of the CABG [Coronary Artery Bypass Graft] trial is of note as the entire study population received prophylactic low dose aspirin as part of the standard of care in this setting to minimize just such events. Given the emerging concern over a possible pro-thrombotic action of certain agents in the COX2 class, these data are of concern."

Meridia (sibutramine-weight reduction) Both the FDA medical officer who reviewed the new drug application for the amphetamine-like weight reduction drug Meridia and the FDA advisory committee were opposed to the drug's approval because of safety concerns such as increased blood pressure. Since approval, there have been reports of a total of 56 cardiovascular deaths in people using Meridia, a large proportion of whom were under the age of 50.

If this legislation is enacted, it will represent the third prong of a three-pronged attack on patients' safety involving the FDA and the drug and device industries:

The two prongs involving the FDA are, as discussed in the above examples, inadequate regulation over the introduction and market removal of unsafe drugs and a sharp (85%) decrease from 1998 through 2004 in FDA enforcement actions concerning illegal prescription drug ads—distorting the power of information into misleading doctors and patients about risks and benefits of drugs. The third prong, reducing the “regulation” of drug and device companies by lessening their liability for injuries and deaths to patients, is all the more onerous in the face of such lax FDA activities. Unless all three forms of “regulation” are allowed to operate in a maximal way, patients will not be adequately protected.

In addition to the four drugs discussed above that are still on the market in this country, all of which we have petitioned the FDA to ban, the newly published edition of our book, *Worst Pills, Best Pills* and our web site, WorstPills.org both list 176 other prescription drugs that we and our consultants urge that people DO NOT USE and discuss safer alternatives to each of these.

Comments Regarding Draconian Limits the House Proposes to Placed on Patients’ Medical Malpractice and Products Liability Lawsuits

Ensuring safe drugs for Americas’ consumers is not just predicated on a strong regulatory system at the FDA. The role of the civil justice system is equally important. Without strong state laws that enable patients and consumers to hold medical providers accountable for negligence or errors, the medical industry – including the drug companies – will have much more incentive to cut corners in pursuit of profits and will have much less incentive to be vigilant about patient safety.

For this reason, Public Citizen strongly objected to the two identical omnibus medical malpractice bills voted approved by the House last Congress (H.R. 5 and H.R. 4280). As it is likely that the same legislation will soon be before this committee and the entire House, I would like to provide our perspective on how inadvisable it is.

This legislation is remarkable in that its provisions not only apply to medical malpractice lawsuits against doctors, hospitals and HMOs, but also to pharmaceutical companies and medical device companies when their products injure or kill. In this way, the legislation is also a product liability bill.

The cumulative effect of the provisions would be to limit the ability of patients to recover for serious injuries and also to limit the ability of patients to find lawyers willing to take their cases. As a result, drug and device companies would have less incentive to ensure that their products are as safe as possible and that adverse effects are known *before* the products are marketed – a consequence that will threaten the health and well-being of us all.

The two bills introduced in the last Congress proposed to cap non-economic damages at \$250,000. Non-economic damages compensate people for pain and suffering—sometimes a lifetime’s worth—resulting from permanent and significant injury such as brain damage, paralysis, disfigurement, or lost childbearing ability. For example, this cap would affect patients with significant kidney damage from a drug such as Rezulin, permanent incapacitating back injury caused by a broken spinal screw, or children who lost their young father from a heart attack induced by a CoX-2 pain reliever. Cases seeking compensation for such injuries are not “frivolous” cases—the usual justification offered by President Bush and others for imposing a damages cap. And a \$250,000 cap will have its biggest impact on the cases that are the most deserving of large compensation—something the legislation’s proponents claim they do not intend. Moreover, because the bill would not allow the damages to account for inflation, its arbitrary limits would become more unjust with each day.

In addition, the two bills introduced in the last Congress would have virtually eliminated the ability of injured patients to recover punitive damages. Punitive damages are awarded to punish and deter serious and wanton wrongdoing. Although they are awarded in only a small fraction of civil cases, the threat of punitive damages is important to deter reckless disregard for patient safety. Last year’s legislation would have eliminated punitive damages *entirely* in cases against drug and medical device companies or restricted them to instances in which the plaintiff could show that the company had marketed the product without FDA approval or that it had committed fraud to get FDA approval. Because prescription drugs and medical devices cannot be sold legally without FDA approval, this latter proposal effectively bans punitives.

Litigation against Merck is still in its early stages, but it may unearth very incriminating documents showing that the company knew Vioxx posed a serious danger to a significant number of patients, that the company knew that Vioxx had limited, if any, improved efficacy over ibuprofen, but that, to protect the company’s investment, the company engaged in a cover-up of information that would have saved lives. If what I have posited about Merck is true, would the American public support sparing a company that engages in such unethical conduct from punitive damages? I can’t imagine it.

The proposal to apply a one-year statute of limitations, running from discovery of the injury, will provide another hurdle to the ability of injured consumers to bring suit. The law in most states starts the limitation period running from the discovery of the *malpractice*, not discovery of the *injury*. This distinction is important because an injury will frequently manifest itself well before its cause is known. For example, the association between the anti-depressant Serzone and liver toxicity was not widely known until 2002, years after the drug came on the market in 1995. The injured party should not have to twice bear the cost of this defective product.

The two medical malpractice bills also would have changed state rules of joint and several liability, leaving patients with no recovery for the share of damages assigned to an uninsured, underinsured, or bankrupt defendant. The doctrine of joint and several liability says that when two defendants, such as a doctor and a hospital, are both found liable for negligence, a plaintiff may collect the entire award from either defendant if the other is unable to pay its share. In essence, the legal system recognizes that the wrongdoing could not have occurred without the participation of all parties and, therefore, that all parties should be accountable for making the victim whole.

Next, by instituting a “periodic payment rule” for future damages over \$100,000, the legislation would allow defendants and insurance companies to string out payments for future damages over the life expectancy of the victim, rather than having to pay up front. Thus, even after the civil justice system has determined that the money rightfully belongs to the plaintiff, defendants and insurers would be able to invest and earn interest on a large piece of the plaintiff’s damages award. Victims would be left to cope with new and unexpected expenses attributable to their injury, such as changing medical costs or increased transportation costs. The bill would provide no protection to the victim if his or her needs change or if the defendant drug manufacturer’s insurance company becomes insolvent.

Finally, the cap on plaintiffs’ attorney fees payable under contingent fee arrangements will drastically cut back on the ability of patients with limited means to get qualified legal counsel. As a result, patients’ ability to bring product liability cases against drug and device companies, which have massive resources to defend themselves, will be reduced significantly.

Medical malpractice and product liability cases are very risky for plaintiffs’ attorneys for three reasons: the costs are especially high, the likelihood of prevailing is quite low compared with other types of tort actions, and the lawyers do not get paid unless they win. But limiting plaintiffs’ attorney fees will create an enormous imbalance in favor of the defendant. While we may disagree on the need for damage caps, we should all be able to agree that our legal system should remain a fair and balanced forum accessible to all Americans.