Product Liability and the Economics of Pharmaceuticals and Medical Devices

Steven Garber
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Product Liability and the Economics of Pharmaceuticals and Medical Devices

Steven Garber
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Foreword

Product liability reform has played a major role in the liability reform movement. There are two reasons for this. First, product liability reform has been the focus of a long and costly legislative effort at both the federal and state levels. Second, and perhaps more importantly, the debate about product liability reform centers on the liability system's ability to perform its deterrence function effectively.

In simple terms, the deterrence argument for the liability system asserts that, by forcing the producers of goods and services to bear the costs of the damages their products cause, the system provides producers with an incentive to produce safer products. Although some dispute whether the liability system should serve a deterrence function, most observers of the system would not argue whether the liability system deters but rather whether it provides too much or too little deterrence. In the product liability context, the deterrence issue revolves around the effects that product liability has on firms. Specifically, do the benefits the liability system induces outweigh the costs it imposes?

This is not an easy question to answer. In addition to the traditional data-gathering problems common to all empirical research, assessing the net benefits of the liability system poses some very special problems.

First, it is very difficult to measure the system's costs and benefits. In addition to the amounts firms spend directly on litigation (e.g., lawyers' fees and jury awards), they also absorb such indirect costs as the time and energy managers devote to suits—not to mention the way they change their procedures and products to avoid being sued in the first place. In addition to the direct and indirect costs to firms, a complete accounting of liability costs should include the costs borne by society in the form of products not produced or workers not hired.

The benefits induced by the liability system are also difficult to measure. The goal of deterrence, of course, is safer products and thus fewer injuries. In principle, these benefits can be measured in terms of lower medical bills and less time lost from work. In reality, it is very difficult to estimate how many injuries have been avoided because of products that have not been produced.

Second, the liability system works its effects through an often complex web of individual decisions that determine firm behavior. This web includes such decisions as whether to invest research funds in particular product areas, where
and how to market a product, and what price to charge. Understanding how the liability system influences such decisions is a complicated task. This task is further complicated by the fact that liability is only one of several factors influencing these decisions. Other factors that must be taken into account include the cost structure of the firm, the potential market for a product, and the regulatory environment. These factors will, of course, vary across industries and by product lines within industries, making generic (as opposed to industry-specific) assessments of these issues problematic.

These difficulties make it unlikely that the research community will ever have a precise estimate of the net benefits of the liability system. Policymakers, of course, do not have the luxury of waiting for definitive answers before making decisions. Thus, the ICJ, with financial assistance from the Sloan Foundation, set out four years ago to shed some light on these issues in two areas of business litigation: employment and product liability. Our goal was to assess empirically the economic costs that the liability system imposes.1

The current report presents our findings on product liability. Recognizing the importance of industry-specific answers to the cost question, the study focuses on two related industries: pharmaceuticals and medical devices. These two industries were chosen for very specific purposes. First, they are often cited as classic examples of industries that have been significantly affected by product liability. Indeed, the roster of noteworthy litigation includes such pharmaceuticals and medical devices as Bendectin, vaccines, the Dalkon Shield, and silicone breast implants. Second, these industries are generally regarded as important to the overall economy and as heavily dependent upon research and development—purportedly one of the key casualties of liability.

The study then tackles the difficult issue of measuring how liability affects decisionmaking in four critical areas, each of which has been a major concern of reform advocates:

- Product availability
- Product pricing
- Safety and effectiveness
- Innovation.

The report assesses the evidence for costs and benefits in each of these areas and then considers what this evidence suggests about the role liability considerations play in different parts of the decisionmaking process. In sum, what effects does the system have, and do they contribute to the liability system’s deterrence function? Finally, the study considers the policy implications of these findings.

The report’s discussion of policy implications represents somewhat of a new role for the ICJ. Traditionally, our role has been that of suppliers of facts, leaving to others the task of discussing the implications of our findings. Although the ICJ is not in the business of making recommendations, and will not become a partisan in the debate, it is important that we attempt to bridge the gap between research and policy.

In this new view, this report makes a number of noteworthy contributions to the policy debate. First, it steers the debate toward the critical questions. Second, it provides a conceptual framework for addressing those questions. Third, it supplies critical empirical information about those questions. Finally, it highlights the importance of addressing these questions at the industry-specific level.

Kevin F. McCarthy
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Executive Summary

Overview

There is currently a very active debate in this country over product liability laws and litigation. The product liability system is, in part, a response to the fact that millions of Americans suffer serious product-related injuries every year. The product liability system allows an injured product user to recover damages from the manufacturer under some circumstances. In so doing, liability is intended to provide companies with incentives to make products safer, because safer products should lead to lower liability risks and costs. However, critics claim that the U.S. product liability system has unintended, detrimental effects on the U.S. economy and have proposed a variety of reforms.

Many who call for reforms claim that liability reduces the availability and usefulness of products, increases prices, discourages innovation, and undermines the competitiveness of U.S. industry. Those who oppose reform claim that product liability improves the national well-being, because it accomplishes the objective of making products safer at an acceptable cost.

Purpose of the Study

To sort out these claims and evaluate proposed reforms, policymakers need answers to three questions:

- What are the actual economic effects of product liability?
- How does the system produce these effects?
- Can policies be structured to increase the benefits of the system while reducing the costs—and, if so, how?

Answering such questions requires systematic information. However, both proponents and opponents of reform rely chiefly on anecdotes to support their claims. Very little systematic information has been developed.

The purpose of this study is to provide such information on the pharmaceutical and medical device industries. Our ultimate objective is to identify the types of product liability reforms in those industries that seem most likely to enhance
their contribution to national economic well-being. Doing so requires detailed consideration of the economic outcomes of the prevailing liability system—but also requires much more.

**What the Study Contributes to the Debate**

Judging whether various reform measures will improve economic well-being requires prediction of the economic outcomes that would occur under liability arrangements that have never been tried. Such prediction requires an empirically grounded understanding of how business decisions are influenced by incentives that liability doctrine and procedures can shape. With that understanding, we do two things: (1) assess the strengths and weaknesses of the current liability system in pharmaceuticals and medical devices as a tool for promoting national economic well-being and (2) provide suggestions for steering the policy debate away from questions that either are not central or are unanswerable.

As an example of a question that is not central, much of the current debate centers on whether the total liability burden on business is too heavy. One side points to behavior of drug and medical device companies that it sees as unacceptably dangerous and concludes that the burden is inadequate to protect users from injury. The other side points to liability imposed in circumstances it sees as inappropriate, and to consequent economic costs, and concludes that the burden is excessive. The study’s findings indicate that both conclusions are right and wrong. Apparently, liability fails to deter some company behavior that society wants to deter and at the same time deters some behavior that society does not want to deter. This suggests that reform should aim at strengthening deterrence of some activities and weakening deterrence of others. A crucial question is: How might this be done?

An example of an often-unanswerable question is whether damages in particular cases or liability costs attributable to particular products are too high or too low. This question is unanswerable and is likely to remain so for many years, because it is not clear which of the many factors involved (e.g., how many injured parties make claims, direct defense costs, effects on company reputation) are most important.

Despite such complexities and unknowns, the study demonstrates that policy guidance can be developed. Building on more detailed understanding of the facts and explicit recognition of crucial issues, the study develops conceptual principles to guide the search for reforms in the pharmaceutical and medical device industries that will promote national economic goals. It uses these
principles to identify policy actions that appear promising in that regard. The
major policy actions involve how the regulatory history of a product should
affect liability, the conditions under which punitive damages should and should
not be assessed, and the means of improving the quality of scientific evidence in
liability cases.

Organizational of the Summary

The sections that follow explain the focus on pharmaceuticals and medical
devices; present the background and approach of the study; describe the liability
system's effect on product availability, pricing, safety and effectiveness of
products; and innovation in these industries; and identify some promising
directions for reform.

Why Pharmaceuticals and Medical Devices?

We focus on these industries for several reasons. First, and quite practically, the
crucial questions cannot be addressed meaningfully in economy-wide terms; they
require analysis at the industry level. Second, there are widespread concerns
about the economic effects of liability on the pharmaceutical and medical device
industries. Third, accounts of experience in these and a handful of other
industries are very influential in shaping views about how product liability
affects the national economy.

On the first point, liability does not affect business decisions in a vacuum. How
it affects economic outcomes will depend on such factors as the nature of product
injuries; the technology and costs of reducing product hazards; and the
competitive, regulatory, and liability environments in which product
manufacturers operate. These factors differ considerably across industries—thus
the need to study effects in particular industries.

On the second and third points, litigation involving pharmaceuticals and medical
deVICES has been very extensive, highly publicized, and a source of major concern
to many observers. Litigation has involved many drugs and medical devices,
and the industries have been the setting for several mass torts. For example, the
drugs DES and Bendectin have generated mass torts extending over decades, and
litigation still continues. Medical devices, such as the Dalkon Shield and, quite
recently, the Shiley heart valve and silicone-gel breast implants, have also
generated mass litigation. These products alone have involved hundreds of
thousand of claims and billions of dollars in litigation costs and compensation
payments. Moreover, claims about the economic effects of this litigation on
company decisions have raised serious concerns about detrimental effects on the economy. The claims are invoked repeatedly and passionately in policy debates about appropriate product liability policy for all industries.

The U.S. pharmaceutical and medical device industries are widely viewed as innovative, high-technology industries that have been very successful in international competition. Further, performance of these industries is viewed as an important consideration in the struggle to provide affordable health care in the United States. It is little wonder, then, that concerns about the effects of product liability on these industries have captured widespread attention and have been very influential in shaping public impressions about the effects of product liability generally.

Thus, systematic information about the economics of liability in pharmaceuticals and medical devices would be useful in reconsidering liability policy for these industries. It should also help clarify the roles of factors specific to these industries and thereby inform the broader policy debate. It cannot be stressed strongly enough, however, that the conclusions depend on features peculiar to the pharmaceutical and medical device industries and cannot be indiscriminately applied to other industries.

Background and Approach

In studying the effects of the product liability system, one could focus on various social concerns raised in the policy debate, such as the system’s effects on national economic competitiveness, fairness of compensation, or distribution of liability’s effects across various groups in society. This study considers how the existing system has affected the contributions of the pharmaceutical and medical device industries to current and future standards of living in the United States and how alternative liability arrangements might affect these contributions. Thus, the focus is on one of the many definitions of national economic competitiveness.

Defining Concepts and Terms

Economists often refer to an industry’s contribution to aggregate standards of living as the industry’s economic performance and generally evaluate it in terms of economic efficiency.

The economic performance of the pharmaceutical and medical device industries depends on the desirable and undesirable consequences of developing,
producing, and using drugs and devices. Desirable consequences are termed 
social benefits and undesirable consequences, social costs. An industry’s economic 
performance (or its contribution to standards of living or economic efficiency) is 
a net economic value: social benefits minus social costs.

The social benefits stem from improvements in the health and well-being of 
product users (patients). Social costs of prescription drugs and devices are of 
two kinds. First, making drugs and devices available to patients requires use of 
productive resources (such as labor, buildings, machines, and materials). 
Second, some patients suffer injuries from drugs and devices. Social costs 
stemming from these sources are referred to, respectively, as resource costs and 
injury costs. (The study focuses on prescription products because these are 
considerably more hazardous than over-the-counter products and, hence, more 
likely to involve liability.)

For convenience, actions furthering the industries’ economic performance are 
termed economically efficient, or desirable, and actions impeding performance are 
termed economically inefficient, or undesirable. Thus, we would call a particular 
change in product liability policy economically efficient if it increased the 
industries’ social benefits net of social costs.

Economic outcomes are driven by company decisions regarding individual 
products. In pursuing economic efficiency, drug and device companies often 
face a conflict between the safety and effectiveness of products. Aiming for 
maximum possible safety is generally not desirable, because the social costs of 
many safety measures are too high: Increasing safety typically involves resource 
costs and often decreases product effectiveness.

There are various examples of the latter point:

1. A product’s injury costs can be eliminated by withdrawing it from the 
market, but this would also eliminate the product’s benefits.
2. Injuries can be averted by more-extensive product warnings, but these 
warnings might also discourage product use by patients who would be 
successfully treated.
3. Safety can be enhanced by more-extensive product testing prior to 
marketing, but delaying availability of products reduces their benefits.

In sum, increasing a product’s safety is economically desirable if, and only if, the 
benefits of the injuries averted outweigh the additional resource costs plus any 
resulting costs of decreased effectiveness.
Balancing safety and effectiveness is not left to drug and device companies alone. In fact, for all prescription drugs and for many—but not all—prescription medical devices, extensive regulations of the U.S. Food and Drug Administration (FDA) govern virtually all company decisions of interest in this study. For example, such a product cannot be marketed in the United States until the FDA reviews extensive information on product safety and effectiveness submitted by a company and approves the product for marketing. Other regulations pertain to product labeling (including product warnings) and to monitoring and reporting of injuries.

Liability’s potential for enhancing or undermining efficiency depends on the levels of product safety and effectiveness that FDA regulation induces. A product’s safety depends not only on the safety standards set by the FDA, embodied in the applicable regulations, but also on the extent to which the manufacturer complies with them. Some companies may substantially fail to comply, especially with requirements to report information to the FDA.

For drugs and many, but not all, devices, FDA safety standards are very rigorous. Many believe, in fact, that they often compromise effectiveness beyond the point warranted by the additional safety benefits. For such products, liability’s major potential for promoting efficient safety and effectiveness lies in improving regulatory compliance. In contrast, for medical devices that have not been extensively regulated by the FDA (for example, the Dalkon Shield and silicone-gel breast implants), liability might promote efficiency in two ways: by encouraging companies to achieve higher levels of safety than FDA regulations require and by increasing compliance with the regulations that do apply.

**Approach**

To analyze the effects of liability, the study considered four sets of industry outcomes:

- availability of existing products
- pricing
- product safety and effectiveness
- innovation.

All these outcomes figure prominently in the debate over economic effects of liability, and they provide a manageable and appropriately encompassing way of structuring the analysis. The first three relate primarily to the industries’ present contributions to standards of living, the last to their future contributions.
The effects of product liability on these outcomes depend on numerous decisions of drug and device manufacturers. There is a substantial empirical base for analyzing these decisions, but the analysis also involves large doses of inference.

Using widely accepted analytic perspectives from various research literatures, we reviewed, synthesized, and interpreted publicly available empirical information, primarily of two basic types: The first is information about the liability environment, including the litigation history of individual products, e.g., published decisions, numbers of suits, sizes and factual bases of awards; legal briefs, commentaries, and analyses; and descriptions of litigation by participants in the policy debate. The second type of information relates to company decisions. This includes product introductions and withdrawals; information provided to physicians and patients; descriptive accounts of company actions; time series data on prices; and numerical simulations of R&D investment evaluation using pharmaceutical industry data. Our search for information and our understanding of it were enhanced by formal, confidential interviews at major pharmaceutical companies, as well as numerous informal, off-the-record discussions with plaintiff and defense attorneys and economists familiar with the industries. But to develop conclusions that might be widely viewed as reliable, the analysis was based entirely on information in the public domain. In the text of this report, this information and its sources are provided, and the method and logic of the analysis are more fully explained.

However, information on many crucial decisions is not available, such as information provided to regulators and details concerning research and development activities. As a result, it is impossible to determine many of the effects of interest, and an overall assessment of the costs and benefits of liability is out of reach. But this does not prevent us from characterizing many of the effects of liability and identifying policy directions that are likely to be economically desirable.

