

[Punitive Damages Legislation Of Interest](#)

Wednesday, May 25, 2011

Thanks to the folks over at the [FDA law blog](#) for tipping us off to interesting provisions of pending legislation that emerged earlier this week from various house committees. The bill, [H.R. 5](#), is part of the ongoing debate over health care, and where it will ultimately go is unclear, but it contains some interesting ideas about punitive damages and it has a raft of sponsors.

There are a variety of provisions governing “health care lawsuits” generally (statute of limitations, caps, contingent fees, periodic payments, *etc.*), but we’re just going to point out those unique to prescription medical product liability litigation. Those are found in section “c” and mostly deal with punitive damages. The bill provides:

- No punitive damages against drug, device, or vaccine makers (or component part makers) where the FDA had allowed the product in the market, whether through “approval, clearance, or licensure,” unless the FDA finds that the defendant did not “substantially comply” with FDA regulations.
- There’s no requirement that the FDA “affirmatively” establish compliance – only non-compliance.
- Plaintiffs can’t name prescribers in the same lawsuit as prescription medical product manufacturers (although court can consolidate separate actions), nor can prescribers be sued in class actions.
- Lawsuits over tamper-resistant packaging must prove “substantial” noncompliance with FDA regulations by “clear and convincing” evidence.
- There’s an exception for fraud on the FDA, which since the legislation is federal, would not seem to be subject to [Buckman](#) preemption.
- There’s an exception for bribery.
- If there’s a conflict with the Vaccine Act, that statute controls.

Like we said, the fate of the aspects of the legislation helpful to prescription medical product manufacturers is tied to the broader issue of health care reform. That’s a subject upon which we have, and will, resolutely decline comment. But we thought that our readers would be interested in legislation that strengthens and extends the compliance defense to punitive damages recognized by a [number of states](#) to all cases involving prescription medical products.