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The Supremacy of Preemption

By ACSH Staff — January 8, 2008

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Patients will benefit if the Supreme Court sides with pharmaceutical companies in two cases this session, establishing the general principle that drug makers can't be sued for unforeseen side effects that emerge after drugs have received Food and Drug Administration (FDA) approval. The alternative is to let pharma slowly be sued into abandoning the introduction of new lifesaving drugs, since new drugs always carry some risk.

The High Court will be deciding, in the next few months, whether the FDA has the power to supersede (preempt) state and local authorities in the regulation of drugs and medical devices. If the Court finds that federal approvals trump states' authority, drugs and medical devices that get through the arduous FDA approval process will be largely protected from liability, absent the intentional manipulation of data. While the Court's ruling in the first of the two cases to which I refer, which involves a Medtronic medical device malfunction, is important, the other upcoming decision may do even more to eliminate frivolous state-level court decisions.

The basis of federal preemption rests with the Supremacy Clause of the U.S. Constitution, which has been interpreted to mean that states are expressly precluded from regulating devices when state regulations--and this applies to jury trials and tort liability as well -- differ in any meaningful way from federal requirements. Thus, it seems that the plaintiffs in the Medtronic case are destined to be rejected by the Supremes, as they were in several lower courts. (These particular plaintiffs may still have recourse to good old medical malpractice claims.)

In the other upcoming case, a group of people who claim to have been injured by the diabetes drug Rezulin--withdrawn by Warner-Lambert in early 2000, shortly before the company was absorbed by Pfizer--want the High Court to allow their lawsuit to be heard. Their case was initially thrown out as violating the preemption policy but reinstated at the Circuit level in the federal appeals system, since the plaintiffs used the issue of drug makers committing "fraud on the FDA" as a basis rather than using mere product liability. Pfizer contends that only the FDA has the authority to litigate such behavior, not the allegedly injured patients.

A Change in the Legal Climate

For the pharmaceutical industry, these cases will determine whether the climate of fear which has chilled new drug development--and FDA drug approvals--will change. Since the Vioxx recall in late 2004, the issue of "safety above all" has dominated the FDA and thus, obviously, the drug manufacturers as well. Fewer new drug applications have been submitted, and fewer still approved, over the past three years than at any prior interval in modern history. A recent trend has been to force applicants to show not only that a drug is safe and effective, as in the past, but that it

is *safer* and *more effective* than older drugs on the market.

If the Court says "enough already" to predatory lawsuits and overgenerous jury decisions--and regulatory bodies are thus inspired to relax a bit as well--perhaps drug R&D will go back to its healthy pace of the "fast-track" approval years of 1997-2003. Even during those years, subsequent serious problems and withdrawals from the market were very uncommon -- perhaps 2%-3% of all new drugs were removed from the market -- while many lifesaving new chemical entities were approved.

The preemption policy at the FDA (the overriding of contradictory state rules), while never formalized in statute, was promulgated by Dr. Scott Gottlieb, then the FDA's Deputy Commissioner for Medical and Scientific Affairs, in early 2006. His position was predictably attacked by various "consumer" groups -- including trial lawyers and Public Citizen, the latter of whom is (not coincidentally) handling the plaintiff's case in the Medtronic lawsuit. The preemption principle has also been ignored by some states -- at least so far.

If the Supremes uphold the preemption policy, fewer tort lawyers will be able to go on fishing expeditions, abusing the "discovery" process in hopes of finding some document or e-mail that will make a drug maker look guilty in the eyes of jurors. Finding such a purported smoking gun is usually an easy task, since the drug development obstacle course typically takes over ten years (and a billion dollars) to navigate, producing plenty of documents and data to sift.

All drugs may have side effects. But their net benefits outweigh their risks, when used appropriately. The decision to allow a new drug on the market should be the FDA's. The decision to prescribe it should belong to the doctor and patient. These decisions should not involve tort lawyers and juries.