To make inferences about many, unobservable decisions of central importance, we use publicly available information and conceptual models of company decisions, based on a synthesis of the literature in economics, psychology, and management. These models incorporate the following assumptions:

- Liability affects decisions by altering profit incentives.
- The eventual liability consequences of decisions can be highly unpredictable.
- Perceptions of the liability environment can be distorted because of psychological factors and incomplete information about liability events.
• Perceptions of very large liability risks can have extreme effects on company decisions.

In sum, the study provides several types of information to support the policy analysis. The report describes the market, technological, regulatory, and liability environments in which company decisions are made. It also presents the results of collecting, reorganizing, synthesizing, and interpreting extensive empirical information concerning the economic effects that the current liability system has on business decisions of major social concern.

Through a synthesis of the empirical information and inferences, we can answer questions about

• how liability promotes—and how it undermines—economic efficiency in the drug and device industries,
• why liability fails to promote economic efficiency more completely, and
• what major reform directions appear most promising.

The following three sections take these issues up in turn.

How Liability Affects Economic Efficiency in These Industries

The analysis leads to the general conclusion that some economic effects claimed by parties to the debate are cause for concern and others are not. Most fundamentally, the prevailing liability system appears to enhance the economic contributions of the drug and device industries in some important ways but to undermine these contributions in others. The major beneficial effects are likely to be hastening the withdrawal of products that are too hazardous for economic efficiency, deterring companies from withholding or distorting safety reports to the FDA, and generating information of use to physicians and the FDA. The major detrimental effects are likely to be limiting the availability of socially valuable products, inefficiently distorting the mix of innovative investments, and encouraging companies to provide excessive information to physicians and no information to patients.

We consider the effects in terms of the four outcomes of interest: product availability, pricing, safety and effectiveness, and innovation.
Availability

Liability has caused companies to withdraw from the market products that had widespread support in the medical community (e.g., some childhood vaccines, some intrauterine devices, and Bendectin). There is little doubt that at least some of these withdrawals were economically inefficient.

Other product withdrawals have been widely attributed to the desire to avoid liability. These include products with injury costs that appear to exceed product benefits (e.g., the Dalkon Shield). These withdrawals would probably have occurred anyway because of market and regulatory forces. But liability probably hastened these withdrawals and thereby improved economic performance. However, it is also important to realize that these products were originally marketed despite the existence of liability.

Small, specialized companies are less-attractive targets for liability suits and have fewer assets at risk. As a result, they appear to be more willing to develop and market products with substantial liability potential. This can avert or eliminate availability crises for socially valuable products, as has been the case with intrauterine devices. However, the replacement of large companies by small companies in some markets also has disadvantages: Liability has less power to deter economically inefficient behavior by small companies, and the scope for them to provide injury compensation is quite limited.

Pricing

Some major price increases are attributable to liability (e.g., increases for some childhood vaccines and Bendectin). For most products, however, the price effects of liability are likely to be nonexistent or small, because many products do not pose substantial liability threats, and pricing in these industries is often a very inexact process.

According to some observers, price increases due to liability do serve some socially useful functions: Such increases finance compensation of injured product users and tend to discourage use of hazardous products. However, the analysis indicates that the price effects of liability further such functions only very crudely.

Safety and Effectiveness

Because the liability, technological, and regulatory conditions driving the relevant decisions differ across product types, liability is likely to have quite
different effects on the designs or physical characteristics of drugs, vaccines, and devices:

- Liability-induced changes in the chemical structure of drugs are likely to be the exception, not the rule, for two reasons: One, the FDA sets a rather high safety threshold for marketing approval. Two, attempts to improve the safety of drugs through design changes are extremely costly and will often not succeed.

- The development and availability of live-virus vaccines may have been discouraged by liability, because these products are considerably more susceptible to liability suits than are killed-virus vaccines. Such effects could be economically undesirable, because the live-virus vaccines are generally more effective than killed-virus vaccines, sufficiently more effective to warrant the extra safety risks.

- Device designs have been more vulnerable than drug designs to liability actions, and devices can often be made safer at low or moderate costs. Accordingly, liability may have induced safer designs for many devices. Such effects may be economically desirable, especially for devices that are not extensively regulated by the FDA.

Most cases of liability require a finding that physicians were not warned of a product’s potential to cause the injury subsequently suffered by a patient. As a result, for almost all prescription drugs and devices, product liability generates powerful incentives for companies to inundate physicians with warnings about possible safety hazards. In contrast, there is generally no legal duty for manufacturers to warn patients directly, but an inadequate patient warning could result in liability anyway. As a result, the liability system discourages manufacturers from warning patients directly or providing any safety information designed for them. The extent to which these incentives affect company behavior is unknown, but such effects could be crucially important for product safety and effectiveness.

Because failure to comply with FDA regulations can be very damaging to the defense of a product liability suit, liability fortifies incentives to comply with FDA regulations. This strengthens deterrence of economically inefficient behavior. For example, liability may deter companies from ignoring safety problems or concealing them from the FDA. If so, it may prevent marketing of products that are too unsafe to be economically desirable or may result in more appropriate product labeling.
Because companies can be held liable even if they conform to FDA safety standards, liability creates incentives for manufacturers to exceed these standards. For drugs and extensively regulated devices, the increments in safety realized are likely to be too small to justify the resource costs and sacrifices in effectiveness. However, for devices that have not been extensively reviewed by the FDA, many responses to these incentives—such as improved designs or more-extensive product testing—are likely to be economically efficient.

**Innovation**

Some products may be viewed as so legally hazardous that companies would not even consider developing or marketing them. The most plausible example is products for conditions specific to pregnancy. Both DES, which was used to prevent miscarriage, and Bendectin, which was a treatment for morning sickness, generated mass torts. This makes the legal hazards of products for such conditions very salient for company decisionmakers. A major consideration is that many pregnancies result in birth defects of unknown cause, and this leaves companies whose products were used during pregnancy vulnerable to suits. There is no indication that companies are attempting to develop such products, even though some such products might offer health benefits greater than their social costs. In these cases, liability’s effect would be economically undesirable.

For most products, however, liability potential is only one factor entering R&D decisions. Nonetheless, numerical simulations suggest that liability can substantially decrease incentives to innovate in product areas for which large liability costs seem plausible or financial disaster from liability is believed to be even a slight possibility. In fact, such beliefs can discourage R&D efforts much more than an extra year of delay in the FDA approval process would. Whether such effects on incentives actually deter particular R&D investments depends on assessments of the profitability of the products that might emerge. Liability is unlikely to deter efforts to develop products believed to have exceptionally large profit potential—so-called “blockbusters” (e.g., Prozac). But liability is likely to deter development efforts for socially valuable products whose profit potential is viewed as more limited (e.g., some contraceptives and vaccines).

**Why Liability Fails To Promote Efficiency More Completely**

As the discussion above makes clear, the current liability system both enhances and undermines the economic efficiency of the pharmaceutical and medical
device industries. The most promising approach to policy reform is to understand the sources of inefficiency and design reforms to mitigate those sources. Liability can lead to inefficiency because of numerous, complex factors. The analysis identifies three major sources of inefficiency under the present liability system: inappropriate incentives, misperception of incentives, and company aversion to risk.

**Inappropriate Incentives**

To provide economically sensible incentives, the liability system must (1) impose liability costs only for behavior that society wants to deter and (2) make these costs the right size to induce the desired behavior. The current liability system falls well short of both these ideals. Companies are sometimes held liable when they should not be (e.g., when the injury was not caused by their product or by shortcomings in their warnings). However, they are sometimes not held liable when they should be (e.g., when the injury is caused by their product but this cannot be proven or when potential plaintiffs with strong cases do not file claims). Moreover, when imposing some liability costs is economically appropriate, the size of these costs may often be much too large or much too small to induce efficient decisions.

Whether liability costs are generally too large or too small—a subject of heated debate—cannot be answered. However, answering this question is not essential to identifying directions for reform that appear to promise substantial improvement over the status quo.

In addition, eventual liability costs resulting from an action are often highly unpredictable at the time a decision must be made. The unpredictability of liability costs underlies the two other general sources of inefficiency discussed next.

**Misperception of Incentives**

In attempting to predict liability costs resulting from various actions under consideration, company decisionmakers may rely on unrepresentative information and misinterpret it because of common psychological biases. For example, what decisionmakers hear about experiences at other companies and what they remember about this may lead to very distorted views of the actual incentives created by the liability system.
It is widely accepted by psychologists that people tend to perceive as likely events that they find easy to imagine or recall. As a result, decisionmakers are likely to overestimate the likelihood of punitive damages in inappropriate circumstances or the likelihood that their products will be blamed for injuries attributable to other causes, because alleged instances of such events are widely and repeatedly publicized in dramatic terms. Moreover, many decisionmakers may underestimate liability risks for products that have not experienced widely publicized liability problems.

**Company Aversion to Risk**

The unpredictability of liability costs introduces an especially salient element of risk in the decisions of interest. While risk is ubiquitous in business decisionmaking, liability risks are unlike most other business risks: Eventual liability costs resulting from an action are not limited to an amount that the company chooses to invest. Liability costs can in principle threaten even large companies with financial disaster. Both the possibility of mass torts and the unlimited nature of punitive damages appear to play important roles in this regard. Companies may often refuse to take such risks, even when it would be socially desirable for them to do so. Development and marketing of an AIDS vaccine is an often-suggested example.

**Types of Reform That Seem Economically Desirable**

Liability policy is an amalgam of state and federal case law, statutes, and legal procedures. Thus, reform might be pursued through several avenues. Nevertheless, it can correct only some sources of inefficiency. For example, the psychological processes of decisionmakers and their willingness to risk financial disaster are not susceptible to policy influence. As another example, reforms aimed at damage levels face the obstacle of very imperfect information.

Given these limitations, the following appear to be the most promising objectives for improving the efficiency of liability in the pharmaceutical and medical device industries:

* Increasing the likelihood that a company is held liable for actions whose social costs outweigh their social benefits (e.g., ignoring signs of safety problems or withholding information from the FDA) and decreasing the likelihood of liability for behavior that is economically desirable (e.g., development and marketing of an AIDS vaccine)
• Reducing the scope for distorted perceptions and economically undesirable company responses to risk by making liability consequences more predictable.

The analysis suggests three general policy actions for meeting these objectives in the pharmaceutical and medical device industries. These are offered for consideration and refinement.

Policy Action #1: Make regulatory compliance central for drugs and extensively regulated devices. Such an arrangement would explicitly establish that liability for defective designs or warnings will be assessed if and only if injury results from a company failure to comply with the relevant FDA regulations.

Manufacturers of drugs and extensively regulated devices would be shielded from liability by compliance with FDA regulations, including conformance with agreed-upon testing protocols and timely submission and complete, accurate description of all required information. While providing for a regulatory-compliance defense, this policy action would also explicitly subject a manufacturer to liability for injuries caused by noncompliance.

Such a policy action would strengthen current incentives to comply with FDA regulations, while attenuating current incentives to exceed FDA safety standards. Both kinds of changes appear economically efficient for drugs and strictly regulated devices. Making regulatory compliance central could be expected to tie company liability costs more predictably to economically undesirable behavior.

Others have advocated a regulatory-compliance defense for pharmaceuticals to eliminate incentives to exceed FDA safety standards. Arguments for such a reform often rely on the view that the FDA is much better equipped than the liability system to promote economic efficiency. These arguments also tend to suggest that liability has little if any economic role to play. We both agree and disagree: The FDA is better equipped to set safety standards efficiently, but liability can contribute substantially to efficiency by helping the FDA with the daunting task of enforcing compliance with its regulations.

Policy Action #2: Specify explicit standards for behavior warranting punitive damages. Three of the issues concerning punitive damages that are currently being debated are: (1) how qualities of actions that warrant punitive damages should be characterized (e.g., outrageous conduct versus reckless disregard for safety), (2) what the standard of proof should be (e.g., clear and convincing versus preponderance of the evidence), and (3) what the dollar amounts of
punitive awards should be. The first issue and the policy action under discussion here are both about the instances in which punitive damages should and should not be awarded. But the analysis suggests that, to make liability consequences more predictable, which is a key policy objective, it seems more promising to specify the kinds of actions—rather than the qualities of actions—that warrant punitive damages. The study provides no guidance about the second issue.

Regarding the third issue, there are various criteria for assessing the size of punitive damages but so far no definitive answers. In *TXO Production Corp. v. Alliances Resources Corp.*, the U.S. Supreme Court recently considered the constitutional limits of awards for punitive damages and declined to articulate a clear quantitative standard. As discussed in our example of an unanswerable question, the analysis suggests that no clear guidance about the size of punitive damages can be derived for the goal of economic efficiency.

The aim of policy action #2 is to restrict punitive damages predictably to obviously inefficient behavior (e.g., ignoring or concealing clear evidence of serious safety hazards) while increasing the likelihood of punitive damages when they are economically desirable. Progress in this direction would require precise specification of the kinds of actions for which punitive damages are and are not appropriate and consistent application of these standards.

Punitive damages can have very pronounced effects on company decisions, because these damages are in principle unlimited in individual instances and can be assessed repeatedly for the same conduct.

Undoubtedly, punitive damages sometimes are not assessed for actions warranting extremely strong deterrence. However, they are also sometimes assessed for actions that are economically desirable (e.g., marketing products whose risks were known and considered acceptable by the FDA, failing to warn of risks that the FDA did not find supported by the scientific evidence). Precise specification of the kinds of actions that do and do not warrant punitive damages and consistent application of these standards could help rectify both types of incentive problems in the pharmaceutical and medical device industries.

However, it is impossible to achieve completely precise and predictable targeting of punitive damages on economically undesirable actions. As a result, how bold policymakers want to be in using this powerful instrument might differ by context. For example, more caution seems warranted the more extensively a product is regulated by the FDA and the greater a product's medical benefits.
Policy Action #3: Improve procedures for weighing scientific evidence of injury causation. Whether an injury was caused by use of a particular product can be very difficult to assess. There have been several proposals to improve the scientific basis for judgments of this kind (e.g., more reliance on court-appointed expert witnesses, convening science panels, or creation of a federal science board). Economic efficiency might be enhanced considerably by such reforms. Interest in the issue of science in the courtroom is indicated by the fact that the U.S. Supreme Court very recently (June 1993) ruled on a major procedural issue involving expert testimony in Daubert v. Merrell Dow Pharmaceuticals, a Bendectin case.

Difficulties in attributing injury causation can undermine deterrence of economically undesirable behavior and exacerbate deterrence of economically desirable behavior. Companies may have inadequate incentives to reduce injuries that are caused by their products but cannot be attributed to them in court. At the same time, they tend to be deterred from developing and marketing products that may be held responsible for injuries due to other causes. These include products to be used by patients with high background rates of unexplained injuries, for example, pregnant women.

The liability system would promote efficiency more effectively if reforms could strengthen the beliefs of company decisionmakers that injuries caused by their products will be recognized as such and, at the same time, allay concerns that companies will be held liable for injuries not caused by their products.

In Conclusion

Many consider national economic performance a crucial concern in formulating product liability policy. The prevailing liability environment in the pharmaceutical and medical device industries undermines—in various ways—the contributions of these industries to current and future standards of living in the United States.

However, the ability to reform the liability system to promote efficiency is limited by the complexity of the task and the incompleteness of our knowledge. Because liability cannot be precisely and predictably limited to undesirable behavior, policies capable of deterring economically undesirable behavior will also deter some desirable behavior. Thus, policymakers must decide how bold to be, recognizing that stronger measures will generally increase deterrence of both desirable and undesirable behavior.
Moreover, it may not be desirable to focus reform efforts entirely on economic goals; other considerations—such as compensation—are also considered crucial by many. The analysis here is offered as a guide to those attempting to identify reforms that would improve efficiency in the pharmaceutical and medical device industries and those considering reforms for other reasons.
Acknowledgments

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Kevin McCarthy made this research possible through his sustained commitment to studying the economic effects of liability policy and his support of this project. He has also contributed greatly to the course, execution, and reporting of the research. Kevin’s advice and input were invaluable in focusing the analysis on issues of central policy concern, improving it in numerous ways, and creating an exposition that is hoped to be accessible to the broad audience for which it is intended.

