

# A "Disclosure Defense" in Liability Law

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In this time of liability reform, pharma deserves the chance to align its economic interests with its ethical obligations to the patient.

**W**e sell medicine. It's a simple sentence, but let's parse it, anyway.

We, of course, are a heterodox, heterogeneous collection of corporations and flesh-and-blood human beings, of many faiths, and many nationalities. We have various competencies, blind spots, prejudices, and shining virtues.

*Sell* is what we do. Yes, we develop new medicines and test them. In the end, though, we sell.

*Medicine* is the object, the goal. The word describes the products we pour by the billions into bottles and vials; it is also our discipline, a culture devoted to healing the sick.

*Sell* has consumers and "caveat emptor." *Medicine* has patients and the Hippocratic Oath. The two words reflect the two fundamental cultures in our industry. And the tension between them brings us to this month's consideration of tort reform.

It's been a big month for restructuring liability law in the US. In his Feb. 2 State of the Union Address, President Bush outlined a broad effort to reduce medical liability expenses. The transformation aims, it's true, to limit lawsuits against providers, not pharmaceutical manufacturers. All the same, industry organizations across the country (except, of course, for the Association of Trial Lawyers of America) are scrambling to board the bandwagon.

The objectives of the Bush medical liability plan are:

- Reduce punitive awards while speeding up compensation for direct economic losses.
- Limit recoveries for noneconomic damages to \$250,000.
- Reserve punitive damages for cases of egregious misconduct.
- Limit the time in which a plaintiff can file suits.
- Reduce "deep pocket" suits by apportioning judgments according to the defendant's fault, not the ability to pay.
- Eliminate plaintiff "forum shopping."

The Class Action Fairness Act of 2005, signed into law on Feb. 18, quickly addressed forum shopping. The measure moves many large class-action lawsuits out of state courts into the more-

consistent Federal judiciary. (Industry tort-reform groups have branded the most plaintiff-friendly local courts "judicial hellholes"; some hyperactive counties register more lawsuits than voters.)

The Bush medical-liability plan incorporates many features of the Pharmaceutical Research and Manufacturers of America (PhRMA) 2001 tort-reform proposal. One additional element of the PhRMA proposal worth considering is an *FDA Defense*, which would limit punitive-damage claims against makers of FDA-approved products, unless they have withheld relevant product-performance information. (Under PhRMA's proposal, plaintiffs could still receive compensatory damages for lost wages, medical expenses, and pain and suffering.)

So, since liability reform is clearly underway, we would like to add a similar element of our own: a *Disclosure Defense*. The current liability system discourages disclosure, penalizing forthrightness. Right now, whole milliseconds may elapse between the moment a pharma company discloses a drug safety problem and the filing of the first massive class-action lawsuits. At a single stroke, the company sacrifices future sales and all but guarantees substantial litigation and settlement charges against what revenue remains.

There is no incentive to do what the culture of medicine would call the right thing.

A drug company that diligently collects and analyzes safety data at whatever stage and then makes early and frank disclosures should earn some liability protection. A company that delays disclosures (or worse, tries to obscure safety issues<sup>1</sup>) should increase its liability. This is not a new concept: the disclosures on the drug label limit our liability; the Consumer Product Safety Act includes similar carrot-and-stick provisions; and courts grant immunity to persuade witnesses to waive their Fifth Amendment rights and make full disclosures.

We deserve the chance to bring our economic interests into line with our ethical obligation to the patient. **PT**

<sup>1</sup>Note to corporate risk managers: Needlepoint the following on a sampler, frame it, and hang it over your desk: "The cover-up is worse than the crime."