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No Court of Last Resort?

FDA Preemption Removes Fear of Liability, Likely Increasing Risks of Harm

Until recently, the U.S. Food and Drug Administration (FDA) officials recognized the importance of product liability suits: “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.”¹ The Bush Administration spearheaded an aggressive legal campaign to protect corporations from liability suits²—as does Michigan’s 1995 shield law.³ Now, cigarette, medical device, and drug manufacturers are all seeking immunity from product liability by invoking the “preemption” (“supremacy”) argument to prevent citizens who have been injured from seeking compensation. Immunity would apply to companies that concealed evidence about their products’ hazardous—even lethal—effects from FDA, physicians, and the public. The preemption defense is a radical departure in a democracy whose citizens have the right to judicial review.⁴ Preemption has nevertheless met with some success: On February 20, 2008, the Supreme Court ruled in favor of Medtronic (8–1)⁵, accepting the argument that FDA approval of a medical device preempts most personal injury lawsuits under state law.

Preemption promoters argue that FDA surveillance alone provides adequate safety. The argument presumes FDA infallibility and overlooks the fact that analysis of all the evidence by independent scientists with different points of view is an essential part of the scientific process. FDA drug evaluation

is limited to assessing the premarketing clinical trial data submitted by manufacturers to determine short-term toxicity and whether a drug produces an effect on a target symptom. Companies have a commercial interest in representing their products’ safety in ways favorable to sales. Drug companies are responsible for communicating their products’ risks; FDA can guide this process, but cannot guarantee that a company will adequately and appropriately warn about the risks of its products.

Information from FDA about Product Risks

Does the FDA currently provide the American public complete and accurate information about the risks of products it regulates? FDA relies on data submitted by manufacturers—without independent validation of completeness or accuracy. Although authorized to prosecute reporting violations and hold top executives criminally accountable, FDA rarely (if ever) exercises that authority.⁶ Lawsuits reveal whether all trial findings were reported to the FDA and made public, or, whether safety information was obscured, ignored, denied, delayed, disguised, or—in the most egregious cases—knowingly suppressed or falsified.⁷

In 2002, FDA’s antidepressant label disclosure requirements were criticized, with demands for the release of unpublished safety/efficacy data for independent review. FDA turned drug safety policy on its head by filing

Amicus Curiae briefs⁸ in liability suits in support of Pfizer and GlaxoSmithKline arguing: “Any warning of a causal relation between Zoloft and suicide would have ‘misbrand[ed]’ the drug . . . Had Pfizer given a warning as to a causal relation between Zoloft and suicide, FDA would have disapproved that warning.”⁹ In 2003, Wyeth added a label warning, informing doctors that data linked its antidepressant Effexor (venlafaxine) to increased risk of suicidal thoughts in young patients. FDA objected, requiring Wyeth to remove that warning, replacing it with a general directive to monitor all patients taking antidepressants.¹⁰ When examined independently,¹¹ data in FDA’s possession warranted the addition of a Black Box warning.

Inexplicably, the preemption battle is being waged when the agency is beset by scandal and its professional and public reputation is at an all-time low.¹² The Institute of Medicine (2006)¹³ painted a devastating picture of a dysfunctional agency unable to ensure the safety of the nation’s drug supply: “the regulator has been ‘captured’ by the industry it regulates” and “the agency is less willing to use the regulatory authority at its disposal.” FDA’s pre-marketing safety assessment¹⁴ was deemed “obsolete,” “antiquated,” and “ineffective”; its postmarketing monitoring “disorganized,” “bureaucratic,” and “dysfunctional.” On March 4, 2008, Senator Charles Grassley asked the General Accounting Office to investigate FDA’s approval of drugs based on surrogate endpoints and its postmarketing practices.

On March 26, 2008, FDA Commissioner Andrew von Eschenbach, who fielded repeated Congressional criticism, acknowledged, “Peril exists.” “The FDA may fail in its mission to protect and promote the health of every American.”¹⁵

Ultimately, the pivotal question is: What is in the best interest of American society?¹⁶ If manufacturers are absolved from disclosing newly discovered lethal drug hazards not required by the FDA, no one will bear responsibility for catastrophic consequences that full disclosure might have prevented.