I also owe a major intellectual debt to Frank Camm, who preceded me as the leader of this project. Frank helped me get started quickly through numerous extended discussions, early development and implementation of the interviewing strategy, and an unpublished draft that insightfully explored, at the industry level, changes over time in many of the factors I analyze in terms of differences across products in the contemporary environment. Throughout the course of the project, Frank generously and patiently served as an insightful and constructively critical sounding board. Finally, he provided a very thorough and thoughtful technical review that led me to think more deeply about several fundamental issues.

Mark Peterson had been working with Frank when I joined the project, and he has also provided extensive and continual help. Mark provided invaluable input on legal principles, issues, and information resources through conversations and an unpublished draft reviewing the evolution of product liability law in the two industries. He also participated in all of the company interviews and made very useful comments on the first draft of this report.

I am also grateful for careful and thoughtful technical reviews by two leading scholars of product liability law: Professor George Priest of the Yale Law School and Professor Gary T. Schwartz of the UCLA School of Law.

The RAND library staff made it possible for me to identify and obtain the many documents and other information resources on which the analysis is based. Every one of them was highly skilled and professional, as well as patient and cheerful in the face of my numerous, extensive, and often sketchy requests.
Susan Adler, Caroline Loeffler, Susan McGlamery, Joan Schlingin, and Roberta Shanman provided extensive reference services. Barbara Neff, Emily Cariaga, Melvin Fujikawa, Karen Hudson, and Betsy Warner dealt efficiently and pleasantly with an uncommon—and perhaps unreasonable—number of requests for documents and articles.

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Despite all of this advice, aid, and encouragement, I alone am responsible for opinions and any remaining errors.
## Abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
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<tr>
<td>ADR</td>
<td>Adverse drug reaction</td>
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<tr>
<td>ALI</td>
<td>American Law Institute</td>
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<td>AMA</td>
<td>American Medical Association</td>
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<tr>
<td>CDC</td>
<td>Centers for Disease Control</td>
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<tr>
<td>DT</td>
<td>Diphtheria and tetanus (vaccine)</td>
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<tr>
<td>DTP</td>
<td>Diphtheria, tetanus, and pertussis (vaccine)</td>
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<tr>
<td>FDA</td>
<td>Food and Drug Administration</td>
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<td>GAO</td>
<td>General Accounting Office</td>
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<td>HIV</td>
<td>Human immunodeficiency virus</td>
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<td>IDE</td>
<td>Investigational device exemption</td>
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<td>IND</td>
<td>Investigational new drug</td>
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<td>IOM</td>
<td>Institute of Medicine</td>
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<td>IUD</td>
<td>Intrauterine device</td>
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<td>MDA</td>
<td>Medical Device Amendments</td>
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<td>MDR</td>
<td>Medical device reporting</td>
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<tr>
<td>MMR</td>
<td>Measles, mumps, and rubella (vaccine)</td>
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<tr>
<td>NCE</td>
<td>New chemical entity</td>
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<td>NCVIA</td>
<td>National Childhood Vaccine Injury Act</td>
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<td>NDA</td>
<td>New Drug Application</td>
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<tr>
<td>OPV</td>
<td>Oral polio vaccine</td>
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<tr>
<td>OTA</td>
<td>Office of Technology Assessment</td>
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<td>OTC</td>
<td>Over-the-counter</td>
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<td>PL</td>
<td>Product license</td>
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<tr>
<td>PMA</td>
<td>Pharmaceutical Manufacturers Association</td>
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<tr>
<td>PPI</td>
<td>Patient package insert</td>
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<td>R&amp;D</td>
<td>Research and development</td>
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1. Introduction

The U.S. product liability system is widely criticized. A major source of concern is the effect of product liability on national economic performance. Product liability is claimed to limit the availability of products, increase prices, reduce the usefulness of products, discourage innovation, and reduce the competitiveness of U.S. industry.\(^1\) Such economic effects are invoked in support of proposals to reduce the burden of liability on manufacturers and distributors.

Particular policy reforms may or may not improve U.S. economic performance. Reliable evaluation of any proposal requires an assessment of how the current liability system affects outcomes determining economic performance. This poses a considerable challenge. But evaluation of a proposed reform also requires a characterization of these outcomes under the liability system that would prevail if the reform proposal were adopted. This is even more challenging. The current state of knowledge is inadequate to provide comprehensive characterizations of either type.

This study targets a fundamental issue that is crucial for policy analysis. Debates concerning product liability reform are fueled mostly by anecdotes. Analyses aimed at providing systematic information generally attempt to assess effects of the prevailing liability system. While potentially useful, such efforts fail to address a critical issue: How would economic outcomes differ under alternative liability regimes? A major objective of this study is to provide a basis for addressing this question.

Addressing this question requires a capability to predict business behavior in liability environments that have never existed. The strategy employed here is to use behavior observed in the prevailing liability environment to develop general insights about business decisionmaking in response to incentives created by product liability. These insights have two orientations. The first is pointed toward the effects of the prevailing liability system on economic outcomes of social concern. The second is pointed toward how company decisions determining such outcomes respond to incentives created by the product liability system. Conclusions about the latter provide a basis for predicting how

\(^1\)See, for example, U.S. Senate (1991).
decisions—and thus economic outcomes—would differ if the system were reformed in particular ways.

This study focuses on the economics of product liability at the industry level. This is because the economic effects of product liability depend on the particular market, technological, and regulatory environments in which product liability operates—conditions that vary considerably from industry to industry.

Studying the economics of product liability at the industry level provides not only information useful for policy reform in those industries, but also information of more general relevance. Specifically, it allows an initial assessment of the extent to which economic effects of product liability are sensitive to conditions that do not characterize American industry at large. Such knowledge could help avoid pitfalls of economywide implementation of policies that seem promising only because of experience in particular industries.

The industries studied are pharmaceuticals and medical devices. These are of special interest for two reasons. First, these industries are widely claimed to involve economic effects that are particularly troublesome. Policy analyses for these industries should be useful in considering reforms targeted at them. Second, views about economic effects of product liability on the national economy rely heavily on events in these and a handful of other industries. Thus, additional knowledge about them would be useful for broader policy deliberations.

The study explores the links between liability and economic outcomes affecting aggregate standards of living in the United States. We do not consider implications of liability policy for the distribution of well-being among members of society or the related questions of compensation and justice. Hence, we focus on concerns that are central to the liability policy debate, but are not the only ones relevant for policy formulation.

Many of the economic outcomes of interest are unobservable. As a consequence, many of the effects of product liability simply cannot be isolated empirically. Consider, for example, the effects of liability on innovation—a central issue in the policy debate. Some argue that the primary effect of liability here is to deter development and marketing of products that are too dangerous to be socially worthwhile. Others argue that the primary effect of liability on innovation is to deter development and marketing of socially valuable products. Such effects may be crucial to economic performance, but they cannot be observed or quantified.
There is a substantial empirical base for the analysis, but it also involves large
doses of inference. Our strategy is to base the analysis entirely on publicly
available information that could be viewed as reliable by individuals no matter
what their views concerning product liability reform. This information includes
public accounts of business actions and industry data collected for purposes
having nothing to do with liability. The empirical information is interpreted and
synthesized using widely accepted analytic perspectives from various research
literatures, and logical implications for unobservable outcomes are developed.

The effort has been aided by formal, confidential interviews at three major
pharmaceutical companies. There have also been numerous informal, off-the-
record discussions with other knowledgeable people (including attorneys who
represent plaintiffs and defendants, and economists familiar with the industry
either through research or consulting activities). Information obtained from such
sources helped in identifying issues, understanding various institutions, and
locating publicly available information. However, for the reason just stated,
information that is not in the public domain is not treated as data.

The remainder of the report contains nine sections organized into three parts.
Part I, which consists of four sections, provides essential background. Section 2
introduces the economic outcomes of social concern and the company decisions
affecting them and presents the analytic framework. Section 3 describes the mar-
et, technological, and regulatory environments in pharmaceuticals and medical
devices. Section 4 considers the product liability environment. Specifically, it
describes many aspects of the legal environment and develops implications for
the profitability of company actions and how these implications differ across
products. Section 5 presents two analytic perspectives on decisionmaking in the
kinds of environments of interest here: those characterized by unpredictability
and major risks. These perspectives are used to interpret outcomes we can
observe and draw inferences about outcomes we cannot observe. One
perspective is widely applied in economics and statistics, and the other is based
on behavioral research in psychology and management.

Part II contains empirical analyses of the effects of the prevailing liability
environment on economic outcomes. It interprets observations and draws
inferences about decisions and outcomes we cannot observe. Sections 6 through
9 consider four different sets of outcomes: availability of existing products,
pricing, safety and effectiveness of existing products, and innovation.

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2For example, it does not rely on results of surveys of the business community concerning the
effects of liability on their decisions (for example, Weber [1987] and McGuire [1988]). Many do not
accept these as reliable because respondents are likely to understand how the results will be used and
have incentives to exaggerate detrimental effects of liability and understate beneficial ones.
Part III develops implications concerning product liability policy and the contribution of the pharmaceutical and medical device industries to U.S. economic performance. The discussion focuses on the following questions:

- How does liability contribute to economic performance?
- How does liability undermine economic performance?
- Why does liability have these effects?
- What reform directions appear most promising?
Part I

Background: The Decisionmaking Context

The next four sections provide factual and conceptual background for the empirical and policy analyses presented in Parts II and III, respectively.

Section 2 introduces the concept of the economic efficiency of the pharmaceutical and medical device industries and explains why efficiency is of central policy concern. This section further focuses the inquiry by introducing the economic outcomes to be analyzed empirically and the company decisions that drive these outcomes.

Attention then turns to the complex environment in which company decisions are made. Section 3 reviews central aspects of three major components of that environment: market forces, technology of new product development, and federal regulation of pharmaceuticals and medical devices.

With this as background, Section 4 analyzes how company incentives are affected by product liability. The analysis is based on a conceptual view of how liability can directly and indirectly affect the profitability of various company decisions and on an extensive review of aspects of legal doctrine and its application. This review of the legal environment provides the basis for analyzing the determinants of liability effects on profits and the financial risks faced by companies as they attempt to respond to incentives created by liability. Section 4 concludes by analyzing how liability incentives differ systematically across products and patients.

Part I concludes with Section 5, which reviews basic principles and insights from two research literatures concerned with company decisionmaking in the face of substantial uncertainties or risks. Views of decisionmaking developed in Section 5 are used to interpret the empirical evidence reviewed in Part II, and this evidence is in turn used to develop a more refined view of pharmaceutical and medical device company decisionmaking in response to incentives created by product liability.
2. Outcomes, Decisions, and Analytic Framework

Developing knowledge useful for considering policy reforms requires a conceptual framework about how product liability affects the U.S. economy. This section presents the framework used to structure the analysis and the rest of this report.

Product Liability, Industrial Performance, and Economic Efficiency

The effects of product liability on economic well-being in the United States depend on effects in various industries. The contribution of an industry to the U.S. economy—its "economic performance"—is the net social value of activity by the industry: "social benefits" minus "social costs." Industrial economic performance is an element of the economywide goal of economic efficiency, which reflects aggregate economic welfare and does not consider distribution among members of society.

The social benefits and social costs of the drug and device industries may be thought of as follows. These industries contribute to economic welfare in the United States by improving the health and well-being of product users (patients). The social benefits of the industries are the economywide values of these contributions. However, the activities that make economic benefits possible also involve undesirable economic consequences, or social costs. First, making drugs and devices available to patients requires the use of productive resources (such as labor, buildings, machinery, and raw materials). By using resources to develop, produce, market, and distribute drugs and devices, society gives up the opportunity to use these resources to produce other products of social value. This is the resource component of social cost. Second, none of the products of concern here can be made completely safe. Injuries attributable to the use of drugs and devices are the other major component of social cost.

In sum, our fundamental concerns are how product liability affects the economic performance of the drug and device industries and how policy reforms might improve matters. These issues are analyzed in terms of economic efficiency. Distribution of welfare among individuals and compensation for injuries are not
addressed. Thus, we are focusing on a crucial, but not the only, social goal in formulating liability policy.

**Profitability, Decisions, and Economic Performance**

The drug and device industries affect economic well-being through company decisions guided by the pursuit of profits. To understand the economic effects of liability in a way that is useful for policy we must consider both social and private perspectives. Consideration of the social perspective illuminates what outcomes are of interest for policy and provides a foundation for evaluating them. Understanding the private perspective is necessary for interpreting what we observe about the effects of liability on outcomes of interest, developing useful inferences about effects we cannot observe, and suggesting how outcomes would change in response to policy reforms.

**Intermediate Outcomes**

Policy discussions of the effects of product liability on the U.S. economy have emphasized several outcomes: innovation, product availability, product safety, product usefulness, cost, price, and competitiveness. These outcomes are also raised in the narrower context of pharmaceuticals and medical devices. Combining outcomes into an overall assessment of how liability affects economic performance requires value judgments and more empirical information than is available. This report does not attempt such an assessment.

The analysis examines the links from liability to company decisions to intermediate outcomes to economic efficiency. The remainder of this section uses Table 2.1 to discusses the outcomes and the decisions that drive them.

**Innovation**

The process of creating and commercializing products is generally known as innovation—the first outcome in Table 2.1. The process of creating products is typically referred to as the research and development (R&D) process. The development of a new drug or device involves many steps and takes many years.\(^1\) Several types of R&D decisions are involved in innovation (see Table 2.1).

\(^1\) The R&D process is discussed in Section 3.
Table 2.1
Outcomes and Company Decisions of Primary Relevance

<table>
<thead>
<tr>
<th>Economic Outcome</th>
<th>Company Decisions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Innovation</td>
<td>R&amp;D</td>
</tr>
<tr>
<td></td>
<td>Developing research capabilities</td>
</tr>
<tr>
<td></td>
<td>Following a research lead</td>
</tr>
<tr>
<td></td>
<td>Designing a product</td>
</tr>
<tr>
<td></td>
<td>Commencing clinical trials</td>
</tr>
<tr>
<td>Marketing</td>
<td>Introducing product in U.S.</td>
</tr>
<tr>
<td>Product availability</td>
<td>Marketing</td>
</tr>
<tr>
<td></td>
<td>Introducing product in U.S.</td>
</tr>
<tr>
<td></td>
<td>Choosing patient indications</td>
</tr>
<tr>
<td></td>
<td>Withdrawing from U.S. market</td>
</tr>
<tr>
<td></td>
<td>Timing</td>
</tr>
<tr>
<td>Safety and effectiveness</td>
<td>Design</td>
</tr>
<tr>
<td></td>
<td>Chemical structure (drugs)</td>
</tr>
<tr>
<td></td>
<td>Biologic agent (biologics)</td>
</tr>
<tr>
<td></td>
<td>Physical and material characteristics (devices)</td>
</tr>
<tr>
<td>Testing</td>
<td>Labeling</td>
</tr>
<tr>
<td></td>
<td>Indications</td>
</tr>
<tr>
<td></td>
<td>Warnings, contraindications, etc.</td>
</tr>
<tr>
<td></td>
<td>Dosage (drugs)</td>
</tr>
<tr>
<td></td>
<td>Product promotion</td>
</tr>
<tr>
<td>(Social) cost of product</td>
<td>Research and development</td>
</tr>
<tr>
<td></td>
<td>Manufacturing</td>
</tr>
<tr>
<td></td>
<td>Promotion</td>
</tr>
<tr>
<td></td>
<td>Distribution</td>
</tr>
<tr>
<td>Product price</td>
<td>Price</td>
</tr>
</tbody>
</table>

First, to be in a position to develop new drugs or devices of particular types, a company must have research capabilities (expertise, laboratory facilities, etc.) in any number of scientific fields. A fundamental decision for a company is the fields in which to develop such capabilities. These decisions have implications for the areas of science in which company researchers are likely to become aware of promising leads for product development and the ability of the company to follow up on such leads. A second kind of R&D decision is whether to follow a lead that does present itself. Third, if such a lead is pursued, the company must decide on a specific product design. Finally, if a design seems sufficiently promising, the company may decide to test it on humans.2

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2 All drugs and many devices must be tested on humans before they can be marketed in the United States. The U.S. Food and Drug Administration (FDA) gets involved at this stage. FDA regulation is discussed in Section 3.
Product Availability

Once a product is developed (and approved by the FDA), it may be marketed in the United States. Market introduction is both the last step of the innovation process and the beginning of product availability. Drugs and many devices are approved for U.S. marketing only for specific patient conditions called indications. The set of approved indications is a determinant of how widely a product is available, and a company must decide the indications for which to seek FDA approval. The list of approved indications may be expanded after the initial marketing, which requires considerable additional development and regulatory activity. The decision to market a product can be reversed at a later date, and the product can be withdrawn from the market. Finally, for all of these activities the company must decide not only whether but when.

