The Liability Maze
The Impact of Liability Law on Safety and Innovation

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Product Liability in Pharmaceuticals: Comments on Chapters Eight and Nine
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Despite the extensive regulatory controls on pharmaceuticals, it is one of the industries most adversely affected by the product liability system. The evidence is mounting that this situation is growing worse in the United States. Our experience appears to be in sharp contrast to that of most other developed countries.

In chapter 3 Viscusi and Moore show that losses notably exceeded premiums for U.S. insurers of pharmaceuticals during the first half of the 1980s. And apparently insurance is becoming less available to pharmaceutical firms. An earlier study by the Rand Corporation found that pharmaceuticals was a leading industry in federal liability suits, with a strong upward trend in the number of case filings in the 1980s.1

There is also evidence that the willingness of pharmaceutical firms to undertake research and development for new products has been adversely affected by product liability concerns in some important therapeutic categories. Vaccines have been shown to be among the most socially beneficial therapies emerging from pharmaceutical R&D. However, the number of U.S. firms undertaking vaccine R&D has declined dramatically. The expected cost from product liability actions is a prime reason for this shift from vaccine R&D.2 Research on contraceptives has experienced a comparable fate in this country.3

1. Dungworth 1988. While the distribution of filings tends to be concentrated in certain products, the effect on industry incentives and decisionmaking can be much more general. For lawsuits can occur well into a product’s market life, can be triggered by unforeseen circumstances, and can involve damages beyond any reasonable expectation in terms of the product benefit-risk profile.

As mentioned, these adverse trends have occurred despite an extensive regulatory umbrella designed to offer strong consumer protection from excessive risk from pharmaceuticals. In particular, all new drug products must receive approval from the Food and Drug Administration before they can be introduced into the marketplace; the clinical research process is subject to direct FDA monitoring; product labeling must be approved by the FDA as part of the new drug application before marketing; and pharmaceutical products can be obtained only by patients through a physician’s prescription.

The United States therefore now has two powerful societal institutions, the tort liability system and regulation, whose effects overlap. Yet little attention has been given to their combined influence on the incentives for risk reduction, innovation, or other objectives. This would hardly seem to be a desirable state of affairs. One would think that the extensive premarket regulation would provide a strong presumption against firm liability in pharmaceuticals and thereby reduce the number of product liability suits relative to those in other industries. However, in her chapter Judith Swazey describes the current situation as one in which FDA regulation serves as a floor rather than a ceiling for tort liability actions. The system basically works in an asymmetrical way. As she notes, regulatory compliance is not a strong shield for defendants to use as a defense against tort liability. But noncompliance is a strong sword for the plaintiffs.

Louis Lasagna’s survey indicates that most other countries have proceeded very differently from the United States.4 They have relied more on social insurance schemes to compensate accident victims and on regulation to provide appropriate incentives for risk reduction. Compared with the United States, they have greatly restricted the scope of their product liability system for pharmaceuticals.

In these comments I compare the tort liability system with regulation in various areas, focusing on the role of each of these social institutions in generating desirable incentives for risk reduction. I conclude by considering the appropriate mix of these public policy alternatives.

Incentives for Risk Reduction

The following table outlines some of the basic characteristics of regulation and tort liability relative to the specific objective of risk reduction.

4. See Shulman and Lasagna 1990 for further discussion of the practices followed in other countries.
Central focus

Regulation

Risks versus benefits

Tort liability

Causality and liability

Ex ante

Ex post

Probabilistic

Deterministic

Regulators and scientific

Juries and judges

advisory committees

Federal

State

Administration

The present U.S. regulatory system is designed to evaluate the benefits relative to the risks of a new drug product before it is allowed to enter the marketplace. An elaborate R&D process has evolved for the scientific testing of benefits and risks, so that it takes an average of twelve years for a new drug to go from first synthesis to regulatory approval and costs more than $200 million. New drug candidates have a large attrition rate as they proceed from the laboratory to animal and human testing. In clinical analysis the product is tested in double-blind trials and measured against the performance of a placebo or alternative therapies. A sufficiently large number of patients are enrolled in the final phase of testing in humans to establish statistical significance regarding a product's benefits and risks.

The timing of this regulatory process is ex ante, or prior to, a product being allowed on the marketplace. Of course, certain rare side effects and long-term effects may not become apparent until a drug has been used in the marketplace by many patients or until considerable time has elapsed. For that reason regulatory reporting and monitoring continue into the postmarketing period. However, the emphasis of our current system is clearly on premarket screening of new drug candidates.

Another important point is that the assessment or risks under regulation is probabilistic. No drug is completely safe or devoid of side effects. The issue is the frequency and severity of any side effects. Specifically, is the risk of a particular toxic reaction 1 in 10 or 1 in 1,000, and how do the overall risks compare with the therapeutic benefits of a new drug? That is the basic trade-off the FDA uses in evaluating whether a new compound can be allowed into the marketplace.

