



Why “Shield Laws” Are Bad for Oklahomans

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“Shield laws” limit liability for companies whose products were in compliance with federal or state safety laws and regulations before the product was offered for sale. Proposed legislation would create “shield laws” to protect manufacturers of drugs and medical devices. If enacted, this law will hurt consumers who purchase these products because companies will have no incentive to remove unsafe products from the marketplace. It is easiest to illustrate this harm using U.S. Food and Drug Administration (FDA) shield laws as an example.

- **Product approval is not a guarantee of safety.** There are many examples of FDA approved products that that were later proven to be extremely dangerous. The most recent, and most publicized example involved the drug Vioxx. The medication was approved by the FDA in 1999, then removed from the market five years later due to safety concerns. More than 20 million people had taken Vioxx during that time, and between 88,000 and 139,000 Americans suffered a heart attack or stroke as the result. This was by no means an isolated incident. Pharmaceuticals¹ and medical devices² are routinely shown to be unsafe despite government approval. Oklahoma’s proposed shield laws would protect big companies from responsibility when their products fail on the market, no matter how many Oklahomans die, or how egregious the manufacturer’s negligence.
- **The integrity of the product approval process is often compromised by politics.** Even though the government is supposed to rely on accurate information when deciding if a product is safe, the integrity of FDA research is often compromised by conflicts of interest. In a recent survey of government scientists, hundreds reported significant political interference with FDA research.³
 - 61% knew of cases in which the “Department of Health & Human Services or FDA political appointees have inappropriately injected themselves into FDA determinations or actions.”
 - 60% knew of cases where “commercial interests have inappropriately induced or attempted to induce the reversal, withdrawal or modification of FDA determinations or actions.”
 - Only 51% feel the “FDA is acting effectively to protect public health”
 - 20% have been asked “explicitly by FDA decision makers to provide incomplete, inaccurate or misleading information to the public, regulated industry, media, or elected/senior government officials,” and 26% feel they are implicitly expected to “provide incomplete, inaccurate, or misleading information.”
 - 18% responded “I have been asked, for non-scientific reasons, to inappropriately exclude or alter technical information or my conclusions in an FDA scientific document”



- **Political conflicts of interest aren't the only problem.** The Institute of Medicine recently identified critical issues of concern regarding the accuracy of FDA product safety testing, including the following:
 - Clinical trials are based on study populations that are different in composition and health status from populations that will use the marketed drug
 - The inaccurate perception that approval is based on a “high degree of clarity and certainty about a drug’s risks and benefits”
 - Varying interpretations from the FDA’s general counsel’s office have led to “significant variation” in using conditions on sale as a condition of approval⁴
- **Even congress doubts the veracity of the government’s product approval process.** A recent congressional investigation found that the FDA flouted the supervision of lawmakers⁵ in their effort to identify the following “systematic” problems with FDA research:
 - “Scientific dissent is discouraged, quashed, and sometimes muzzled inside the FDA”
 - The “FDA’s relationship with drug makers is too cozy. The FDA worries about smoothing things over with industry much more than it should with its regulatory responsibilities.”
 - “Inside the FDA there’s widespread fear of retaliation for speaking up about problems.”
 - “Public safety would be better served if the agency was more transparent and forthcoming about drug safety and drug risks.”⁶
- **The government has little power to assure a product’s safety after it has been approved for release on the open market.** FDA rules and policies have long held that a company can later change the manufacture or labeling of a dangerous product without any requirement to make sure it continues to meet federal safety standards..⁷ This critical flaw in the product approval process was highlighted in two recent studies that detailed FDA ineffectiveness.⁸ As FDA approval fails to ensure how a product will be manufactured, used, or labeled, it makes little sense that manufacturers would be granted immunity from liability simply because of their original FDA approval.
- **Compliance with the FDA’s minimum warning requirements does not satisfy the manufacturer’s common law duty to warn the consumer.** It is a widely held view the FDA sets minimum standards, and these minimum standards do not necessarily complete the manufacturer’s duty.⁹ Compliance can be used as evidence of negligence, but it does not mean that the defendant was free of negligence, since the defendant still owes a duty to warn of dangers. Creating a rebuttable presumption against liability would essentially reduce a manufacturer’s duty to the public.



¹ Other dangerous drugs which the FDA approved include the pain medication Zomax; the anti-depressant Merital (withdrawn from the market within six months of its approval, and when approved by the FDA there had been thirty deaths associated with its use), the blood pressure medication Selacyn (caused sixty deaths and over 500 cases of liver damage); the arthritis drug Oralflex (withdrawn from the market after four months and an estimated fifty deaths); and most recently the drug Ketek (approved by the FDA in 2004, but has since been linked to fatal liver failure. (Annals of Internal Medicine, vol. 144, issue 6, “Brief Communication: Severe Hepatotoxicity of Telithromycin, March 21, 2006.)) Pending more investigation, the FDA has left Ketek on the market. Nevertheless, in February 2007, the FDA announced that it had determined the balance of benefits & risks no longer supported two of the three previously approved indications, announced revisions to Ketek’s labeling, and added a “boxed warning.”

² Heart valves manufactured by Shiley, Inc. received FDA approval in 1979, and stayed on the market for ten years, even though there was proof that the valves tended to leak and fracture. By January 1990, 389 people had suffered heart valve fractures, and 248 people had died.

³ Union of Concerned Scientists, *Voices of Scientists at FDA: Protecting Public Health Depends on Independent Science* (2006).

⁴ Institute of Medicine, *Assessment of the U.S. Drug Safety System* (2006).

⁵ Statement of U.S. Senator Chuck Grassley of Iowa, *The Adequacy of FDA Efforts to Assure the Safety of the Drug Supply*, Subcommittee on Oversight and Investigations, House of Representatives Committee on Energy and Commerce, February 13, 2007.

- FDA has “disregard for Congress’ responsibility to conduct oversight.”
 - (1) Denied access to documents requested by subpoena, often without saying what had been withheld or why.
 - (2) Subpoenas compel a privilege log, but the FDA will not provide one.
 - (3) In what was provided, FDA redacted whole pages & paragraphs, but do not explain why.
- Despite resistance, investigation has revealed:
 - (1) “FDA gave its advisory committee questionable data on Ketek and did not tell them about problems with that data.”
 - (2) “FDA approved Ketek without much safety data from the U.S.; the agency relied almost exclusively on foreign, post-marketing safety data.”

⁶ *Id.*

⁷ 21 C.F.R. 814.39(d)

⁸ Institute of Medicine, *Assessment of the U.S. Drug Safety System* (2006).

- Imbalance in the regulatory attention and resources available before and after approval
- Organizational and cultural problems hinder post-approval drug safety activities
- Further study commitments are often not met and not even undertaken
 - 1997 Modernization Act required annual updates on progress of postmarketing study commitments, but no additional resources or authorities were provided to enforce
 - 47% of annual reports due were not submitted (2005)



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- FDA has no recourse when sponsors don't report on these commitments, and are not a high priority in the FDA
 - FDA lacks authority & enforcement tools after approval. The FDA has only a limited ability to ask for and negotiate with manufacturers on these regulatory matters, i.e. label changes, marketing, and distribution restrictions
 - FDA can request changes, but the manufacturer does not have to comply. The FDA has to resort to negotiating with the manufacturer, which can be a long process with the potential for adverse safety repercussions.

⁹ *Edwards v. Basel Pharmaceuticals*, 1997 OK 22, ¶¶ 17, 20, 933 P.2d 298.