Safety and Effectiveness

If a product is made available, its safety and usefulness are crucial determinants of its contribution to economic efficiency. Safety refers to the prevalence and severity of side effects or patient injuries resulting from use of the drug or device. In the context of pharmaceuticals and medical devices, the standard, medically based view of product usefulness is the prospect that it will improve the condition of an individual patient. But from an economic point of view, the usefulness of a product also depends on the number and attributes of people who use it. In this study, we use the term product effectiveness to refer to this broader (economywide or population) view of product usefulness.

Product safety and product effectiveness are listed jointly in Table 2.1 because the decisions driving these outcomes are largely the same. Advances in scientific knowledge may allow both safety and effectiveness to be enhanced. However, there are also some direct trade-offs between these outcomes: Often, safety can be enhanced only by sacrificing effectiveness, and vice versa. The key issues are the physical attributes of a product, who uses the product, and how they use it. As highlighted in Table 2.1, the critical company decisions affecting product safety and effectiveness involve product design, testing, labeling, and promotion.

Design decisions determine the chemical, biological, and physical attributes of the product. For any product, the design is the same for all patients, but its safety and effectiveness are not. A product that is effective and safe for many

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Specifically, the approved indications are the only ones for which a company may promote a product. Physicians may prescribe products for other conditions.
individuals can be quite ineffective or hazardous for others. Thus, the safety and effectiveness of a product depend not only on its design but also on who uses it and how. Product labeling and promotion come into play in this regard.

The product labeling prepared by the drug or device company (with the advice and approval of the FDA) is a key source of information for the physicians who play a central role in deciding what patients use a product and how. This term refers principally to the contents of the lengthy package insert and its so-called "brief summary" and to product advertisements in medical and other scientific journals. This information—provided by companies to physicians—is written for their use and may be incomprehensible to patients lacking medical training. The information includes approved indications, contraindications (situations in which use is not advisable), warnings of possible side effects or injuries, dosage forms and levels, and descriptions of experience with the product. The product labeling is revised periodically as more information becomes available.

Sales efforts for drugs and devices involve direct contacts by sales representatives with health professionals, advertisements in medical journals, and (quite recently) advertising directly to consumers for some products. Product promotion efforts of companies are intended to widen the use of a product. Besides affecting how many patients use a product, they can also affect what types of patients use it and how it is used. Thus, product promotion may have substantial effects on product safety and effectiveness.

There are several important conflicts or trade-offs between safety and effectiveness in design, labeling, and promotion. For example, labeling a product in a way that deters physicians from prescribing it or patients from using it is likely to reduce both the number of people effectively treated and the number of injuries resulting from its use. For pharmaceuticals, an important design trade-off is that, within some range, an increase in dosage is likely to increase effectiveness but also to increase the prevalence of side effects. An important design trade-off specific to vaccines pertains to the choice between using live (attenuated) and killed viruses. Live-virus vaccines are generally more effective in conferring immunity on individuals who are vaccinated and can serve to immunize even people who are not vaccinated, while this cannot occur with

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4 As discussed in Section 3, the analysis focuses on prescription drugs and devices. As discussed in Section 4, product labeling plays a major role in liability.
5 Such as tests with laboratory animals, humans in controlled studies, reports concerning experience in uncontrolled settings both in the United States and abroad, and scientific studies of this or similar products.
6 Because they can be exposed to the virus through contact with people who have been vaccinated.
vaccines using killed viruses. However, live-virus vaccines can cause contraction of the disease for which immunity is sought, while killed vaccines cannot.

**Cost**

Product cost refers to the economic value of the resources used up (and thus unavailable for other social uses) to provide a product and to any costs associated with use of the product (such as injuries). Clearly, the decisions indicated in Table 2.1 affect not only the company's own costs of doing business but also costs borne by patients and the public at large.

**Price**

The product price is the dollars that patients and their public or private insurers must pay to enable the patient to use the product. A fundamental determinant of a price set by a company is its cost of making the product available. But, as discussed in Section 3, market conditions for many drugs and devices allow for substantial divergence between price and cost.

**Competitiveness**

There is widespread agreement that economic "competitiveness" is an important social goal but also much disagreement about what it is. Competitiveness is often discussed as though international trade outcomes are the key. But most economists—including the author—believe that such a narrow focus in economic policymaking is inappropriate. International trade outcomes may be an important means to some national economic end, but they are not the end. Competitiveness worth pursuing is fundamentally about current and future standards of living in the United States, an all-encompassing goal indistinguishable from what we have called national economic performance and economic efficiency. While this analysis does not separately pursue effects on international trade, economic efficiency can have major implications for trade.
The Complexity of the Decision Environment

These company decisions are made in an environment shaped by many factors other than product liability. Figure 2.1 highlights three sets of factors that are crucial in the drug and device industries: market, technology, and regulation. To understand the effects of product liability, the analysis must confront this larger context. The essential background is developed in Section 3.

The Central Role of Decisionmaking

Developing an understanding of how liability enters decisionmaking within this complex system is required to address the issue of central concern: How would the economic performance of the drug and device industries change if the product liability environment were reformed in particular ways? Figure 2.1 depicts the conceptual framework used to structure the analysis and report.

Figure 2.1—Analytic Framework and Structure of the Report

(a) It is harder for U.S. product users to sue foreign companies than U.S. companies; (b) product liability insurance is more costly for U.S. than foreign companies, even if they serve the same markets; and (c) foreign product users may be able to sue U.S. companies in U.S. courts. (See U.S. Senate [1991, pp. 9-10] and American Law Institute [1991a, p. 278].) These issues are not analyzed below, largely for lack of the necessary information. However, we do return to the questions of the importance of liability insurance to company behavior and the extent to which U.S. companies are vulnerable to suits brought by foreigners in U.S. courts.
3. Markets, Technology, and Regulation

Understanding the larger context in which liability operates is essential for analyzing how it affects decisions and outcomes relating to product availability, pricing, safety and effectiveness, and innovation. This section describes that context. The market environment is discussed first. The role of technology—focusing on the development of new pharmaceuticals—is discussed in the following subsection. The final subsection discusses the role of the FDA. The liability environment is discussed in Section 4.

The Market Context

This subsection discusses the aspects of the market environment that seem most important for understanding the effects of product liability. It begins by considering the production sides of the pharmaceutical and medical device industries.

Industry Profiles

The global nature of the pharmaceutical and medical device industries implies that, to analyze the issues of concern here, our economic perspective must be wider than that of the United States alone. For example, some of the outcomes—e.g., U.S. product availability and prices—depend on the decisions of foreign firms that market products in the United States. In addition, substantial portions of the sales of U.S.-based companies are made overseas; hence, some features of foreign markets are important for understanding the decisions of these companies.

Pharmaceuticals. Companies that participate in U.S. pharmaceutical markets may be usefully distinguished according to whether or not they develop new drugs. Companies with active development efforts are referred to as “research-based companies.” Companies that do not develop new drugs do manufacture or distribute products developed by others. In pharmaceuticals, the most important activity of these companies pertains to so-called generic drugs—drugs

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1Conanor (1986) surveys the economic literature on the pharmaceutical industry. Conanor reviews most of the economic issues raised here, but not product liability.
whose active ingredient is identical to those of other companies. Generics can be marketed in the United States after patents on new drugs have expired.

Research-based pharmaceutical companies tend to be quite large. Smaller scales seem more viable for medical device companies and for companies attempting to develop pharmaceuticals using biotechnology. In the United States, innovative drugs are dispensed only by prescription and are marketed for roughly ten years under patent. Substantial experience with the drug accumulates before generic producers enter or before a drug is approved for over-the-counter (OTC) sale. As a result, liability is generally not a major factor for generic producers or for OTC drugs. Accordingly, the focus here is on research-based companies and prescription products.

In 1989, roughly 790 companies in the United States manufactured and marketed pharmaceuticals. The roughly 100 research-based companies accounted for about 90 percent of U.S. sales of these firms. The industry is widely regarded as one of the most profitable manufacturing industries in the United States.

In 1991, global human-dosage sales by members of the Pharmaceutical Manufacturers Association (PMA) totaled about $53 billion, of which $40.7 billion (65 percent) were made in the United States. In that same year, these companies spent roughly $5.9 billion on R&D—about 14 percent of worldwide sales. Total U.S. employment of PMA members in 1989 (the latest year for which data are available) was roughly 186,000 workers, with another 155,000 employees abroad.

Medical Devices. Medical devices are products other than drugs intended for a medical purpose. Examples include bandages, tongue depressors, canes, crutches, all varieties of medical instruments and equipment, computer software used in conjunction with various equipment, and devices implanted in humans.
These products are much more heterogeneous than drugs. Some medical devices seem to involve virtually no threat of product liability actions (e.g., canes, adhesive tape). The most prominent product liability actions have involved implanted devices, such as heart valves, intrauterine devices, and breast implants.\textsuperscript{10}

According to Kessler et al. (1987, pp. 357–358), there are more than 1,700 types of medical devices; 50,000 separate products; and 7,000 manufacturers. The number of manufacturers of medium- or high-risk devices is unknown.\textsuperscript{11} Statistical information on the industry is generally reported in a form that combines medical devices from the entire spectrum of risk levels.\textsuperscript{12} Total shipments for 1991 were about $30 billion.\textsuperscript{13} Total U.S. employment in these industries in 1991 was about 234,000, including roughly 142,000 production workers. For the 43 companies included under “Medical Products and Services” in Business Week (1991), R&D expenses accounted for 6.2 percent of sales.\textsuperscript{14}

\textbf{Economic Aspects of Markets for Drugs and Devices}

Much more is publicly known about the economics of pharmaceutical markets and product development than about those for medical devices. This may reflect the fact that devices are considerably more diverse than drugs—so diverse, perhaps, that reliable generalizations are just not possible. In addition, the sheer number of companies in the device industry makes collection of information very costly. Finally, policy interest in pharmaceuticals has stimulated much research. Because of this relative lack of information about medical devices, much of the discussion below focuses on pharmaceuticals.

For analytic purposes, the fundamental driving force for company decisions is taken to be the pursuit of profits.\textsuperscript{15} On the demand side of the market are physicians and their patients, as well as third-party payers.\textsuperscript{16}

\begin{itemize}
  \item \textsuperscript{10}In addition, there have been roughly 500 liability suits involving tampons, which are marketed without a prescription. (Rheingold, 1989, p. 136.)
  \item \textsuperscript{11}Ingersoll (1992) reports that the FDA is uncertain about how many manufacturers there are under its jurisdiction, and he provides an estimate of 5,500 manufacturers of medium- to high-risk medical devices in the United States.
  \item \textsuperscript{12}For example, statistics compiled and reported by the U.S. government. Less-aggregated, systematic data are simply unavailable.
  \item \textsuperscript{13}Unless otherwise indicated, data are from U.S. Department of Commerce (1992, Chapter 45).
  \item \textsuperscript{14}This percentage ranged from 11 percent to 13.4 percent.
  \item \textsuperscript{15}This is not to suggest that companies are unconcerned with other goals, but merely that the most promising basis for understanding their decisions is focusing on profit incentives.
  \item \textsuperscript{16}Examples are state Medicare and Medicaid programs; large private insurers, such as Blue Cross; and health-maintenance organizations.
\end{itemize}
The discussion of market forces here focuses on profit incentives provided by U.S. markets. This focus reflects three considerations. First, many outcomes—such as U.S. availability, prices, and labeling—reflect decisions specific to the U.S. market. Second, the U.S. market accounts for a large fraction of the profits of multinational pharmaceutical companies, because U.S. sales are a substantial portion of world sales for U.S.-based companies and for many foreign multinationals\(^\text{17}\) and because U.S. profit margins on sales are likely to be substantially higher than for the rest of the world.\(^\text{18}\) Finally, foreign markets receive little explicit attention here, because little systematic information is available. The available information suggests that the fundamental features of U.S. markets discussed here also characterize many foreign markets.\(^\text{19}\)

Markets and Submarkets. Individual drugs or devices are used to treat a relatively small number of more or less specific conditions or diseases. In many cases, there are few, if any, alternatives to a specific product that is useful for a specific treatment or diagnostic purpose. Thus, the market for pharmaceuticals and medical devices is really a collection of distinct submarkets corresponding to different ailments or conditions. These submarkets differ substantially in terms of total size, the numbers of companies and products competing at any time, profitability, etc.

The most enviable position for a company is to have developed and patented a product that is the only effective remedy for a common and serious ailment. The profits afforded by such a market position can be enormous, as can the value to society of such a product.

Drug Sales Profiles—Duration and Variability. Sales data for specific pharmaceutical products illustrate important features of the market environment. Individual drugs exhibit a typical sales profile, which is illustrated in Figure 3.1. The figure depicts the annual profiles of U.S. sales—expressed here in millions of 1987 dollars—for three individual drugs.\(^\text{20}\) As can be seen from the figure, real (i.e., inflation adjusted) product sales grow over time and then

\(^{17}\)For example, recall that for PMA members this fraction is 65 percent.

\(^{18}\)Prices are directly regulated in many foreign countries, but not in the United States.

\(^{19}\)There are, however, major differences between the regulatory and liability environments in the United States and their counterparts abroad. The differences relevant to the analysis are discussed below.

