

WEDNESDAY

THURSDAY

FRIDAY

MONDAY

TODAY

Questions and Comments

TODAY'S COLUMNS

LIBRARY

NEWS

RULINGS

VERDICTS

Search >>

Tuesday, July 16, 2013

Previous

Next

Bookmark Reprints

Between a rock and zero liability

Erwin Chemerinsky is dean and distinguished professor of law, Raymond Pryke Professor of First Amendment Law, University of California, Irvine School of Law.



Amidst the flurry of end of term decisions in late June, one which may have been overlooked has a frightening message that can affect all of us: think carefully before you take generic drugs. In *Mutual Pharmaceuticals Co., Inc. v. Bartlett*, 133 S.Ct. 2466 (2013), the court held that makers of generic drugs cannot be sued for

design defects. This follows the court's decision two years ago in *Pliva v. Mensing*, 131 S.Ct. 2567 (2011), which held that generic drug manufacturers cannot be held liable on a failure to warn theory. The effect is to give broad immunity to makers of generic drugs, even when patients suffer horrible injuries.

Mutual Pharmaceuticals is the third case in the last several years to deal with whether claims against drug companies are preempted by federal law. In *Wyeth v. Levine*, 555 U.S. 555 (2009), the court held that a drug company could be held liable on a failure to warn theory even if the warning label had been approved by the Food and Drug Administration. Justice John Paul Stevens wrote the opinion in a 6-3 decision and concluded that tort liability would further the underlying regulatory goal of protecting consumers. The court explained that drug companies always can engage in more speech to inform consumers and physicians of dangers, including take out ads in the media, writing dear doctor letters, and asking the FDA to change the warning label.

But two years later, in *Pliva v. Mensing*, the court held that makers of generic drugs cannot be sued on a failure to warn theory. The case involved a drug sometimes prescribed for those with diabetes to speed digestion. It is now known that in about 30 percent of cases prolonged users will suffer horrible irreversible neurological side effects. But the court, in a 5-4 decision with Justice Clarence Thomas writing for the majority, concluded that suits against generic drug companies on a failure to warn theory are preempted by federal law.

Justice Thomas, joined by Chief Justice John Roberts and Justices Antonin Scalia, Anthony Kennedy, and Samuel Alito, reasoned that the Food and Drug Act allows a generic drug to be sold so long as they are chemically the same as the brand name drug, and so long as it has the warning label approved for the brand name drug. The court said that because the generic drug had to have the warning label approved for the brand name drug and could not change it, a suit on a failure to warn theory was preempted by federal law.

Justice Sonia Sotomayor wrote a vehement dissent, joined by Justices Ruth Bader Ginsburg, Stephen Breyer, and Elena Kagan. She said that it made no sense to allow a suit against the maker of a brand name drug and bar a suit against the maker of a generic which is the identical chemical compound. The dissent argued that the majority was undermining the goal of Congress: protecting consumers.

In *Mutual Pharmaceuticals v. Bartlett*, the court extended *Pliva v. Mensing* and

Government

Court worker unions take on court's use of service contractors with bill

Court workers' biggest battle this legislative session could be AB 566, a bill that would severely curtail courts' ability to contract with third-party companies for services instead of using unionized staff.

Litigation

Attorneys for lead paint makers say Bay Area counties using 'hindsight' to seek damages

A trial against lead paint makers kicked off Monday with defense attorneys arguing that their clients did not know 40 years ago what they do today about their products harming children.

Mergers & Acquisitions

Sullivan represents AT&T in bid to buy San Diego wireless carrier

Sullivan & Cromwell LLP is representing AT&T Inc. in its prospective acquisition of San Diego-based prepaid wireless provider Leap Wireless International Inc. for \$1.2 billion in cash.

Law Practice

Orrick grabs former SEC rule writer

Orrick, Herrington & Sutcliffe LLP added a former Securities and Exchange Commission attorney as a capital markets partner. Andrew D. Thorpe, most recently at Morrison & Foerster LLP, helped write the agency's major post-Enron rule changes.

Government

After avoiding cuts, Orange County begins to feel hit to its court system

While court budgets have been hammered up and down the state for some time, triggering closures, layoffs and other belt-tightening, Orange County is just beginning to feel the pressure.

U.S. Court of Appeals for the 9th Circuit Federal arbitration policy withstands challenge from Internet users

The federal courts' strong pro-arbitration policy withstood another challenge invoking state laws, a 9th U.S. Circuit Court of Appeals panel held Monday in a decision out of Montana.

Mergers & Acquisitions

Dealmakers

A roundup of recent mergers and acquisitions and financing activity and the lawyers involved.

found that design defect suits against generic drug makers are also preempted by federal law. Karen Bartlett took a generic form of the prescription pain reliever, Sulindac. She then experiences a horrific side effect, called toxic epidermal necrolysis. Sixty to 65 percent of the surface of her skin deteriorated, was burned off, or turned into an open wound. She spent months in a medically induced coma, underwent 12 eye surgeries, and was tube-fed for a year. She is now severely disfigured, has a number of physical disabilities, and is nearly blind. She sued Mutual Pharmaceuticals on a design defect claim and the jury awarded her \$21 million.

The Supreme Court held that this claim was preempted by federal law. Justice Alito wrote for the court in a 5-4 decision. The court concluded: "In the instant case, it was impossible for Mutual to comply with both its state-law duty to strengthen the warnings on sulindac's label and its federal-law duty not to alter sulindac's label. Accordingly, the state law is pre-empted."

