

lowering serum cholesterol or the safety of all NSAID pain relievers (Topol 2004a; Wadman 2007).

Conclusions

The question of whether FDA regulatory rulings should preempt state or common law tort liability litigation for failure to warn and similar allegations turns on the question of whether such litigation would improve the pharmaceutical market in terms of compensation, information, and product safety. For three reasons, the absence of preemption is likely to worsen markets and harm patients on the whole. First, the liability system is an extraordinarily inefficient mechanism to achieve compensation for harms from pharmaceuticals. The attempt to provide compensation through comprehensive liability litigation is likely to burden pharmaceuticals with excessive costs that would raise prices and tend to discourage the use of valuable drugs.

Second, the absence of preemption would make it far easier for litigation to induce new contra-indications and other warnings that on the whole are more likely to cause over-warning and under-use of essential drugs instead of improving the pharmaceutical information environment. One reason is that the pressure for excessive warnings is sufficiently intense that the FDA is unlikely to forego useful warnings, and will sometimes mandate excessively detailed warnings. And third, there is little reason to think that drug safety has suffered in recent years or that FDA incentives are such as to cause the agency to slight drug safety. Indeed, strong forces exert pressure to give too much weight to safety in comparison to approving new drugs and new indications. Further growth in liability litigation would reinforce these tendencies, to the disadvantage of patients, while preemption can provide a valuable check on these adverse consequences of litigation.