\(^{20}\)Figure 3.1 is based on Logiekar and Paterson (1986), who studied drugstore and hospital sales (1976 dollars) using IMS data for the years 1962 to 1981 for all 218 new chemical entities (NCEs) introduced in the United States from 1962 to 1977. In constructing Figure 3.1, these have been smoothed and reexpressed in 1987 dollars using the implicit price deflator for GNP. (Economic Report of the President, January 1989, Table B-3.)
decline. For the profiles in the figure, the number of years from introduction until real sales peak ranges from 7 to 15, and sales remain substantial 20 years after market introduction and beyond. Joglekar and Paterson (1986) ranked products according to their average annual sales levels and displayed sales profiles for products in various parts of the distribution. The profiles of different drugs exhibit the same qualitative patterns, but there is enormous quantitative variation in sales levels across products. The highest curve in Figure 3.1 depicts the sales history of a drug among the top 10 percent in terms of sales. The curve labeled “third decile” presents corresponding information for a product whose sales performance led

\[\text{Figure 3.1—Annual Sales Profiles of Individual Drugs}\]

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\[\text{\footnotesize 21 The growth phase generally reflects spreading awareness of the product by physicians and sometimes growing awareness by patients that their condition is treatable. Market decline is typically caused by the introduction of a new product (either by a competitor or the company itself) or by patent expiration and competition from generics. Market decline can also result from a spreading disenchanted with a product on the part of physicians and patients. For our purposes, the most important source of disenchanted is concern about product safety.}\]

\[\text{\footnotesize 22 The qualitative features of Figure 3.1 are used in Section 9 to study the effects of product liability on incentives to innovate.}\]

\[\text{\footnotesize 23 They write in the footnote to their Figure 2: “Though all NCEs in a decile will not have this NCE’s pattern, variations are minor and the NCE shown is generally representative of its decile.”}\]
to a ranking in the third tenth of the distribution, and the one labeled “median” is a product whose performance ranks it near the middle of the distribution.

Figure 3.1 indicates that the distribution of sales is highly skewed—a small number of products have very large sales relative to all other products. The especially successful product (i.e., top decile) had sales of roughly three times that of a good (i.e., third decile) performer, and roughly ten times that of the median performer. In addition, many products never achieve any substantial level of sales. Joglekar and Paterson report that the seventh decile product (not shown in Figure 3.1) never reaches annual sales of even $2 million, and its sales fall to zero within 15 years of U.S. market introduction.

**Short-Term Competition.** As explained above, most of the decisions of interest here are made a decade or more before the advent of generic competition. In the absence of generic competition, many submarkets have no more than a few competing products, especially in the early years after the introduction of a pioneering drug or device. Price competition is rather restrained in these settings. But even in submarkets with several competing products, price competition often seems to be more restrained than economists unfamiliar with the industry might expect.

In addition to a small number of competitors, many of these markets are characterized by somewhat price-inelastic demand. When there is little competition and inelastic demand, the profit-maximizing price can be many times the marginal cost of production, marketing, and distribution. Some drug therapies are priced at thousands of dollars per year per patient.

Sales—and, apparently, profits—associated with particular drugs can be very large. A handful of drugs achieve annual worldwide sales of $1 billion. The relatively few drugs that achieve exceptional marketing success—sales of several hundred million dollars per year in the United States, say—are commonly

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24 Joglekar and Paterson (1986, pp. 161-162) report average annual sales for the mean profile of $7.9 million and a corresponding figure for the median product of $1.9 million (1976 dollars).

25 Factors that tend to make demand less sensitive to price include the following: Effective products are very valuable to patients with serious conditions; many products lack close substitutes; many prescribing physicians are quite ignorant or unconcerned about prices; and many patients are relatively unconcerned about price because of reimbursement from public or private health insurance programs. See Office of Technology Assessment (OTA) (1983) for more extensive discussion. Recent developments in the industry, however, suggest that many buyers are becoming more sensitive to price. (Winslow, 1992; Weber, 1993b.)

26 Recent, highly publicized examples include prices for AZT (the first approved treatment for AIDS) and Captopril (discussed in Section 6). Explanations by industry representatives of the levels of drug prices generally emphasize development costs, not such costs as production, distribution, and marketing. (For example, Vaselos, 1991.) A major study of R&D costs and drug prices was published by OTA in early 1993, as the present report was being finalized. (OTA, 1993.) The issue of drug prices became very prominent during the early days of the Clinton administration.
known as “blockbusters.” Although profitability figures for individual drugs are unavailable, all indications are that the lion’s share of profits in most companies is attributable to a small number of exceptionally successful products. In fact, variation in sales exemplified in Figure 3.1 is likely to underestimate the variation in profitability, because profits as a percentage of sales should be expected to increase with sales.

As high as some drug prices often seem, they may, in fact, be lower than simple textbook models of pricing would predict. In markets in which a company has no effective current competition and demand is very inelastic, one might wonder whether the price of a drug is nearly as high as the short-run profit maximizing price. Here the facts that drug prices often receive considerable attention in political arenas and companies generally sell various products to the same buyers (physicians, hospitals, third-party payers) may be factors in determining profit-maximizing prices.

Drug prices are not directly regulated in the United States, but congressional discussion of the possibility and public jabling about drug prices are very common. However, fear of triggering regulation may not be a major factor in restraining prices. Recognizing that there are dozens of major pharmaceutical companies operating in the United States, individual firms may be expected to reason that the effect of their prices on the probability of industrywide price regulation is likely to be rather slight. Absent a private, collective mechanism for achieving joint pricing restraint, the threat of price regulation may not restrain pricing much.

A more plausible mechanism operates through the behavior of buyers. In particular, a company whose prices are perceived as being unreasonable is likely to sacrifice goodwill with some physicians and, especially, third-party payers. This reduction of goodwill can lead to reduced demand for a product when a substitute is introduced, or for others of the company’s products.

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27. Most annual reports of pharmaceutical companies and discussions of pharmaceuticals in the business press reinforce this view. Comanor (1986, p. 1182) writes: “For some major firms, three products alone account for 70 to 80 percent of total pharmaceutical sales, and for most firms, these percentages are substantial.” Magnet (1981, p. 112) recounts how a single blockbuster (Tagamet, an ulcer treatment) reversed the fortunes of a major pharmaceutical company (SmithKline).

28. Many costs associated with a product are likely to rise less than proportionately with sales. For example, development costs may be no higher for successful products than for unsuccessful products that reach the market, and unit production and distribution costs may be lower for more successful products because of economies of scale.

29. Specifically, any model of profit-maximizing pricing for a company facing a downward-sloping demand curve.

30. For example, if the price elasticity of demand is -0.01, standard models predict that the price will be 100 times marginal cost of production, sales, and distribution.
While price competition is often rather restrained, marketing competition is often fierce and costly. Direct contact between physicians (and other health-care professionals) and sales representatives of the companies is often the primary form of sales promotion. Advertising to physicians in medical journals is very extensive, and direct mailings are also used. In addition, direct-to-consumer advertising is becoming important for some products. Sales promotion efforts are extensive even for drugs with no present competitors. A major purpose of promotion in such a context is to make physicians (and, less often, patients) aware that a treatment is available.

**Long-Term Competition.** The competition that seems most important for the financial performance of the industry is the long-term competition to develop new pharmaceuticals. Development of new products is of central concern for policy as well. One reason is the contributions of innovation in these industries to the recent improvements in health care and the hope that new drugs and medical devices can play a comparable, if not greater, role in the future. Also emphasized in many policy discussions is the success of U.S. pharmaceutical companies in international competition and the implications of this success for the maintenance of high-quality jobs in the United States.

Development of new pharmaceuticals is costly, risky, and time consuming. While dozens of companies together spend billions of dollars in the United States each year to try to develop new drugs, typically only 20 to 30 new drugs are marketed in the United States each year. In addition, available evidence indicates that most drugs that are marketed never return the average cost of development.

Why do companies spend billions of dollars trying to develop new drugs under such conditions? Because the major successors—blockbusters—are very profitable, and the development of major new products is essential to the long-

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31 For example, the PMA data indicate 55,500 marketing employees of a total of 186,000.
33 For a discussion of pharmaceutical therapies available before World War II and the "therapeutic revolution," see Temin (1980, Chapter 4). In the case of devices, various very useful (e.g., life-sustaining and diagnostic) equipment and implantable devices (such as pacemakers, heart valves, and artificial joints) are the products of relatively recent innovations.
34 This aspect of international competitiveness is emphasized by Porter (1990).
35 Joglekar and Paterson (1986) and Grabowski and Vernon (1990).
term viability of the research-based companies. Companies that fail to innovate will suffer severely declining financial performance.\textsuperscript{36}

As in many markets, being first seems to have major advantages. The first company to market a treatment for a particular disease or condition often retains the largest share of the market even after competitive introduction of various largely similar products.\textsuperscript{37} If the market for such a product is large (e.g., because many people suffer from a serious condition that it relieves), the profits associated with the product can be enormous. To the extent that major financial rewards are likely to accrue to the developers of such products, the market provides substantial incentives to develop the kinds of products that are very valuable from a social point of view. Thus, in the long term, competitive effort focuses on the discovery and development of new blockbusters.\textsuperscript{38}

Technology and the Economics of Drug Development

Central to long-term competition, then, are efforts to develop new products. Much more information is publicly available concerning the economics of pharmaceutical development than medical devices. One major difference between the economics of most product development in pharmaceuticals and medical devices is apparent, however. For reasons explained presently, the state of the art in chemical-based approaches to developing new pharmaceuticals implies substantial advantages to diversified, and hence relatively large, R&D operations.\textsuperscript{39} In contrast, it appears that smaller companies are a more typical source of innovation in medical devices than in pharmaceuticals.\textsuperscript{40} For lack of

\textsuperscript{36}For example, in financial profiles of pharmaceutical companies, a somewhat common, and very troublesome, report is the fact that major products are nearing patent expiration, with no apparent blockbusters "in the pipeline."

\textsuperscript{37}Tennin (1980, pp. 105–119) argues that "custom" in prescribing plays an important role here.

\textsuperscript{38}The first treatment for a widespread and serious condition can be expected to be a blockbuster. However, other types of products can be major marketing successes, for example, products that (a) offer substantial improvement in effectiveness, safety, or ease of administration; and (b) involve only arguable improvements, but nonetheless capture a modest share of a large submarket, or some part of a smaller one.

\textsuperscript{39}In addition, Thomas (1990) argues that FDA regulation contributes to the advantages of large pharmaceutical companies over smaller ones.

\textsuperscript{40}Small R&D operations appear to be quite viable for at least some types of medical devices, and this may go a long way toward explaining the large number of such companies. For example, many medical devices (such as implants) compensate for visible, physical deficiencies that are generally easier to detect and understand than the diseases or conditions for which drug therapy appears more promising. This makes narrowly targeted R&D efforts more viable for such devices than it is often the case with drug development.
information, the discussion here focuses on the economics of drug development.\textsuperscript{41}

\textit{Trial, Error, and Surprises}

The development of new drugs relies on a science base that is continually expanding, but remains perhaps surprisingly incomplete.\textsuperscript{42} Many of the basic scientific activities relevant to drug development are performed outside of pharmaceutical companies and are heavily subsidized by the government, philanthropic organizations, and private companies. Pharmaceutical companies tend to focus their efforts on more applied activities, and much of their work is proprietary.

While they rely on an ever-improving base of knowledge concerning disease processes, efforts to develop new pharmaceuticals are still very much a matter of trial and error. Most R&D activities never lead to a marketable product. Efforts that begin with the hope of developing a treatment for one type of ailment (e.g., cancer)—if successful at all—may result in a treatment for an entirely different condition (e.g., heart disease).\textsuperscript{43} Most drugs that have been developed to treat some form of cancer were discovered by accident.\textsuperscript{44} But, despite the unpredictability of the drug development process, there is ample reason to believe that the areas a company chooses to target have major effects on what

\textsuperscript{41}For example, the paucity of knowledge about the innovative process in medical devices is indicated by Appendix C of OTA (1984), which is entitled "The Innovative Process in the Medical Devices Field." The introduction reads in part:

There are, of course, many stories about the introduction of specific new devices. . . . These individual cases demonstrate the diversity of the developmental pathways taken. They suggest that simple generalizations of the process are impossible. Yet, some elements of the process may be common to all medical devices and, indeed, to all new technologies. . . . This appendix explores the process of technological change in general. (OTA, 1984, p. 186.)


\textsuperscript{43}For example, the developers of AZT (an AIDS treatment) first hoped that it would "inhibit the growth of tumor cells," and minoxidil (the only drug approved in the United States to treat baldness) was first used internally to treat high blood pressure (Pitta, 1991.) Freundlich (1989) recounts that some drugs originally developed as acne remedies have shown some promise for skin cancer. Elumenthal (1989) discusses examples of serendipitous discovery, triggered by side effects or adverse reactions, of new uses for five drugs.

\textsuperscript{44}For example, see The Economist (1989).
types of products it is likely to develop.45 For example, companies place great emphasis on these decisions (e.g., they are a—if not the—fundamental concern in strategic planning efforts).

The trial-and-error nature, the large costs, and the potential importance of perspectives from various scientific specialties seem to go a long way toward explaining why diversified, relatively large companies appear to dominate chemical-based pharmaceutical innovation. However, relatively small companies are quite prominent in many types of development efforts based on biotechnology, because many promising development strategies here involve more narrow targeting.46

Various Strategies of Drug Development

The traditional, chemical-based approach to drug development is based on sketchy understanding of disease processes and involves synthesis and laboratory screening of large numbers of chemicals.47 Despite the expansion of knowledge, this development strategy remains quite common. One variant involves “tinkering” with the chemical structure of a drug that has proven useful in the hope of developing a similarly or even more safe and effective product.48

A variety of modern strategies—often referred to as “rational drug design”—are based on relatively detailed understanding (or hypotheses) concerning the chemistry of individual disease processes. This might involve synthesis of chemicals designed to have particular effects on particular types of cells. Because the chemical action is by design more specific in such cases, such drugs are expected to have fewer side effects than drugs developed in more traditional ways. But even the so-called rational approach involves much trial and error. While there is still considerable enthusiasm for rational drug design, it is safe to conclude that it has not become the panacea that some had predicted a decade or so ago.49

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45 Decisions about R&D capabilities have fundamental implications for where companies look for research leads and what types they are positioned to follow.
46 Most of these companies have yet to market a product. Whether a small scale is viable for companies that succeed in developing marketable products remains to be seen.
47 For example, the National Cancer Institute screens about 10,000 chemicals per year, and a decade of such effort had produced only one potentially promising product by 1989. (The Economist, 1989.)
48 This strategy, generally referred to as the development of “me too” drugs, is disparaged by many but can result in substantial therapeutic improvements. (Wasielewski, Ulickas, and Losagna, 1989.)
49 See, for example, The Economist (1991b), the summary of which reads: “Using precise scientific knowledge to design the perfect drug is an alluring idea. Trying everything you can think of is less elegant—but it may work better.”
Development efforts involving biotechnology are increasingly important.\textsuperscript{50} One such approach is isolation of naturally occurring substances the deficiencies of which are associated with a disease or ailment and the use of biological methods to produce these substances on a commercial scale.\textsuperscript{51} But laborious methods and trial and error also play major roles in development efforts involving biotechnology.\textsuperscript{52}

\textbf{Stages of Drug Development}

Development of a new drug is a sequential process often described roughly as follows.\textsuperscript{53} Once a substance is discovered—either chemically synthesized or found in nature—and appears sufficiently promising on the basis of in vitro tests, it is tested on laboratory animals using high doses for short periods of time.\textsuperscript{54} While such preclinical testing can provide very useful information, encouraging laboratory and animal tests merely suggest that a product might be reasonably safe and effective in humans. The subsequent clinical (human) testing generally involves three phases,\textsuperscript{55} with each later stage undertaken only if the results of the prior stage are sufficiently encouraging:

- **Phase I.** A small number—usually dozens—of healthy volunteers are used to examine the toxicity of the substance and gauge the dosage levels that appear safe.

- **Phase II.** A larger number—100 or more, but typically less than 1000—of people with the condition that the substance is intended to treat are used to study effectiveness and safety.