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Drug safety disasters have involved aggressively advertised, widely prescribed drugs;¹⁷ 18 were recalled for safety reasons¹⁸—among them, Vioxx (rofecoxib)¹⁹ and Trasyolol (aprotinin).²⁰ Dozens more required added warnings—including the class of antidepressants and antipsychotics. Drug safety disasters demonstrate FDA’s failure to ensure disclosure of vital data, validating the need for independent checks and balances. GSK concealed Avandia (rosiglitazone) data (2001–07) linking its best selling diabetes drug to increased cardiovascular events and deaths.²¹ FDA conceded: “The specific violations . . . are serious and may be symptomatic of underlying postmarketing safety reporting failures.”²²

Lawsuits Uncover Vital Drug Safety Evidence²³

The discovery process afforded only by litigation is our most effective tool for disentangling the scientific evidence—i.e., quantifiable drug safety information—from marketing hype,⁷ and uncovering deceptive practices that endanger the safety of all consumers. “Litigation has helped the medical community reassess drugs by bringing to light new information about adverse effects.”²⁴ The contentious 17-year debate about the safety of SSRI antidepressants came to a head when the New York State Attorney General charged GSK with fraud for failure to disclose pediatric data showing Paxil (paroxetine) lacked efficacy but increased a sui-

cide risk. Only then did FDA require Black Box label warnings acknowledging a twofold increased risk.

Zyprexa (olanzapine), approved for schizophrenia (1996) with only “proof in principle” of efficacy,²⁵ is Eli Lilly’s best selling drug. Zyprexa lawsuits opened a Pandora’s box of documents,²⁶ confirming the drug’s life-threatening risks, including, diabetes and hyperglycemia.²⁷ Diabetes specialists warned (2000): “Unless we come clean on this, it could get much more serious than we might anticipate.” Lilly executives responded: “We will NOT proactively address the diabetes concerns.”²⁸ Lilly then promoted Zyprexa for unapproved uses: “We must seize the opportunity to expand our work with Zyprexa in [the] child-adolescent population.”²⁹

Lilly has paid more than \$1.2 billion in two sealed class action settlements. Nine State Attorneys General filed suits—including a criminal suit under the federal Racketeering Influenced and Corrupt Organizations Act.³⁰ Charges include: “fraudulent clinical trials; an unlawful marketing campaign; payments to public officials; bogus educational events and ghostwritten promotional articles summarizing suspect studies”; and “knowingly misrepresenting and deceptively concealing the risks associated with Zyprexa.”

Fear of litigation is a safeguard acknowledged by Alan Goldhammer of the Pharmaceutical Research and Manufacturers Association: “There is also a liability concern[sic] for the company that also means that they need to address all safety considerations promptly.”³¹ Preemption would eliminate that “liability concern” by absolving manufacturers from disclosing accurate, emerging drug safety information. Such data are inaccessible to the scientific community, but are accessible through the judicial process.

Eliminating judicial review would give FDA unilateral control over drug safety information that companies disclose to doctors without independent validation. Doctors’ prescribing practices would be governed by outdated FDA label assessments. In essence, a demonstrably dysfunctional Big Brother

agency would dictate physicians' prescribing decisions by restricting the information that companies disclose to physicians. Are physicians prepared to surrender their professional decision-making to a government agency?

The Supreme Court is scheduled to rule on two cases invoking FDA preemption and involving Philip Morris and Wyeth. Each company argues that its product should be shielded from personal injury suits because they were approved for use by a federal agency. If the Court immunizes the pharmaceutical industry against liability, the integrity of drug safety and the very foundation of evidence-based medicine will be undermined.

Medicine depends on access to accurate, scientifically verifiable information. If that information is inaccurate, incomplete, or dishonest, then the medicine is untrustworthy. The Court should not sanction an FDA oversight system whose flaws are measurable in the approval of dozens of unsafe drugs that continued to be marketed long after their hazards were known to manufacturers and FDA.^{13, 14, 22, 26} In short, for millions of Americans, when it comes to safety of the drugs they depend upon, the courts should be available, even as a last resort.

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- See www.supremecourtus.gov/opinions/07pdf/06-179.pdf; See also <http://ahrp.blogspot.com/2008/02/us-supreme-court-favors-big-pharma.html>.
- Two cases from the 1980s involved the drugs Oraflex (Eli Lilly) and Selacryn (SmithKline). In both cases, the companies admitted that (a) their drug killed people in pre- and postmarketing use and (b) they did not report those deaths to the FDA. What the companies also argued was that they simply "neglected" to report the deaths. The FDA

- believed the evidence developed mainly in civil litigation, which showed knowing and willful coverup and pressed for criminal felony prosecution. Lilly was convicted of 25 misdemeanor counts, with a resultant fine of \$25,000. See Greenspan, H. 2007. Testimony submitted in support of HB 4044, Judiciary Committee of the Michigan House, Feb. 2007.
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