The court explained that New Hampshire law requires that manufacturers not sell drugs, or other products, that are "unreasonably dangerous." The court said that in assessing this, courts look to "the usefulness and desirability of the product to the public as a whole, whether the risk of danger could have been reduced without significantly affecting either the product's effectiveness or manufacturing cost, and the presence and efficacy of a warning to avoid an unreasonable risk of harm from hidden dangers or from foreseeable uses."

The court said that in the context of prescription drugs it would be necessary to redesign a drug to increase its usefulness or reduce its risk of danger. But the maker of a generic drug cannot redesign it; federal law requires that for it to be sold it must be identical to the brand name version. Therefore, Justice Alito reasoned the only way for a generic drug company to reduce the risk would be to strengthen the warning for consumer. *Pliva v. Mensing*, though, held that generic drug companies cannot change the warning label, but instead must include exactly the same warning label approved for the brand name drug.

The result is that makers of generic drugs cannot be sued on a design defect theory or a failure to warn theory. Justice Breyer wrote a dissenting opinion joined by Justice Kagan and disputed the majority's contention that it is impossible to comply with both federal and state law. He said that there was a way for the drug company to do this: cease selling the product in the state or decide to pay the penalty for doing so.

Justice Sotomayor wrote a dissent joined by Justice Ginsburg and strongly objected to the court extending *Pliva* to design defect claims. She said that it was not impossible for a drug company to comply with both federal and state law. She explained that "[a] manufacturer of a drug that is unreasonably dangerous under New Hampshire law has multiple options: It can change the drug's design or label in an effort to alter its risk-benefit profile, remove the drug from the market, or pay compensation as a cost of doing business." She recognized that this may be an "unwelcome choice" for a manufacturer, but she said that "it is a choice that a sovereign State may impose to protect its citizens from dangerous drugs or at least ensure that seriously injured consumers receive compensation."

From the perspective of tort law, the court's decisions in *Pliva v. Mensing* and *Mutual Pharmaceuticals v. Bartlett* are deeply disturbing. Makers of generic drugs cannot be sued for failure to warn or a design defect, no matter how badly the drugs injure people. From the perspective of preemption law, this makes no sense because it was Congress's goal to protect consumers from the harms of prescription drugs. It was precisely for this reason that *Wyeth v. Levine* held that tort liability of drug companies furthered the underlying regulatory goals of the Food and Drug Act.

According to the FDA, nearly 80 percent of all prescriptions are filled with generic drugs. When there is a generic equivalent to a brand name, over 90 percent of the time a generic is prescribed. All who take generic drugs are at risk; if they are injured from the drug, they will not be able to recover.

Pliva v. Mensing and *Mutual Pharmaceuticals v. Bartlett* involved the Supreme Court interpreting federal statutes. Congress can remedy this by revising these statutes to make clear that makers of generic drugs can be sued, just as makers of brand name drugs, for claims based on failure to warn or design defects. Such statutory changes are truly essential to protect all of us.

Intellectual Property

Latham beats Quinn Emanuel in patent trial

A little more than two months after officially joining the Menlo Park office of Latham & Watkins LLP, Douglas E. Lumish scored a patent infringement trial victory in Oakland late Friday for New York-based TransPerfect Global Inc.

Government

Former governors rally to halt court-ordered prisoner release

Four former California governors have allied themselves with Gov. Jerry Brown in his quest to stay a recent federal court order demanding the reduction of roughly 9,600 inmates from state prisons.

California Supreme Court

State high court won't stay resumption of same-sex marriage

The state Supreme Court denied a request Monday by proponents of Proposition 8 to immediately halt the resumption of same-sex marriages in the state.

Bankruptcy

San Bernardino seeks ruling on bankruptcy eligibility

Nearly a year after filing for bankruptcy, San Bernardino city leaders want to know once and for all whether the city is eligible for Chapter 9 protection. A judge is set to hear arguments next month on the municipality's eligibility.

U.S. Supreme Court

Between a rock and zero liability

Since generic drugs are regulated by the Food and Drug Act, the U.S. high court has ruled that design defect and failure to warn suits are both preempted by federal law. By **Erwin Chemerinsky**

Tax

IRS looks to US high court to resolve circuit split

Is severance pay "wages" or not? Circuits are split, and the IRS has petitioned the Supreme Court to get an answer. By **Robert W. Wood**

Criminal

'Not guilty' was the jurors' only option

My intention here is not to celebrate the tragic death of a 17-year-old boy. Rather, it is to explain why the jurors were left with no choice given the evidence in this case. By **Lou Shapiro**

Why defend criminals you know to be guilty?

So many times we in the legal profession hear the question asked: "How can you defend those

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[Previous](#) [Next](#)

criminals - particularly if you know they are guilty?" We should respond that the answer is at least fourfold. By **James P. Gray**

What happened to a jury of our peers? What happened to the requirement that juries represent a cross-section of the community, particularly in a case dripping with racial division, controversy and animus? By **Aram James**

Environmental

EPA and logging industry make for odd bedfellows before US high court

The Supreme Court's recent decision regarding stormwater discharges from a logging operation involved a rare alliance between the EPA and the logging industry. By **Jad T. Davis**

Judicial Profile

Judith McConnell

Administrative Presiding Justice California Court of Appeal 4th Appellate District, Division One (San Diego)

Corporate

'Crowdfunding' carries opportunity, risk for small ventures

Copyright infringement, breach of contract, intellectual property disputes, labor code violations, inadvertent tax evasion and fraud are just a few of the issues that have arisen as crowdfunding grows in popularity as a fundraising tool.