- **Phase III.** A larger number—hundreds, sometimes tens of thousands—of subjects are studied in a randomized design to develop further effectiveness

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\textsuperscript{50}PMA (1990) reports that the first biotech drug approval in the United States was in 1982 (human insulin), and results from a 1990 survey indicate that 104 "genetically engineered medicines and vaccines" were being tested on humans or were under review at the FDA. Burkholder (1991) reports that as of mid-1991, "only 14 biotechnology-derived products have been licensed so far by FDA." Hamilton (1992, p. 67) reports that, in 1991, biotechnology companies received five of the 30 FDA product approvals, and sales of biotech products (vaccines, drugs, and diagnostic agents) accounted for more than $4 billion worldwide.

\textsuperscript{51}For example, insulin and human growth hormone.

\textsuperscript{52}Hamilton (1992) describes various strategies and biological processes involved in biotechnology drug development efforts.

\textsuperscript{53}For example, Hansen (1979), Wiggins (1981b), DiMasi et al. (1991), and CTA (1993).

\textsuperscript{54}Hansen (1979, p. 153) refers to the activities preceding animal testing as the "discovery" phase of drug development, which includes activities before "a new chemical entity is selected for extensive testing," such as "synthesizing new chemicals, early pharmacologic studies on these chemicals, and attempts to improve the understanding of physiopathological processes."

\textsuperscript{55}So-called "Phase IV" clinical trials typically involve less formal study of patients using the product after it is introduced commercially. More formal Phase IV studies are sometimes conducted.
information and to afford a better opportunity to learn of relatively rare adverse reactions or side effects.

If the early clinical tests are sufficiently encouraging, long-term tests on laboratory animals are started.

Of the many thousands of chemicals synthesized in the industry each year, only about 20 to 30 NCEs enter the U.S. market annually. The costs and time involved are very considerable. DiMasi et al. (1991) provide the most recent and complete information concerning these issues. They obtained information from 12 U.S. pharmaceutical firms on the development programs for 93 NCEs first tested on humans from 1970 to 1982. They estimate that only 23 percent of these products will ever receive approval for marketing in the United States. (DiMasi et al., 1991, p. 124 and Appendix B.)

The average duration of preclinical testing for the NCEs studied by DiMasi et al. (1991) was about three and one-half years, and the average duration of the three stages of clinical testing combined was almost six years. Total development costs—including the costs of having money tied up for many years—averaged over products that reached the market were estimated to be $230.8 million (1987 dollars), two-thirds of which represented the costs of preclinical activities.56 This reflects the trial-and-error nature of the processes for discovering new drugs.

By the time clinical information is available for a product, many years and many millions of dollars have been invested in it. Clinical experience may indicate that a product is not as safe or effective as was hoped. But if it still seems sufficiently promising that FDA approval can reasonably be anticipated, there are powerful incentives to continue the effort to bring this drug to market. Changing the chemical structure makes the product a different drug and requires return to the preclinical stage. Doing this is extremely costly in financial terms. But perhaps more important, the delay could allow another company to get to the market first with a competing product, which would be very costly in terms of eventual sales. The very high costs of returning to preclinical activities and the odds against finding a better product suggest that it is unlikely that a company would abandon a product that has been through some clinical testing if it still has much potential to reach the market.

This does not mean that companies may typically pursue efforts to develop products that evidence serious safety problems or do not seem to be effective. FDA approval for such products would be doubtful. The point is that a product

56See DiMasi et al. (1991, Table 4).
that seems sufficiently safe and effective to qualify for FDA approval is unlikely to be abandoned even if the clinical experience is somewhat disappointing.

**Regulation of Safety and Effectiveness in the United States**

In the United States, the paramount authority for regulation of pharmaceuticals, biologics, and medical devices is the FDA. Its mandate is to assure both safety and effectiveness, but the numerous trade-offs between these objectives require the FDA to make difficult choices in attempting to strike appropriate balances. The discussion here focuses on aspects of FDA regulation that seem most important for understanding the economic effects of product liability. 57

Since the 1962 amendments to the federal Food, Drug, and Cosmetic Act, the FDA mandate has been to assure both safety and efficacy of drugs (including biologics). FDA regulates clinical testing, approval for marketing, initial product labeling, manufacturing practices, monitoring and reporting of experience with marketed products, and changes in product labeling of virtually all drugs and biologics. Regulatory requirements are applied to all new drugs and biologics partly because they are all presumed to pose substantial safety hazards.

Major extension of FDA authority to regulate medical devices, including introduction of FDA authority to require preapproval for the marketing of some devices, came into effect with the 1976 Medical Device Amendments. Only some medical devices are regulated as extensively as pharmaceuticals and biologics. Some medical devices are much less tightly controlled by FDA, since they are not considered sufficiently risky to call for regulation. 58 Many other devices are not extensively regulated because of the lingering effects of grandfathering provisions of the 1976 amendments. In particular, it appears that many devices that may be quite risky have not been subjected to extensive FDA review—a concern that has received much public attention recently.

57 Much that has been written on the effects of FDA regulation makes no reference to interactions with product liability and focuses on the process of FDA approval for marketing. Gibbs and Mackler (1987), whose main concern is how FDA action affects product liability outcomes, provide a very useful review of this and various other aspects of FDA regulation. OTA (1993, pp. 138–150) provides a detailed discussion of many aspects of pharmaceutical regulation.

58 The least-risky devices are assigned to Class I under the 1976 amendments and include such devices as tongue depressors, bandages, casts, and crutches. Class II devices are viewed as posing more potential risk. The devices that seem to pose the most risk are in Class III—these include "devices such as implants or devices that are used to sustain human life." (Gibbs and Mackler, 1987, p. 207.)
The strictness with which various activities bearing on product safety are regulated may have important implications for assessing the economic effects of product liability. Thus, major differences between the stringency of regulation for drugs on the one hand and some medical devices on the other and the reasons for these differences are of special relevance for this study.

Profile of Regulations

To gain FDA approval to begin marketing a drug or biologic, or to market one of these products for a new patient condition ("indication"), clinical trials must be performed.59 Before a company may commence clinical trials, it must file an investigational new drug (IND) exemption application with the FDA.60 This filing includes results of animal tests, a literature review, information about human experience with the product in the United States or abroad, and plans for the clinical testing, including plans for obtaining informed consent from all participating patients.51

Once sufficient clinical and long-term animal testing is completed, if the company still wishes to market the drug in the United States (or market it for a new indication for which it was tested), it files a New Drug Application (NDA) (or, in the case of a biologic, a product license [PL]). These often massive sets of documents detail the results of the animal and clinical trials, updated information from the literature and experiences outside the United States, and the proposed product labeling.62 Approval for marketing in the United States awaits a judgment by FDA that there is sufficient evidence of safety and effectiveness. Sometimes, panels of outside experts are used by the FDA to provide advice. DiMasi et al. (1991, p. 123) report an average FDA review time (time from filing of the NDA to approval) of 30.3 months.

In the case of medical devices, the analog to an NDA or PL is a premarket approval application. Medical devices can also enter the market by use of a 510(k) premarket notification if the device is "substantially equivalent" to a

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59. Some medical devices do not require FDA approval for marketing, and those that do require approval generally require clinical testing. (Gibbs and Mackler, 1987, p. 207.)

60. The analog to an IND in the case of medical devices is called an investigational device exemption (IDE). An IDE must be filed to commence testing a "significant risk" device. (Gibbs and Mackler, 1987, pp. 207-208.)


62. Isaac and Holt (1987, p. 536) write: "Each NDA consists of about two to 15 volumes of summary material accompanied by 10 to 100 volumes (sometimes up to 200,000 pages) of raw data." OTA (1993, p. 152) reports: "The typical NDA consists of 30 separate volumes of technical information totaling 100,000 pages of text, data tabulations, statistical analyses, and patient case report forms..."
device that was in commercial distribution before May 28, 1976." (Gibbs and Mackler, 1987, p. 209.) In fact, this route to the market has been much more widely used than the premarket approval application. FDA can require extensive information in support of the claim of substantial equivalence, and this blurs somewhat the distinction between a premarket approval application and a 510(k) notification. This grandfathering mechanism does, however, seem to lead to an important difference between the stringency of medical device regulation and that for drugs and biologics. In particular, Gibbs and Mackler (1987, p. 210) write:

Under the Amendments, the FDA ultimately must require the filing of safety and effectiveness data for all Class III devices, i.e., the most risk-laden devices, that have entered the market through the 510(k) process. The agency, however, has required PMAs [premarket approval applications] from only a handful of Class III devices that were on the market before May 28, 1976.

Average review times of applications for approval to market devices have been substantially shorter than for drugs: Kessler et al. (1987, p. 359) report an average premarket approval time of one year.

FDA regulation of medical devices has been widely criticized in the policy arena. In 1990, the perceived problems were the extent of use of the 510(k) procedure, which has been characterized as "an enormous loophole"; that less than one percent of device problems at hospitals was being reported to the FDA; and that, even though allegedly defective or dangerous devices were on the market, the FDA had never used its authority to require recall or notification, relying instead on voluntary measures. (Congressional Quarterly, 1990, p. 580.) In response, new legislation emerged: the Safe Medical Devices Act of 1990. This act attempts to strengthen regulation of medical devices in various ways. It is too early to tell what its effects will be.

Marketing in the United States also requires FDA approval of the labeling of the product, which includes the indications for which FDA approval has been granted. This labeling plays a critical role in product liability. Most importantly, labeling includes the package insert (intended for prescribing physicians, not...

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62 Kessler et al. (1987, p. 359): "Approximately 55 'substantially equivalent' premarketing notifications are filed for each PMA [premarket approval application]."

64 For example, citations in Kessler et al. (1987, ins. 5–6) and media reports concerning silicone-gel breast implants (see Section 6).

65 Among other things, this measure prohibits a finding of substantial equivalence with a pre-1976 device if there are concerns about safety or effectiveness, requires the Secretary of Health and Human Services to order immediate cessation of marketing of a device that seems likely to cause injury or death, and requires increased record keeping and reporting. (Congressional Quarterly, 1990, p. 580.)
patients) and the "brief summary" of this information to be included in product advertisements in medical and other journals.  

When a product is approved for U.S. marketing, there is often much more to be learned about its safety, despite all of the tests and regulatory oversight. The reasons for this are important to an understanding of the economic effects of product liability. One reason is that clinical trials involve relatively small numbers of patients. Thus, side effects that are relatively rare may not be detected in clinical trials. Another reason is that clinical trials—as time-consuming as they are—may fail to detect adverse effects of products intended for long-term use or substantially delayed or latent effects of products intended for either short- or long-term use. Because of such possibilities, FDA regulation continues beyond the time of market introduction. The two most important aspects of postmarketing regulation are procedures for modifying product labeling and regulations requiring monitoring and reporting of adverse outcomes experienced by patients.

FDA policies concerning changes in product labeling have important implications for the effects of product liability. Regulations instituted in 1986 allow companies to add warnings or to attenuate claims of effectiveness without prior FDA approval. But subsequent approval is required, and companies cannot presume that the FDA will approve all such changes.

Regulations requiring reporting of so-called adverse drug reactions (ADRs) in the case of drugs and medical device reports (MDRs) in the case of devices can

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66 Labeling information designed for patients—a patient packet insert (PPI)—is also required for four products. See, for example, Bushwood and Simonsmeier (1986, p. 280, fn. 6).

67 Some drugs for chronic conditions may be used for the remainder of a patient's life, and many medical devices are permanently implanted. DES—which was banned in 1971—provides a stark example of potential latent, long-term effects of a drug taken for short periods. It was used by pregnant women to prevent miscarriage, and various adulthood injuries to daughters exposed in utero have been linked to it. DES has been the target of more than 2,000 product liability suits, and litigation continues even today. Various aspects of the DES case are discussed in Epstein (1984), Wernig (1989), and Wright (1992).

68 These are especially important in the product liability context, because labeling plays a central role in the legal doctrine, and compliance or noncompliance with FDA regulations can be a central issue in product liability suits.

69 The material in this paragraph is based on Cooper (1986, pp. 234–236), Gibbs and Mackler (1987, pp. 233–234), and Shulman and Ullickas (1989, p. 97).

70 Gibbs and Mackler (1987) and Shulman and Ullickas (1989). Shulman and Ullickas (1989, p. 97, fn. 10) indicate that subsequent FDA approval of the changes is also required. Prior to these changes in regulation, FDA approval was required before any changes in labeling could be made. (Walsh and Klein, 1986, p. 185.) Richard Cooper—Chief Counsel of FDA from 1977 to 1979—apparently referring to the earlier regulations, writes: "FDA thus retains, as a practical matter, complete control over package inserts." (Cooper, 1986, p. 236.)
also play an important role in product liability actions. This is often an important role in modification of product labeling, and if sufficiently severe safety problems become apparent, the FDA can and does play a role in product withdrawal or limitation of product use. Information developed or publicized as a result of product liability suits also can affect FDA policies in this regard.

**Economic Effects of Regulation**

Thus, product liability operates on company decisions in an environment characterized by extensive regulation of drugs and many medical devices. FDA regulation is widely believed to be important in determining safety and effectiveness (the explicit goals) and in determining the other outcomes under study here (product availability, innovation, and prices). Analyses of the effects of FDA regulation provide essential perspective for studying the effects of product liability.

The most obvious ways that FDA can affect economic outcomes operate through its authority to restrict marketing of products. The FDA does not merely influence whether a product is marketed in the United States: It influences when. The effects of FDA regulation on whether and when products become available in the United States have been the focus of the literature on the economic effects of FDA regulation.

The social benefits of restricting or delaying product availability include avoidance of injuries and resource costs associated with products that would be marketed in the absence of regulatory controls. Less obviously, these benefits also include avoidance of health costs that would result from use of ineffective products when effective alternatives would be used instead. The social costs of

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72 With devices, such information can lead the FDA to reclassify devices and subject them to more stringent regulations and controls. (Gibbs and Mackler, 1987, p. 207.)

73 Examples are discussed in Section 6.

74 Like most major regulatory programs, FDA regulation of drugs has received considerable attention and criticism from economists and policy analysts. See, for example, Grabowski and Vernon (1989) and Comanor (1986, pp. 122-1211) for a discussion of many of the issues. Dranove (1991) provides a succinct, recent overview. Regulation of devices has received relatively little attention until recently.

75 These effects are central to the analysis of liability effects on safety and effectiveness in Section 8, and play important roles in the analysis of product availability in Section 6 and innovation in Section 9.

76 There appears to be little, if any, empirical research on the economic effects of FDA regulation of product labeling and postmarketing monitoring and reporting of adverse product experiences, or of compliance with FDA regulations of any sort. These aspects of regulation are central to the analysis of Section 8.
restricting or delaying product availability include the costs of the extra testing required to meet FDA standards, the administrative costs of the regulatory process, and the health costs to patients who could have benefited from a product whose availability was restricted or delayed.

