This product is part of the RAND Corporation monograph series. RAND monographs present major research findings that address the challenges facing the public and private sectors. All RAND monographs undergo rigorous peer review to ensure high standards for research quality and objectivity.

Institute for Civil Justice

Economic Effects of Product Liability and Other Litigation Involving the Safety and Effectiveness of Pharmaceuticals

Steven Garber

The research reported here was conducted in the RAND Institute for Civil Justice, a program of RAND Justice, Infrastructure, and Environment.

Published 2013 by the RAND Corporation
1776 Main Street, P.O. Box 2138, Santa Monica, CA 90407-2138
1200 South Hayes Street, Arlington, VA 22202-5050
4570 Fifth Avenue, Suite 600, Pittsburgh, PA 15213-2665
RAND URL: http://www.rand.org
To order RAND documents or to obtain additional information, contact
Distribution Services: Telephone: (310) 451-7002;
Fax: (310) 451-6915; Email: order@rand.org

Summary

Product safety is a major policy concern in the United States, and potentially dangerous products are regulated by several federal agencies. Moreover, markets can penalize manufacturers and sellers of hazardous products by reducing demand. To further promote product safety, U.S. product sellers are also subject to product liability, which in some circumstances imposes legal obligations to compensate people injured by their products and thereby gives sellers additional financial incentives to reduce product hazards. Many product-liability proponents and policymakers point to compensation of injured product users as another worthy social goal served by product liability.

Critics argue, however, that compensation for injuries through product liability is socially undesirable. One reason is that legal disputing uses up many more scarce resources per dollar transferred than other compensation mechanisms. Moreover, product-liability critics argue that company responses to incentives from product liability have unintended and socially undesirable effects on economic outcomes, such as undermining product safety and effectiveness, discouraging innovation, increasing product prices, and driving good products off the market. In short, product-liability critics emphasize socially undesirable economic effects.

Prescription drugs are often in the forefront in public and scholarly debates about the economic effects of product liability. Economic effects of pharmaceutical product liability, however, are surprisingly difficult to analyze empirically, and there is little direct empirical knowledge about them. To further complicate matters, other forms of legal liability also penalize drug companies financially for acts affecting drug safety and effectiveness and as a result are likely to affect company decisions and economic outcomes.

Despite these difficulties, this monograph analyzes economic effects of several kinds of legal liability for pharmaceutical companies with an emphasis on drug safety and effectiveness. In addition to product liability for personal injuries, the monograph considers three other types of litigation related to safety and effectiveness that often allege deceptive marketing and/or illegal (*off-label*) promotion of drugs for uses not approved by the U.S. Food and Drug Administration (FDA):

- Civil and criminal actions brought by the U.S. Department of Justice (DOJ) under the federal Food, Drug, and Cosmetics Act, the federal False Claims Act (FCA), or both
- Civil and criminal actions brought by state attorneys general (AGs) under state consumer protection acts (CPAs) and/or other causes of action

- Civil actions alleging financial injury brought by private plaintiffs under state CPAs and/or other causes of action.[1]

Analytic Approach

The analysis comprises several components: developing a conceptual framework of company decisionmaking in response to liability exposure, reviewing and assessing previous empirical studies of economic effects of pharmaceutical product liability, examining the histories of several mass (product-liability) torts since 1990, reviewing instances of each of the other types of liability, characterizing how company decisionmakers are likely to perceive the connections between their decisions and potential future liability costs, and drawing inferences about how potential liability costs are likely to affect company decisions and economic outcomes. Finally, the monograph identifies socially desirable and undesirable outcomes of pharmaceutical liability and encourages policymakers to consider policy reforms to reinforce desirable outcomes and attenuate undesirable ones in the future.

A major challenge in connecting economic outcomes to liability is that, with few exceptions, outsiders cannot observe key company decisions or their consequences for economic outcomes. In response, much of the analysis relies on (1) developing empirical information about companies' liability costs resulting from different company actions,[2] (2) applying well-established perspectives on decisionmaking to draw inferences about likely company responses to liability induced incentives, and (3) assessing the social consequences of such responses.[3]

Conceptual Framework

Drawing reliable inferences about company responses to liability exposure requires a suitable conceptual foundation addressing company decisionmaking, as summarized here. Economic outcomes result from decisions made by drug companies seeking to maximize future profits, which can be reduced by future liability costs. These costs may be revealed only years after decisions are made and thus can be extremely uncertain. Decisions depend on company decisionmakers' perceptions about their incentives stemming from liability—equivalently, the perceived financial implications of different courses of action. When making decisions, then, companies try to anticipate their future liability environments, presumably in large measure on the basis of fairly recent history.

Several kinds of drug-company decisions affect drug safety and effectiveness. For example, companies choose a drug's design or physical properties as well as how and how extensively to study safety and effectiveness. Moreover, a drug's safety and effectiveness depend on who takes it and how, which depend on company decisions such as (1) the medical purposes for which the drug is intended, (2) recommended dosage levels, (3) product warnings, (4) what

---

[1] The monograph also considers civil litigation brought by drug company shareholders, which seems insubstantial relative to the other kinds of liability.