As shown in the table, the decisionmaking framework is very different for tort liability. The process is driven by accident cases that occur after the fact. The focus is on whether the drug caused the adverse event, who is liable, and what damages should be assessed. In contrast to what occurs under regulation, risks are not weighed against benefits in any kind of aggregate social benefit-cost calculus.

Another basic difference is that the decisionmaking process is deterministic for tort liability actions. In particular, courts seek to answer the question whether a preponderance of the evidence supports causality and liability. The courts have been traditionally uncomfortable with probabilistic judgments and assessments of liability on the basis of multiple probable causes even when science leads to such conclusions. Hence tort liability tends to have an "all or nothing" quality in contrast to the probabilistic assessments routinely considered under regulation.

Many drug liability suits are centrally concerned with what warnings about risks were communicated to providers and users. Was a warning of the adverse event included in the product label? If so, was it adequate to properly alert users of the risk? If a warning was not included, should it have been? These questions of course have a large element of subjectivity. One might expect that the FDA-approved warnings would have a strong presumption against liability in an industry like pharmaceuticals, but that is usually not true in tort liability actions.

Regulation and the tort liability system also have different decisionmakers. For regulation the key decisionmakers are trained professionals—regulatory officials and scientific advisory committees. By contrast, the key people in the tort liability system, judges and jurors, are not scientific experts. Scientists do participate in the process as expert witnesses. But in this adversarial process the hired experts often disagree with one another. As a rule, lay persons will have trouble in resolving these scientific disputes objectively. Consequently, many observers have called for a scientific court, or a panel of experts, to assess scientific issues instead of juries. This recommendation, however, has so far received only limited application.

Administration of the tort liability system is also balkanized in the sense that there are fifty separate state systems, each with its own set of higher appellate courts and judges. As a result, inconsistent rulings and different policies may emerge across the various states. That has been true, for example, with respect to long-run latent effects from pharma-

5. Grabowski and Vernon 1983; DiMasi and others 1990.

7. See Swazey's chapter.
Comments on Chapters Eight and Nine

Choosing the Appropriate Policy Mix

The table strongly supports the proposition that regulation is conceptually better suited to the management of societal risks from pharmaceuticals in almost all the areas considered. The drug regulatory process is designed to undertake ex ante evaluations of benefits versus risks and uses scientific experts to assess the relevant evidence. By contrast, the tort liability system occurs after the fact, focuses only on risks rather than benefits, and has lay persons as the main decisionmakers.

A case for a strong tort liability system in pharmaceuticals might be made if one could show that regulators in practice systematically err on the side of excessive risks in their premarket approval decisions. However, a large academic literature indicates that the opposite is true. In our present system regulators have the incentive to avoid type-two errors (acceptance of nonbeneficial drugs) at the possible expense of type-one errors (rejections or delay of beneficial drugs).9 Evidence from several academic studies, using different approaches, suggests that the United States has been on the very stringent end of the regulatory spectrum compared with other countries. At the same time FDA regulation has greatly increased R&D costs and lessened the availability of new drug introductions.10

Given the extensive role of FDA regulation in protecting consumers from risk, a strong case exists for a regulatory standards defense for tort liability actions in pharmaceuticals.11 Under this approach firm liability would be restricted to cases of fraud or deception, essentially cases in which firms submitted false information to regulators in their premarket applications or failed to report new information on side effects in the postmarketing period in a timely fashion in accordance with the current regulations. Tort liability would then reinforce regulatory incentives for risk reduction but avoid the extra costs and disincentives for drug innovation now present.12

Our current liability system is often justified on grounds other than its incentives for risk reduction. In particular, it also serves an insurance function or as a means for the compensation of unexpected product-related injuries. But as a system for compensating drug-related injuries, the tort liability system also exhibits several undesirable properties, including a high variance in outcomes, significant administrative costs, and long delays. These characteristics have caused many other countries to substitute social insurance schemes, often financed from earmarked taxes on the sales of drugs, to provide for compensation of certain drug-related injuries.13 To the extent that the United States wishes to provide societal insurance for drug-related injuries, this approach is a much more efficient and equitable way to do so than the tort liability system. This country has the beginning of such a program in the area of vaccines: the U.S. national vaccine injury compensation program went into effect in late 1988.14 Although it is still too early to evaluate this program, it seems worthy of further development and encouragement.

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8. States have come up with different approaches for dealing with this problem. These include “market share” liability (the Sindell decision in California) and several variants of that approach. At the same time many states have also retained traditional rules for liability requiring identification before any damages can be assessed. Dorfman 1989.


10. For a survey of these studies, see Grabowski and Vernon 1983, 29–48.

11. For an analysis of the relationship between product liability and regulation in other industries, see Viscusi 1988.

12. Free-market-reform advocates have occasionally advocated that drug regulation be relaxed in favor of the tort liability system as a way of lessening the adverse consequences of regulation on innovation. Such proposals, however, have not received serious consideration in the political arena. It is difficult to conceive of such ideas taking root under the present tort liability system.


References