Costs that have received extensive attention are those associated with delays in bringing new drugs to the U.S. market. Particularly prominent in this regard is the amount of time it takes for an NDA to receive approval.77 In addition, the stringency of FDA requirements78 for demonstrating safety and effectiveness contributes to delays in reaching the points at which viable INDs or NDAs can be submitted. Various studies have documented, discussed, and criticized the fact that new drugs are typically available in other countries before they are approved for marketing in the United States.79

The evidence on the costs and benefits of FDA restrictions or delays of drug availability is not conclusive. But the view is widespread that expediting the approval process—or even making it less stringent—could provide benefits well in excess of the costs of safety decreases. One important reason for this view is that the incentives the FDA faces push it to be too conservative—from an economic point of view—in protecting safety. This is because the legislative mandate of the FDA is to assure the safety and effectiveness of products that are marketed; the costs to FDA officials of injuries caused by approved products are typically much higher than the costs to FDA officials of a loss of effectiveness because of delay or lack of product availability.80

Steps have been taken to respond to such concerns.81 For example, the FDA attempts to expedite the approval process for drugs in situations where the costs of delay are particularly obvious, such as treatments for cancer and AIDS.82 Federal legislation in the fall of 1992 imposed user fees on manufacturers of prescription drugs and biologicals, with the funds to be used by the FDA to add

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77 These approval times are regularly documented and trends analyzed. Most prominent are numerous studies of the Center for the Study of Drug Development. See, for example, DiMasi, Bryant, and Lathan (1991).
78 For example, FDA requirements are often claimed to be more stringent than those in most other countries. See, for example, Drasche (1991, p. 236).
80 See Grabowski and Vernon (1983, Chapter 1).
81 See OTA (1993, pp. 151–158) for an extensive discussion.
staff and speed consideration of approval applications.\(^{83}\) There has also been discussion of cooperation with regulatory authorities in Europe.\(^{84}\)

Despite the widespread view that the FDA attempts to protect safety at costs that exceed benefits, the FDA is also subjected to extensive criticism—by Congress, consumer advocates, and others—because of injuries that do occur. For our purposes, it is critical to distinguish between FDA safety standards and levels of compliance with FDA regulations. Safety standards refer to the level of safety that would be achieved if all FDA regulations were obeyed strictly—i.e., with full compliance. Clearly, the FDA does not have the resources necessary to approach this ideal.\(^{85}\)

Some product injuries are attributable to the fact that FDA standards are not as strict as they might be, and other injuries are attributable to failures of compliance.\(^{86}\) As detailed in Section 8, the relative importance of these sources of injury seems very different in the cases of drugs and extensively regulated devices\(^{87}\) on the one hand and less-regulated devices on the other.\(^{88}\) This distinction has important implications for the analysis of economic effects of product liability and for the evaluation of policy reform.

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\(^{84}\)See, for example, The Economist (1991a).

\(^{85}\)See, for example, Burkholz (1991). Consistent with the view here of the paramount concerns about shortcomings of FDA regulation, and writing the day after David Kessler was sworn in as FDA Commissioner, Hills (1991) begins: “Saying he intended to revitalize an overburdened agency, the new Commissioner of the Food and Drug Administration said today that he would get tough in enforcing its regulations while seeking to approve new drugs more quickly.”

\(^{86}\)For example, a product might be approved for marketing or mislabeled because the company ignored or failed to report evidence of a particular safety problem. In such a case, injuries are attributable to compliance problems, not the level of the FDA safety standard.

\(^{87}\)Specifically, those devices subjected to the premarket approval process or extensive review within a hybrid 510(k) procedure.

\(^{88}\)Specifically, those devices that are marketed on the basis of “substantial equivalence to pre-1976 devices” through the 510(k) procedure.
4. The Effects of Product Liability on the Profitability of Actions

This section reviews and characterizes the aspects of the product liability environment that seem most important for understanding its effects on the economic outcomes of interest. A key problem for policy is to provide incentives for firms to choose socially beneficial actions and to avoid socially harmful ones. Profits are the fundamental incentive of company decisionmakers. Accordingly, product liability affects company decisions—and, in turn, economic outcomes—through its effects on the profitability of various courses of action.

To design policy, one must understand how different policies lead to different decisions and outcomes. Specifically, to link liability to economic outcomes, we must consider (a) how elements of the liability system affect the profitability of various actions—i.e., alter company incentives—within the context determined by market, technological, and regulatory factors; (b) how decisions and actions change in response to such changes in profit incentives; and (c) how these changes in decisions and actions affect the economic outcomes of concern.

This section focuses on the first of these tasks. It contains six subsections, each building on the previous ones. The first considers in general terms how product liability can affect profits and hence company incentives to take various actions. The second subsection reviews the aspects of legal doctrine and its application that seem most important for understanding the economics of product liability in drugs and devices. The third decomposes the effects of liability on profits and discusses determinants of the components. The focus of the fourth subsection is on company uncertainties and risks associated with liability. The fifth analyzes how the potential for liability to affect profits differs according to attributes of products and patients. The final subsection summarizes the entire section.

Effects of Product Liability on Company Incentives—Overview

Profits are the difference between the revenues a company receives from product sales and the costs it incurs as a result of its business activities. Product liability can affect company costs and revenues directly and indirectly.
Most obviously, liability actions brought against a company can impose direct costs. These include the costs of defending liability suits and the costs of paying settlements and court awards. The precise extent to which drug and device companies carry commercial insurance coverage for such costs is unknown and undoubtedly varies by company. But self-insurance for product liability seems to have become prevalent over the last two decades,\textsuperscript{2} and drug and device companies are often specifically mentioned in this regard.\textsuperscript{2} Moreover, even liability costs that are reimbursed by commercial insurance are costly to a company, because adverse liability experiences are likely to lead to higher future premiums or withdrawal of insurance coverage. For our purposes, it is sufficient that a significant portion of the total—i.e., direct plus indirect—costs of liability is borne by the company, and satisfaction of this condition seems safely presumed.

Systematic data on direct liability costs are unavailable. But, as detailed in Section 6, such costs have been substantial for selected drugs and devices. Systematic information on case filings points in the same direction. For example, Dungworth (1988, pp. 38–42) reviewed federal case filings from 1974 to 1986 and found over 11,000 such suits against “defendants in the pharmaceutical and health products group” during that period.

The indirect mechanisms by which the liability system can affect profits are more subtle.\textsuperscript{3} Developments within the liability system can set in motion events leading to changes in the behavior of patients and their attorneys, the FDA, and physicians. Such changes are relevant to the extent that they affect a company’s revenues or costs.\textsuperscript{4}

Plaintiffs’ attorneys have financial incentives to develop and publicize sources of doubt about the safety of products.\textsuperscript{5} New information uncovered in the course of a suit—for example, evidence of failure to comply with FDA regulations—can be very helpful to a plaintiff’s case. Potential media attention resulting from

\textsuperscript{1}For example: “The large manufacturers we interviewed had all, during the 1970s, greatly decreased the proportion of their insurance coverage from outside companies.” (Eads and Reuter [1983, p. 132]. They focused on product liability and conducted interviews with nine large manufacturers.) Priest (1991, pp. 45–46) provides quantitative information on the trend toward corporate self-insurance for liability since 1970, concluding that “total self-insurance costs must have been at least as much as the range of 60–80 percent of aggregate liability insurance expenditures in 1986.”

\textsuperscript{2}For example, Viscusi (1991b, p. 189): “Notable examples of firms that have self-insured or sought special coverage... are those firms in the pharmaceutical industry and the asbestos industry.” Mastroianni et al. (1990, p. 139) discuss insurance arrangements in the context of contraceptives. See OTA (1993, pp. 172–173) for a discussion of self-insurance in pharmaceuticals.

\textsuperscript{3}The indirect costs of liability—discussed presently—are not insurable externally.

\textsuperscript{4}Viscusi and Hersh (1990) present estimates of effects of \textit{Wall Street Journal} reports of liability suits on the stock prices of pharmaceutical companies. Such effects should reflect uninsured direct costs plus indirect costs of these events.

\textsuperscript{5}Just as the analysis emphasizes the pursuit of profits as the motivation for company behavior, it emphasizes economic incentives in understanding the behavior of plaintiffs’ attorneys.
large awards can pressure a defendant to settle to avoid additional suits\(^6\) and attract new clients for the attorney.

New information and publicity can generate substantial pressure on the FDA to reevaluate its previous decisions.\(^7\) Whether or not new information is brought to light, changes in regulatory treatment may result from publicity. Requirement of additional or strengthened warnings, elimination of some approved indications, or removal of the product from the market can decrease company sales and profits. Even if the FDA does not require such changes, an FDA investigation can be costly to a company both in terms of direct costs of the process and in terms of possible adverse publicity.

Information and publicity generated by product liability actions can heighten awareness and concerns about product hazards and deter physicians from prescribing the product involved in the suit.\(^8\) Even if a physician's beliefs about the safety of the product are not altered, product liability suits might discourage physicians from prescribing a product. For example, physicians might be concerned about malpractice suits involving products that they believe to be quite safe or (at least) worth the risk to the patients for whom they prescribe them.\(^9\) In addition, if the liability action leads patients to be concerned about the product's safety, physicians may not prescribe it for that reason, or patients may fail to seek treatment\(^10\) or fill the prescription.\(^11\)

Often, it seems, information discovered in product liability cases does not become public, at least for some time. Kolata (1992b) writes: "It has become routine in product liability cases for companies to insist on these secrecy orders,

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\(^6\) Settlements are generally not extensively publicized, and the amounts paid in settlement are often kept confidential as a condition of the settlement.

\(^7\) Political pressure triggered by safety concerns can be considerable: Congressional hearings probing the safety of pharmaceuticals and medical devices and the actions of the FDA are not unusual.

\(^8\) It is also possible that heightened awareness that compensation is available for product injuries tends to increase product sales, but the mechanism emphasized in the text seems much more important. For example, companies rarely choose to publicize the availability of compensation through the tort system.

\(^9\) For example, to guard against such an effect, the manufacturer of Prozac—discussed in Section 6—has recently offered to defend physicians if they are sued as a consequence of prescribing it. (Herbst, 1991 and Freuss, 1991.)

\(^10\) For example, OTA (1979, p. 3): "Finally, in light of recent court cases broadening vaccine manufacturers' liability... Widespread publicity of the potential, though statistically remote, dangers associated with nondefective vaccines may be eroding overall public confidence in the safety of vaccine products."

\(^11\) Many prescriptions written by physicians are never filled, and "patient acceptance" is a standard consideration in the prescribing decisions of physicians.
called protective orders, before allowing plaintiffs' lawyers to examine company documents. Judges most always go along with these requests.\textsuperscript{12}

**Legal Doctrine and Its Interpretation and Application**

This subsection describes in broad terms aspects of the legal environment that are most important for understanding the incentives faced by drug and device companies. It proves useful to distinguish between legal doctrine and issues concerning its interpretation and application.\textsuperscript{13}

Product liability doctrine for drugs and devices differs in some important ways from general product liability doctrine. The discussion here relies primarily on sources and cases specific to drugs or devices. Discussions of general product liability doctrine are used when they are applicable and when sufficient information specific to drugs and devices is not available.

**Product Liability Doctrine in Pharmaceuticals and Medical Devices**

There is no federal product liability law in the United States. Liability actions are governed by state statutes and common law, and both continue to evolve. As a result, "the product liability environment" for pharmaceutical and medical device companies—who market products nationally—is determined by a complex of disparate and ever-changing statutes and case law in numerous jurisdictions. The complexities, diversity, and uncertainties engendered are important in assessing the effects of the product liability environment on economic outcomes. They also dictate that any discussion of this environment is necessarily a series of generalizations, each with exceptions.

**Strict Liability, Negligence, and Comment k.** In the general context of product liability, a much-discussed distinction is between the standards of strict liability and negligence. The distinction—and, indeed, the concept of strict liability—is

\textsuperscript{12}Kolata (1992b) considers at length the role of protective orders in preventing plaintiff attorneys from disclosing information about the Shiley heart valve even to the FDA. The article claims that protective orders have also been used in cases involving breast implants and Haldol to "keep information from the public and, for a time, the FDA." (All of these products are discussed in Section 6.)

largely a distraction for our purposes, especially in the case of drugs. But it cannot be set aside without explanation.\textsuperscript{14}

In theory, under strict liability, a company can be held liable for injuries caused by its product no matter how much care was taken to make the product safe. Under strict liability, the behavior of the producer is not the issue—it is the behavior of the product. In the case of a negligence standard, the company is held liable only if its actions are judged to be faulty. Under a negligence standard, the behavior of the company is the central issue.

The adoption of strict liability is one of the most discussed, analyzed, and controversial aspects of tort policy. In the general context of product liability, Section 402A of Restatement (Second) of Torts\textsuperscript{15} specifies strict liability for a “product in a defective condition unreasonably dangerous to the user...” However, a comment included in Restatement (Second) of Torts that is cited with deference by many courts is especially important for our purposes. In particular, comment k reads in part:

Unavoidably unsafe products. There are some products which, in the present stage of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs. An outstanding example is the vaccine for the Pasteur treatment of rabies, which not uncommonly leads to very serious and damaging consequences when it is injected. Since the disease itself invariably leads to a dreadful death, both the marketing and use of the vaccine are justified, notwithstanding the unavoidable high degree of risk which they involve. Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it unreasonably dangerous. The same is true of many other drugs, vaccines and the like, many of which for this very reason cannot legally be sold except to physicians, or under the prescription of a physician... The seller of such products... is not to be held to strict liability for unfortunate consequences attending their use, merely because he has undertaken to supply the public with an apparently useful product, attended with a known but apparently reasonable risk.

\textsuperscript{14}This claim seems entirely consistent with Henderson and Twerski (1992, pp. 1537–1546), who review case law regarding prescription drugs. One of their general conclusions is that “Case law that is unintelligible cannot be intelligently restated.” Specific other aspects of their conclusions are cited below as the relevant background becomes available.

\textsuperscript{15}American Law Institute (1965). The American Law Institute is an influential group of legal scholars.
As suggested by this comment, and discussed presently, prescription drugs and biologicals are not often subjected to liability for design defects. It is unclear whether comment k has been as widely applied to devices as to drugs and biologicals. As the comment suggests, the duty to warn is a central issue in drug and device liability.

The Primary Importance of Warning Defects. Three types of defects can expose a product to tort action if the product is judged to have caused injury. A unit of product suffers from a manufacturing defect if that unit does not comply with the manufacturer's standards and an injury is attributable to this deficiency. In contrast, all units of a product have a design defect if the product causes injuries because of its attributes even when manufactured properly. Finally, a product is subject to liability action because of a warning defect if the instructions or warnings accompanying the product are judged inadequate and responsible for an injury.

Manufacturing defects are the only one of the three contexts in which it is meaningful to say that strict liability prevails. Manufacturing defects seem relatively unimportant in the pharmaceutical industry, but they appear more important for medical devices.

Design defects also seem relatively unimportant in drug cases. Many courts, relying on comment k and sometimes on the fact of FDA approval, have ruled that companies are immune from liability for design defects. In other jurisdictions, juries have been allowed to consider the issue of design defects. But it seems rare for design defects to be found. Design defects appear more

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16Schwartz (1985, p. 1144) writes that "the basic public policy thrust that underlies comment k is to encourage the development of new drugs that have the potential of conquering disease."

17For example, Gibbs and Mackler (1987, p. 229) write: "Because of the unique nature of the risk/benefit analysis for medical products, the Restatement (Second) of Torts provides a special defense for drug, biologic, and medical device manufacturers." But Mastrototaro et al. (1990, p. 127) repeatedly refer to drugs in discussing comment k, even though devices (such as IUDs) are central to their concerns. Finally, Lynn (1992, p. 64) writes: "A few courts have taken the important step of declaring certain implantable medical devices to be comment k products..."

18This seems to reflect the fact that quality control is generally excellent in drug production. Some problems have occurred with vaccines, which are especially difficult to manufacture. (See the cases described in Institute for Medicine [1985, p. 86].)

19Many would cite the Shiley heart valve as an example. (See Section 6.) In addition, Gibbs and Mackler (1987, p. 229) report that between 1983 and 1985 there were 415 medical device recalls by the FDA due to manufacturing problems. Lynn (1992) reviews manufacturing defect cases involving implantable medical devices.

20See Henderson and Tverski (1992, pp. 1533–1545) and Henderson and Eisenberg (1980, pp. 490–491). Prior to the mid-1980s, the trend seemed to be toward less immunity for drug design defects, but this trend seems to have been reversed more recently.

