Center for Justice & Democracy
90 Broad Street, Suite 401
New York, NY 10004
Tel: 212.267.2801
centerjd@centerjd.org
http://centerjd.org

WYETH V. LEVINE - KEY FINDINGS

On March 4, 2009, the U.S. Supreme Court ruled in a 6-3 decision, *Wyeth v. Levine*, that drug companies were not immune from liability for injuring or killing patients with unsafe drugs. Moreover, they found that lawsuits were critical for both supplementing the Food and Drug Administration (FDA)'s efforts to ensure drug safety and compensating those who are injured.

Among the Court's key findings are:

Drug safety, including the adequacy of a drug's warning label, is the "ultimate responsibility" of the manufacturer "at all times."

> "It has remained a central premise of federal drug regulation that the manufacturer bears responsibility for the content of its label at all times. It is charged both with crafting an adequate label and with ensuring that its warnings remain adequate as long as the drug is on the market."

Congress never meant to wipe out lawsuits for those who are injured, and in fact, both Congress and the FDA have encouraged such lawsuits to supplement FDA regulation.

- There has been a "longstanding coexistence of state and federal law and FDA's traditional recognition of state-law remedies."
- "As it enlarged the FDA's powers to 'protect the public health' and 'assure the safety, effectiveness and reliability of drugs, Congress took care to preserve state law'" and "state common-law suits 'continued unabated despite FDA regulation.'"
- "Congress did not provide a federal remedy for consumers harmed by unsafe or ineffective drugs … Evidently, it determined that widely available state rights of action provided appropriate relief for injured consumers. It may also have recognized that state-law remedies further consumer protection by motivating manufacturers to produce safe and effective drugs and to give adequate warnings."
- "State tort suits uncover unknown drug hazards and provide incentives for drug manufacturers to disclose safety risks promptly."
- State tort suits "serve a distinct compensatory function that may motivate injured persons to come forward with information."

"Congress did not intend FDA oversight to be the exclusive means of ensuring drug safety and effectiveness."

- "The FDA has limited resources to monitor the 11,000 drugs on the market and manufacturers have superior access to information about their drugs, especially in the postmarketing phase as new risks emerge."
- "[T]he FDA long maintained that state law offers an additional, and important, layer of consumer protection that complements FDA regulation."

The policy of the Bush administration to try to eliminate tort rights in "preambles" of federal regulations is not supportable and does not "merit deference."

- "[T]he FDA's 2006 preamble does not merit deference" because the public had "no notice or opportunity to comment"; is "at odds with the available evidence of Congress' purpose; and it reverses the FDA's own longstanding position that state law is a complementary form of drug regulation without providing a reasoned explanation including any discussion of how state law has interfered with the FDA's regulation of drug labeling during decades of coexistence."
- "[T]he FDA's recently adopted position that state tort suits interfere with its statutory mandate is entitled to no weight."