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

The Harvard community has made this article openly available. Please share how this access benefits you. Your story matters

<table>
<thead>
<tr>
<th>Citation</th>
<th>Haley Horowitz, Accounting for Prescription Drugs’ Unforeseen Risks: A Regulatory Alternative to Tort Liability (May 2009).</th>
</tr>
</thead>
<tbody>
<tr>
<td>Citable link</td>
<td><a href="http://nrs.harvard.edu/urn-3:HUL.InstRepos:10015295">http://nrs.harvard.edu/urn-3:HUL.InstRepos:10015295</a></td>
</tr>
<tr>
<td>Terms of Use</td>
<td>This article was downloaded from Harvard University’s DASH repository, and is made available under the terms and conditions applicable to Other Posted Material, as set forth at <a href="http://nrs.harvard.edu/urn-3:HUL.InstRepos:dash.current.terms-of-use#LAA">http://nrs.harvard.edu/urn-3:HUL.InstRepos:dash.current.terms-of-use#LAA</a></td>
</tr>
</tbody>
</table>
Accounting for Prescription Drugs’ Unforeseen Risks:
A Regulatory Alternative to Tort Liability

by

Hayley Horowitz

Harvard Law School
Class of 2009

May 15, 2009

Submitted in satisfaction of the course requirement for
Food & Drug Law, Winter Term, 2009
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.