[2] Sources of empirical information include drug company reports to shareholders, litigation reports, articles in law and medical journals, and print and online reports from popular, legal, and trade news services.

[3] Statistical analyses and case studies are alternatives to this inferential approach. However, as explained in the monograph, these other approaches are not promising for the purposes of this monograph, namely, characterizing the overall or typical economic effects of liability.

information is reported to the FDA, and (5) how products are marketed and promoted to prescribers and consumers.

Evaluating the Social Desirability of Economic Effects

The monograph evaluates the social desirability of economic effects of liability in terms of economic efficiency, which can be thought of as what the pharmaceutical industry contributes to the aggregate economic well-being of U.S. residents. Economic efficiency can be improved in three ways, namely (1) increasing the population-level health benefits of pharmaceuticals, (2) decreasing social costs of drug-related injuries, and (3) decreasing the resource or "transaction" costs of legal disputing.

Thus, assessing the social desirability of different liability policies raises three questions: How do incentives from the liability system affect the health benefits of prescription drugs? How do these incentives affect the social costs of drug-related injuries? And what is the social cost of the resources used in disputing liability claims, such as the time of lawyers, experts, judges, and jurors?

Case Studies of Mass Torts

The new empirical content of the monograph pertaining to product liability focuses on incentives of drug companies to avoid mass torts, which are fairly common for prescription drugs and can involve extremely high costs for drug companies. The analysis considers six mass torts since 1990 that resulted in indemnity payments of roughly $1 billion or more (Fen-phen diet pills, Baycol, Rezulin, Vioxx, hormone replacement therapies, and Zyprexa) as well as four other mass torts that resulted in considerably smaller aggregate payouts.

Key Findings

Based on Review and Assessment of Previous Empirical Literature and New Empirical Analysis, What Does the Analysis Reveal About Economic Effects of Pharmaceutical Liability?

Evidence from Previous Studies

The monograph reviews empirical studies of economic effects of pharmaceutical product liability.[4] To provide an overview of the state of the policy debate concerning product liability, the monograph reviews arguments about economic effects set out in *amici* briefs filed with the U.S. Supreme Court in the case of *Wyeth v. Levine*. The issue before the court in this case was whether state product-liability claims against drug manufacturers alleging failure to warn of potential injuries—which comprise the lion's share of pharmaceutical product-liability claims—are preempted by federal law. In March 2009, the court ruled that such claims are not preempted.

Those who supported preemption (opponents of product liability) argued that pharmaceutical product liability has reduced product availability, increased drug prices, discouraged innovation, and affected drug safety in two economically inefficient ways. Surprisingly, preemption supporters paid little attention to the transaction costs of litigation.

[4] It appears that there are no analogous studies concerning the other forms of liability considered in this monograph.

Those who opposed preemption argued that product-liability litigation uncovers new information about drug hazards and deters "questionable practices" (socially undesirable corporate behavior). Surprisingly, preemption opponents paid little attention to the role of product liability in leading to withdrawals—with or without FDA intervention—of drugs that many in the medical community viewed as too dangerous in relation their health benefits to remain on the market.

What is the evidence concerning these arguments? Most importantly, there is scant empirical evidence to support the claims asserted on either side of the debate, and the literature provides little reliable information about common or typical economic effects of pharmaceutical product liability.

There is some empirical support for the view that product liability *can* have undesirable economic effects, but almost no support for sweeping claims about product liability *often having* such effects. Literature provides substantial evidence that product liability caused the withdrawals of Bendectin in 1983, some vaccines during the 1980s and 1990s, and the contraceptive Norplant in 2002. There is also strong evidence that sharp increases in the prices of some vaccines during the 1980s were caused by product liability, but the reliability of econometric evidence suggesting that product-liability exposure increased the prices of other kinds of drugs (in 1990) is equivocal. It appears impossible to develop direct empirical evidence about the effects of product liability on innovation, although there is a fairly strong qualitative basis for inferring that product liability has been a major factor in discouraging efforts to develop new contraceptives. The only econometric study of product liability and pharmaceutical innovation focused on vaccines and found that decreased liability increased efforts to develop new vaccines, but it also concluded that these increases probably undermined economic efficiency.

Critics of liability have made two claims about product liability reducing product safety. The first is that excessively detailed and extensive product warnings—so-called "overwarning"—interfere with effective drug prescribing and thereby undermine safety and effectiveness. That claim is controversial within the medical community, and there is no direct empirical evidence about it. However, there is some indirect supporting evidence from FDA surveys and focus groups with physicians conducted in 1992. The second claim is that the FDA's safety standards are higher than efficient levels and, thus, liability-induced increases in safety would undermine economic efficiency; this claim is plausible but entirely theoretical.

