The FDA, Preemption, and Public Safety: Antiregulatory Effects and Maddening Inconsistency

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by Lawrence O. Gostin

Most people think of preemption as a technical, constitutional doctrine, but it is pivotally important to health and safety and opens the door to broad judicial discretion. The Rehnquist and Roberts Courts’ jurisprudence, with its support for both business and preemption, has been distinctly antiregulatory, invalidating major state public health rules in occupational safety, tobacco control, and motor vehicle safety, among other things. And apart from these antiregulatory stances, the Supreme Court has also been maddeningly inconsistent. Consider three relatively recent cases.

In its 2008 decision in Riegel v. Medtronic, Inc., the Court held that federal law bars injured consumers from challenging the safety or effectiveness of medical devices approved by the Food and Drug Administration. A year later, however, in Wyeth v. Levine, the Court came to the opposite conclusion, ruling that injured consumers could sue pharmaceutical companies for failing to warn about the risks of taking brand-name drugs. Yet on June 23, 2011, in PLIVA, Inc., v. Mensing, the Court found that injured consumers could not bring failure-to-warn claims for injuries caused by FDA-approved generic pharmaceuticals. Thus, in less than four years, the Court barred state health and safety litigation for FDA-approved medical devices, allowed failure-to-warn claims for branded pharmaceuticals, and then barred those same claims for generic pharmaceuticals.

What is the rational basis for treating brand-name and generic medicines differently when, by law, the products must be equivalent? Or for treating brand-name drugs and medical devices differently even though they go through similar approval processes? As Justice Sotomayor (dissenting in PLIVA) put it, this “leads to so many absurd consequences that I cannot fathom that Congress would have intended to preempt state law,” while even Justice Thomas, writing for the Court, admitted this outcome “makes little sense.”

In order to figure out how we reached this predicament, let’s take a step back and find out more about the perversion of the preemption doctrine, the newest ruling on generic medicines, and the public health value of consumer litigation.

Public Health and Preemption

Preemption is a doctrine undergirded by the supremacy clause, which holds that federal law prevails over state law if there is a conflict. The two cornerstones of preemption are Congress’s intent as the “ultimate touchstone” and the strong presumption against preemption when the state exercises its historic police powers.

The Supreme Court has repeatedly perverted these two key criteria. Congress intended for federal and state food and drug regulation to work side by side, each providing a significant yet distinct layer of consumer protection. If Congress thought state lawsuits posed an obstacle to its objectives, it surely would have said so explicitly at some point during the Food, Drug, and Cosmetic Act’s seventy-year history. How could Congress have intended such irrational inconsistencies between brand-name and generic drugs?

Is it reasonable for the nation’s highest court to conclude that Congress actually intended to bar injured patients from judicial recourse against companies that, knowing the risks, aggressively market hazardous drugs or medical devices? The public might express even greater skepticism if tort immunity were granted to corporations that defraud the agency. But that is precisely the position of the Supreme Court, which permits a corporation to use FDA approval as a shield against litigation even if it deceived the agency into granting that approval. In Buckman Company v. Plaintiffs’ Legal Committee, the Court held that state law fraud-on-the-FDA claims were preempted. The Court split four against four when asked if consumer litigation was also preempted when drug companies defraud the agency. Since Chief Justice Roberts did not participate in the decision, the Court would likely side with the pharmaceutical industry, even if it intentionally hides safety data.

Consumer safety regulation, moreover, is a classic state police power. State public health regulation has a long history and remains a robust activity today. The common law has traditionally granted causes of action for consumer products that are defective or for which companies fail to adequately disclose known risks. And although the Court admonishes against preemption of state safety rules, it did not even mention this doctrine in Riegel, PLIVA, or Buckman.

