

Research Brief

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Can Reform Improve the Economic Effects of Product Liability?

Evidence from the Pharmaceutical and Medical Device Industries

When people are injured by drugs and medical devices (like heart valves or IUDs), the product liability system lets them recover damages from the manufacturer—under some circumstances. Product liability aims to provide companies with incentives to make their products safer. But critics of the system claim it has unintended effects with high social costs. These effects include making products less available and useful, increasing prices, and discouraging innovation. Defenders of the system argue that the system is doing its job of making products safer, at an acceptable cost.

In a recent ICJ study, Steven Garber takes a comprehensive look at the economic effects of liability in the pharmaceutical and medical device industries. He concludes that both sides are right—and wrong. The liability system has both good and bad economic effects for society. The policy challenge is to increase the benefits and decrease the costs.

In *Product Liability and the Economics of Pharmaceuticals and Medical Devices*, Garber provides the kind of systematic, analytical information that policymakers need to evaluate proposed reforms by addressing three key questions:

- What are the economic effects of product liability in these industries?
- How does the system produce these effects?
- What kinds of reform could increase the system's benefits while reducing the costs?

The study analyzed four sets of industry outcomes that figure prominently in the liability debate: availability of products, pricing, product safety and effectiveness, and innovation. To measure outcomes, understand company incentives, and draw inferences about company decisions, the study involved synthesis of publicly available information, simulation of innovation decisions, and interviews with decisionmakers at major pharmaceutical companies.

What are the economic effects of liability in the industries?

The present liability system enhances the contributions of these industries to national economic performance in some ways and undermines them in others. On the positive side, it hastens withdrawal of unacceptably hazardous products, encourages compliance with FDA regulations, and provides strong incentives to improve the design of less-regulated medical devices. On the negative side, it keeps some medically valuable products off the market and discourages innovation in certain product areas. For most—but not all—products, liability seems to have little or no effect on price.

How does the system produce these effects?

The decisions companies make about individual products depend on liability risk, competitive and

regulatory factors, and the technology and costs of reducing product hazards. Liability risk is especially important because it can threaten even large companies with financial disaster. Two considerations seem to play critical roles: the potential for mass litigation—thousands or more of suits over a single product—and the unlimited nature of punitive damages.

Innovation in drugs and devices has great potential to improve health care and make it more affordable. While it is widely agreed that liability reduces incentives for research and development (R&D), it is controversial whether these effects are trivial or profound. The study's simulations indicate that, in certain *product areas*, such effects are much greater than might be supposed. For example, even moderate liability risk can reduce incentives for product development twice as much as an additional year of regulatory delay would. And such a delay would be widely viewed as a major disincentive to drug development.

Whether liability potential deters a *specific* R&D investment generally depends on the product's profit potential. Major liability risks are unlikely to deter R&D for products projected to be exceptionally profitable. However, even a moderate liability risk may scuttle a marginally profitable product, and such products can be very socially valuable. In extreme cases, companies may view a product as too legally hazardous even to consider developing or marketing it, regardless of profit potential. The best example is any product used only during pregnancy: Many birth defects come from unknown causes, and this makes such products especially vulnerable to liability.

In decisionmaking, drug and device companies often also face a conflict between product safety and effectiveness: For example, reducing the recommended dosage level for a drug, delaying a product's introduction, or withdrawing a product from the market increases safety but may also reduce health benefits. Balancing safety and effectiveness is not left to companies alone. For all prescription drugs and many—but not all—prescription medical devices, the FDA has established extensive regulations governing marketing approval and product labeling, as well as

monitoring and reporting injuries. However, a product's safety depends on how fully companies comply with these regulations.

What reforms are economically promising?

In the public debate, the problem is usually presented as either "too much" or "too little" liability. A more selective approach is required to identify reforms that will enhance the system's good effects and reduce its bad effects. Further, policy reform can address only some reasons the system does not fulfill its potential. The study concludes that policy reform can improve the "targeting" of liability on behavior society wants to deter and make liability more predictable. Three policy actions appear especially promising:

Improve procedures for weighing scientific evidence about the cause of injury. Several proposals of this sort have been advanced—for example, relying more on *court-appointed* expert witnesses or using science panels to develop evidence in mass litigation situations. The aim is to make manufacturers more fearful that they *will* be held liable if their products cause injuries and more confident that they *will not* be held liable otherwise.

For drugs and strictly regulated devices, make FDA compliance a shield and noncompliance grounds for liability. This would establish that a company is liable for a design or warning defect *if, and only if*, injury results from company failure to comply with FDA regulations. This action would provide for a "regulatory-compliance defense" and also explicitly subject a manufacturer to liability for injuries caused by failure to comply. The aim is to improve regulatory compliance while reducing incentives to increase safety past the point where it is worth the additional costs.

Specify explicit standards for behavior warranting punitive damages. This action would specify precisely the kinds of company behavior that *do and do not* warrant punitive damages and thereby provide judges and juries with clearer guidance. As a result, punitive damages could be both more predictable and more precisely targeted on behavior that calls for strong deterrence.



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