The literature also provides limited evidence to support the claims of proponents of product liability. For example, studies have demonstrated that litigation has uncovered important, safety-related information previously unknown to the FDA, prescribers, and the public. In principle, this information could provide a basis for FDA actions to improve the safety with which particular drugs are used or to improve FDA policies more broadly. There appears to be no systematic empirical information about such FDA responses, however. There is also a substantial theoretical basis for expecting that exposing "questionable practices" by drug companies will deter some future instances of such practices; again, however, there is no direct empirical information bearing on this hypothesis.

New Empirical Analyses

Employing the conceptual framework described above, the monograph also considers what might be reasonably inferred about economic effects based on new empirical information. Consider the different kinds of liability in turn, beginning with product liability for personal injuries.

The potential cost of a mass tort to a drug company is in the billions of dollars. Such a large financial threat almost certainly commands attention from company decisionmakers and leads them to consider ways to reduce the likelihood of a mass tort attempt involving one of their drugs, the company's likely cost if such an attempt is made, or both. Company decisionmakers are likely to be willing to sacrifice substantial amounts in profits in the near term to avoid behavior that they view as substantially increasing their future exposure to mass torts.

Lawsuits brought by DOJ have resulted in several settlements of $500 million or more, with at least a few exceeding $1 billion. Such litigation will tend to discourage behavior that DOJ investigates and sanctions such as off-label promotion and/or deceptive marketing. Several actions brought by state AGs have been settled for tens of millions of dollars, and there have also been jury verdicts of roughly $250 million and $325 million. Many of the state AG suits are likely to fortify deterrence effects of DOJ actions.

It is more difficult to gauge the financial threat perceived by drug company decisionmakers from private lawsuits. Many of these financial-injury lawsuits are brought by third-party payers alleging that they would not have willingly paid as much as they did for particular drugs were it not for illegal or deceptive behavior by drug companies. A key unknown about the future financial threats to drug companies—and the likelihood that these threats will substantially alter future company decisions—is the frequency with which financial injury lawsuits brought as class actions will be certified.

Direct Empirical Evidence: Summary

In sum, *there is little direct empirical evidence concerning the economic effects of product liability or the other forms of liability considered in this monograph*. Most of the direct evidence available about product liability pertains to particular drugs, and almost all of that evidence pertains to events that occurred a decade or more ago. Moreover, there appears to be essentially no direct empirical information about economic effects of the other forms of pharmaceutical liability considered in this monograph. Policymakers should, then, be wary of broad claims about economic effects of pharmaceutical liability, including generalizations based on anecdotes or examples.

Implications for Public Policy

The overall economic effects of liability—and comparison of total social costs and benefits—are the fundamental issue only when the policy question is whether to eliminate liability. This is rarely the policy question despite the counterexample of *Wyeth v. Levine* in the case of product-liability, failure-to-warn litigation.

Previous studies and new analyses contained in this monograph offer some, albeit limited, guidance about how policy changes designed to alter company incentives could improve the economic effects of liability. The liability exposure of drug companies creates both socially desirable and socially undesirable incentives for drug companies.

Features of the liability system create socially desirable incentives, including:

- **Incentives to comply with FDA regulations.** In most states, compliance with FDA regulations does not shield companies from liability, while evidence of failure to comply can be extremely costly to them. Imposing liability costs for regulatory noncompliance tends to encourage compliance. With the possible exception of restrictions on truthful off-label promotion, increasing compliance with major FDA regulations—requiring, for example, post-market clinical studies and honest reporting to the FDA—seems likely to promote economic efficiency.
- **Discovery of safety-related information.** Liability litigation sometimes uncovers evidence of company failures to provide safety-related information to the FDA, prescribers, and consumers. Examples include withholding or distorting information about the frequency and severity of injuries and withholding the results of selected clinical trials. Discovering such information in the course of litigation and penalizing it through legal liability tend to discourage it.

Other features of the liability system create socially undesirable incentives, including:

- **Incentives to overwarn.** Product-liability doctrine holds firms liable for failure to warn, as contrasted with, for example, failure to provide warnings that best promote public health through prescribing decisions and consumer compliance with their doctors' prescriptions.
- **Vague standards for punitive damages.** Punitive damages are likely to loom large in the minds of company decisionmakers. Under the laws of many states, the circumstances under which punitive damages are available are described as actions that are "outrageous," "oppressive," "malicious," and so on. The vagueness of these standards can leave corporate decisionmakers with great uncertainty about what behavior is required on their parts to avoid punitive damages and, as a result, can deter socially desirable corporate behavior.

Policymakers are encouraged to identify and implement changes in the liability environment that would alter company incentives and thereby lessen socially undesirable economic effects while maintaining or strengthening the desirable ones. No silver bullets are likely to be found. In view of the apparently high social stakes, however, identifying and implementing such policy changes could be well worth the considerable efforts required. This monograph offers information that could aid such efforts.