Accounting for Prescription Drugs’ Unforeseen Risks: A Regulatory Alternative to Tort Liability

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Abstract

In the context of prescription drugs, tort law is traditionally understood to providing added incentive for drug manufacturers to adhere to regulations of the Food and Drug Administration (FDA) and to account for risks unknown at the time of regulation. However, holding drug manufacturers liable for risks that were unforeseen at the time of FDA approval may lead to a suboptimally high level of risk avoidance. On the other hand, preemption of all tort liability would eliminate valuable incentives created by the tort system for the on-going, post-market monitoring of prescription drugs. I therefore propose an alternate system that would harness the resources of the private sector to invest the optimal amount in researching prescription drugs’ risks and makes this information available to the parties best suited to weigh any newly discovered risks, without holding manufacturers liable for these risks in such a way as to distort the FDA’s social utility determination.