The Irrational Consequences of PLIVA

In the aftermath of PLIVA, an injured consumer’s access to the civil justice system is even more restricted. PLIVA acts as a virtual shield against litigation for any number of drugs that, once approved, are marketed in a manner that is not disclosed to the agency. The Court’s decision points out an 11-year period during which the Food and Drug Administration approved a pain reliever that produced adverse reactions in some patients. If a patient harmed by the drug is denied a remedy under PLIVA, he or she may be denied a remedy under the common law as well. What do we conclude from this outcome? It is reasonable to believe that Congress thought state lawsuits posed an obstacle to its objectives, it surely would have said so explicitly at some point during the Food, Drug, and Cosmetic Act’s seventy-year history. How could Congress have intended such irrational inconsistencies between brand-name and generic drugs?
system turns solely on “the happen-
stance of whether her pharmacist filled
her prescription with a brand-name
drug or a generic.” Yet 78 percent of
all prescription drugs dispensed are ge-
erics, and with patents expiring this
year on blockbuster drugs like Lipitor,
Plavix, and Zyprexa, the generic market
share will rise further. This is happen-
ing by design—the express purpose of
the Hatch-Waxman Amendments is
to make generic drugs affordable and
available. State law, moreover, autho-
rizes pharmacists to substitute generic
for brand-name drugs when filling pre-
scriptions. Currently, the prescriptions
for more than 90 percent of drugs for
which a generic version exists are filled
with generics. Consequently, most con-
sumers harmed by medications now
lack access to justice.

Generic manufacturers—often large,
multinational companies—now have
little incentive to monitor and disclose
safety risks. Brand-name manufacturers
also may leave the market once the ge-
eric version is available, so no one will
have the incentive to strengthen warn-
ing labels or to remove dangerous prod-
ucts from the market.

The Value of Consumer Safety
Litigation

Why do we need litigation when the
FDA already has a duty to pro-
tect the public’s safety? Lawsuits bring
advantages for the agency as well as for
consumers because gaping resource and
informational deficits hamper its over-
sight. The FDA’s responsibilities are vast
and cover 25 percent of all consumer
spending, including food, drugs, vac-
cines, and medical devices. Yet it lacks
adequate staffing and resources, even as
its mandate and public safety concerns
continue to increase, and it does not
have the information it needs for effec-
tive oversight. Consequently, it is forced
to rely on manufacturers to find and
disclose hazards.

Further hampering the FDA’s over-
sight is the fact that its approval deci-
sions consider relatively small numbers
in clinical trials, so that any given drug’s
full safety and effectiveness profile
emerges only after it is marketed to a
large population. Tort litigants, unlike
the FDA, have subpoena power, and
discovery can be a potent way to inform
the agency and public of undisclosed
risks. Litigation can also be socially and
politically mobilizing: uncovering poor
industry practices can drive regulatory
reform.

These resource and informational
deficits have resulted in high-profile
regulatory failures involving the FDA-
approved COX-2 selective nonsteroidal
anti-inflammatory drugs Vioxx and Ce-
lebrex, the type 2 diabetes drug Avandia,
and the Dalkon Shield intrauterine de-
vice. In 2009, the FDA issued a “black
box warning” about the very drug at
issue in PLIVA—metoclopramide, also
known as Reglan. Litigation revealed
that manufacturers knew the risks but
did not promptly inform the FDA.

State tort law provides a system of civil
justice designed to compensate patients,
deter unreasonably hazardous conduct,
and encourage innovation in product
design, packaging, labeling, and ad-
vertising. Tort law, therefore, closes
regulatory gaps in the FDA’s premarket
approval process, providing much-need-
ed postmarketing surveillance.

In the end, the public is caught in a
catch-22. While the FDA is perceived
as ineffectual and the hazards of widely-
used drugs and devices continue to be
revealed, the Supreme Court makes it
harder for patients to discover wrongdo-
ing—even fraud—and to be fairly com-
pensated for their avoidable injuries.

1. L.O. Gostin, “The Deregulatory State,”
2. Riegel v. Medtronic, Inc., 552 U.S. 312
(2008).
5. L.O. Gostin, “Regulating the Safety of
Pharmaceuticals: The FDA, Preemption, and
the Public’s Health,” Journal of the American
6. Buckman Co. v. Plaintiffs’ Legal Commit-
8. PLIVA, Inc., v. Mensing, No. 09-993, Slip Opinion (2011), at 19 (Sotomayor, J.,
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9. IMS Institute for Health Care Informat-
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