21An exception is Johnson v. American Cyanamid Co. (81 C. 2470 [18th Jud. Dist., Sedgwick Co., Kansas June 1984]) where a jury ruled the Sabin live polio vaccine to be defective because the alternative Salk killed-vaccine was safer. (See, for example, Institute of Medicine [1985, p. 115], Henley [1988], and the discussion below.) Reilly (1989) discusses other findings of defective drug
relevant for medical devices, which appear to receive less comment k protection, as exemplified by the Dalkon Shield intrauterine device and silicone-gel breast implants (discussed in Section 6).22 But even when comment k is not applied to devices, the question of design defect is fundamentally an issue of negligence under general product liability doctrine.23

In the context of drugs, and seemingly devices as well, by far the most important type of defect is the warning defect.24 Most claims of warning defects question the adequacy of labeling revisions, apparently because explicit FDA approval of the initial labeling can be quite helpful to the defense.25 Companies are liable for failing to warn of risks of which they knew or should have known at the time that the product was sold.26 This, of course, is a negligence standard.27

A particularly important legal issue regarding warnings is: Who must be warned? For prescription products, the duty to warn is generally owed only to physicians, whom courts generally view as "learned intermediaries" (between the companies and the patients) responsible to their patients for considering the information provided to them and making sound medical judgments and recommendations on a patient-specific basis.28

Injury Causation. According to legal doctrine, a company is to be held liable only if the product defect caused the injury. Two types of causation are relevant. In the case of any type of defect, liability requires a finding that the injury was in fact caused by use of the product. This question often raises scientific and medical issues. In the case of a warning defect, it must also be the case that the injury would not have occurred if a legally adequate warning had been given. Clearly, it is hard to know how physicians and patients would have acted if they had different information. As with product liability doctrine in general, in drugs

22Lynn (1992) reviews design defect cases involving implantable medical devices.

23For example, Henderson and Twerski (1992, fn. 60) write: "Thus, the notion that comment k exempts drugs from actions for strict liability based on defective design or failure to warn seems strangely inconsistent with Prosser’s position that all design and warning claims are based on negligence. See also American Law Institute (1991a, pp. 20–21) and American Law Institute (1991b, p. 11)."

24See, for example, Gibbs and Mackler (1987), Henderson and Twerski (1992, p. 1538), and Shulman and Uliczka (1989, p. 94).


26E.g., Gibbs and Mackler (1987, p. 235), Henderson and Twerski (1992, p. 1543). Schwartz (1992, p. 627) writes: "There are no cases . . . in which drug manufacturers have been held liable for their failure to warn of ‘unknowable risks.’"


28See, for example, Rheingold (1985).
and devices there seems generally to be a presumption in favor of the plaintiff in
this regard.  

Exceptions to the Learned Intermediary Rule. Some courts have found that
pharmaceutical companies have a duty to warn patients directly. The exceptions
to date involve two types of products: vaccines and oral contraceptives.

In the vaccine context, the leading rationale for a duty to warn patients is that
vaccines are often administered in mass inoculation programs without a
physician present (and thus no physician plays the role of learned intermediary
for individual patients).

The decisions rejecting the learned intermediary rule for oral contraceptives
invoked various special characteristics of these products. These characteristics
included the following: Patients often play a major role in the decision to
prescribe; the product was actively promoted directly to consumers; FDA had
mandated warnings directly to consumers (in the form of PPIs); and the product
involves serious risks and is used for long periods without supervision of a
physician. It appears that these decisions have not been followed by other
courts, but that companies remain apprehensive about that possibility.

Although courts allowing an exception for oral contraceptives have generally
emphasized that their reasoning applies only to oral contraceptives, numerous
commentators have suggested that the characteristics cited as the basis for an
exception to the learned intermediary rule are not unique to oral contraceptives
and that further exceptions are likely. For example, Rheingold (1985, pp. 137–
138) suggests that exceptions may be made in such situations as lack of

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that this presumption was recently rejected by the Fifth Circuit in Thomas v. Hoffman-LaRoche, Inc., 449
F.2d 806 (5th Cir. 1971), which involved Accutane, a product discussed in Section 6.

30 See Ferr (1986), Brushwood and Simonsemeier (1986), Rheingold (1985), Schwartz (1986), and
Rector (1989). Discussions specific to vaccines and contraceptives can be found in Office of
Technology Assessment (1979) and Institute of Medicine (1985) and in Mastroianni et al. (eds.) (1990),
respectively.

31 The two key cases are Davis v. Wyeth Laboratories inc., 399 F.2d 121 (9th Cir. 1968) and Reyes v.
Wyeth Laboratories, 488 F.2d 1264 (5th Cir. 1974). Brushwood and Simonsemeier (1986, p. 289) write
that this “modification of the learned intermediary doctrine has received widespread acceptance.”
But, in an especially controversial case—Searle v. Lederle, 526 F.2d 1341 (8th Cir. 1977)—the
manufacturer was found to have a duty to warn the patient even though the vaccination took place in
the office of a physician.

32 Three landmark cases in this area were decided in 1985: Stephens v. G.D. Searle & Co., 602 F.

33 For example, Mastroianni et al. (1990, pp. 130–131) indicate that, even by 1980, the 1985 cases
appear to be the leading, if not sole, exceptions to the learned intermediary rule in oral contraceptive
cases.

34 For example, Rheingold (1985), Ferr (1986), Brushwood and Simonsemeier (1986), Schwartz
(1986), and Rector (1989) all emphasize this point.
individualized prescribing or extensive post-prescribing supervision by a physician, a healthy patient using a product for protection rather than treatment of illness, side effects that can be mitigated if they are recognized, promotion directly to the consumer, and an OTC drug formerly dispensed only by prescription.

Most of these characteristics enumerated by Rheingold are largely beyond the control of the company, but two are not: whether the product is advertised to consumers and whether a prescription drug is later offered over the counter. The former seems more important.\(^\text{35}\)

Various considerations suggest that direct-to-consumer advertising could be very risky from the point of view of liability exposure.\(^\text{36}\) Especially risky, it seems, are advertisements that name a specific product and condition, rather than merely indicating that treatment for a condition is available and "see your doctor": These directly undermine the rationale for the learned intermediary rule. Moreover, FDA regulations require that such advertisements include the "brief summary" of the package insert.\(^\text{37}\) The adequacy of such a warning to consumers could be problematic in court, because the legal burden of warning patients directly seems considerably more difficult to satisfy than the burden of warning physicians. For example, the detailed and jargon-laden warnings prepared for physicians may be incomprehensible to many patients, and it is difficult to presume that all courts will find such warnings adequate.\(^\text{38}\)

The strategy of translating warning information into plain English for patients may also be ineffective because of the difficulty of doing so in a defensible manner. Moreover, the sheer volume of such information could obscure the

\(^{35}\) Because over-the-counter products are generally regarded as being much safer than prescription products.

\(^{36}\) Nonetheless, direct-to-consumer advertising in mass media—a relatively new phenomenon—has become widespread in the last few years. (See Section 8.)

\(^{37}\) See, for example, Rubin (1991), and Kessler and Pines (1990, pp. 2413–2414)—the latter provides a more detailed discussion. While it seems clear that the brief summary must be included in advertisements that name both a condition and a product, the precise conditions under which the brief summary may be omitted are less clear. For example, the discussion of Kessler and Pines suggests that there is considerable judgment involved, and a key issue is whether advertisements "clearly have promotional objectives for a particular product." (p. 2413) It appears that this conclusion is more likely if the company running the advertisement has the only approved product for treating the condition named in the advertisement.

\(^{38}\) For example, in MacDonald v. Ortho Pharmaceuticals (cited above) the patient package insert for an oral contraceptive warned of "abnormal blood clotting which can be fatal," but the warning was ruled inadequate for failure to warn explicitly of the possibility of a "stroke." It is not hard to imagine that some courts will apply the standards appropriate to over-the-counter drugs to patient warnings for prescription drugs. Bruskewitz and Simonsen (1986, p. 209) describe the standards for OTC warnings as: "According to the court, the warning on the label of a nonprescription drug must be reasonably readable, and it must apprise the consumer, exercising reasonable care under the circumstances, of the existence and seriousness of the danger, sufficient to enable the consumer to protect against it."
warning concerning the injury that, in fact, occurred. To avoid this problem, a company might choose to be selective about the information given to patient, which involves obvious legal risks. In short, liability costs are especially unpredictable where the learned intermediary rule is vulnerable to exception, and some products are more vulnerable on this score than others.

**FDA Regulation.** Companies often claim that their compliance with regulatory requirements provides a defense against some or all of the allegations in a product liability suit, and plaintiffs often cite failure to comply with FDA regulations as evidence of negligence and thus liability. Courts have generally ruled that FDA regulations define minimum standards for avoiding liability: Compliance with regulations does not preempt liability. In addition, failure to comply with regulations is often taken as evidence of negligence per se. Gibbs and Mackler (1987) review connections between FDA regulation and product liability and conclude (p. 243): “Under current law, compliance with the FDA requirements affords only modest protection against the successful lawsuit. . . . Conversely, evidence of noncompliance can be a highly valuable offensive weapon for the plaintiff, virtually establishing liability.” Thus the product liability system may both considerably strengthen incentives to comply with FDA regulations and provide strong incentives to exceed FDA safety standards.

**Punitive Damages.** If a company is found liable, damages are typically assessed in an amount intended to compensate the plaintiff for (economic and non-economic) losses attributable to the injury. In addition to such compensatory damages, punitive (or exemplary) damages have been awarded in several cases involving drugs and devices.

Doctrine specifying the conditions under which punitive damages should be awarded varies from state to state. In describing such standards, American Law Institute (1991b, pp. 243–244) refers to “[a] wide, indeed bewildering, variety of tests . . .” and reports that “[s]tate cases and statutes often contain terms such as ‘malicious,’ ‘outrageous,’ ‘oppressive,’ ‘fraudulent,’ ‘wilful,’ ‘wanton,’ ‘reckless disregard of the rights or safety of others,’ or ‘gross negligence.’”

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39Gibbs and Mackler (1987, pp. 215–243) provide an extensive discussion; Henderson and Twerdik (1990, p. 320) focus on failure to warn; and Shulman and Ullickas (1989) provide a detailed discussion in the context of ADRs.

40Very recent holdings by two federal appeals courts may signal a fundamental change in this doctrine for medical devices having undergone the premarket approval process. Specifically, in both King v. Collagen Corp., 1st Cir., No. 92-1278, 1/15/93, and Stumpf v. Collagen Corp., 9th Cir., No. 92-2804, 2/19/93, liability claims were found to be preempted by the language of the 1976 Medical Device Amendments. (National Law Journal, 1993; Bureau of National Affairs, 1993a.)

41Moreover, Shulman and Ullickas (1989, p. 99) report that regulatory noncompliance “could be highly persuasive in the awarding of punitive damages.”
Regarding the amounts that may be awarded as punitive damages, doctrine often provides little guidance. American Law Institute (1991b, p. 238) summarizes the situation: "[T]he law simply gives civil juries open-ended authority to award whatever amounts they deem appropriate in cases they find especially egregious." Besides the potential for large punitive awards in individual suits, doctrine allows for assessment of punitive damages for the same conduct in multiple suits. As discussed by American Law Institute (1991b, p. 260), this is especially important when liability arises from design or warning defects and there is potential for mass injury: "If liability for punitive damages can be established for any of the resulting tort claims, then such an award should be available for all the claims arising out of the single corporate misdeed."

Punitive damages are among the most prominent and contentious issues in product liability policy. American Law Institute (1991b, p. 235) reports that during the 1980s "more than thirty states . . . enacted reforms designed to circumscribe both the circumstances in which punitive damages may be awarded and the size of possible awards." But the doctrinal landscape continues to be characterized by considerable state-to-state variation and broadly stated standards for when punitive damages should be assessed and in what amounts.

Statutes of Limitation. The statute of limitations on product suits does not begin at the time a product is sold or used. In some jurisdictions it begins when an injury occurs, in others when an injury becomes apparent to the injured, and in others when the cause of the injury is discovered by that person. Because drugs and devices may involve latent injuries that do not appear for years or even decades after product sale, large numbers of injuries that may eventually lead to liability suits can become inevitable before safety problems become apparent.

Proportionate Liability. If more than one company markets the same or very similar products, an injured product user may be unable to identify which company's product was responsible for the injury. Many such cases arose with DES, a generic drug discussed in Section 3. In a very widely noted 1980 DES

The U.S. Supreme Court has taken up the issue of punitive damages twice since 1991. In Pacific Mutual Life Insurance Co. v. Haslip, 113 S. Ct. 1032 (1991), the Court indicated that punitive damages could in some circumstances violate constitutional rights to due process, but did not provide clear standards. Substantial guidance from the Court was anticipated from the Supreme Court decision in TXO Production Corp. v. Alliance Resources Corp., 499 S.E.2d 370 (W. Va.), cert. granted, 113 S. Ct. 594 (1992), (Birchbaum and Crawford, 1993; Carmody, 1993). However, the June 1995 decision in TXO leaves the issue largely unsettled. (Greenhouse, 1995b; Barrett, 1995a.)

See U.S. Senate (1991, pp. 38-40). The interval of time during which a claim must be filed varies across states. For example, General Accounting Office (1989, p. 99) reports a range of two to six years for the five states studied.
decision—*Sindell v. Abbott Laboratories*—the California Supreme Court held that individual DES producers could be held liable for a particular DES injury in proportion to their shares of the DES market. Schwartz (1992, p. 671) reports that courts in several states have accepted some version of this "proportionate" or "market share" liability doctrine in DES cases, but that "[i]t has been rejected outright, however, by several others. . . ." He further reports that "courts have almost uniformly declined to extend the Sindell rule beyond its DES setting," including cases involving DTP vaccines and breast implants, products that are discussed in Section 6. (Schwartz, 1992, p. 671.)

**Foreign Product Users in U.S. Courts.** The final doctrinal issue involves the possibility that even foreign patients who purchase and use the products of U.S.-based companies abroad may be able to bring product liability suits in the United States under U.S. law. This can expand greatly the potential number of suits in a legal environment widely claimed to be the world's most hospitable to plaintiffs. The number of such actions does not appear to be large to date, but some courts have shown signs of being receptive to such cases. The potential costs to defendants and the uncertainty seem to be of substantial concern to business.

**Interpretation and Application of Doctrine—Sources and Uses of Discretion**

Whether a company is liable in a particular instance depends on doctrine and the facts of the case. Doctrine must be interpreted. This is the responsibility of judges, who rule on "matters of law." "Matters of fact" are typically for juries to decide. Interpreting the law and fact-finding can never be done mechanistically, but in some instances there is especially broad scope for differences of opinion. This leaves juries and juries with substantial discretion in determining liability in particular cases.

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45If they had "substantial shares" of the DES market and unless they could show that their product could not have been responsible for the injury. (See, for example, Winer and Geyer (1989, p. 152).)

46Foreign and U.S. companies are equally subject to U.S. law for sales made in the United States. The issue here is the possibility that U.S.-based companies are handicapped relative to their foreign competitors for sales made outside the United States.

47The defendant may move for dismissal of a suit brought by a foreign plaintiff—under the doctrine of *forum non conveniens*—arguing that trying the case in the jurisdiction in which it was filed is unreasonably burdensome. (Harvard Law Review, 1992.) Two states viewed as relatively receptive to suits by foreign plaintiffs have recently taken steps that may aid defendants. (Harvard Law Review, 1992) discusses a 1991 California Supreme Court decision, and Bureau of National Affairs (1993b) discusses 1993 legislation in Texas.

48In a bench trial there is no jury, and the facts are determined by a judge.
Major Sources of Discretion: Scientific Uncertainty and Punitive Damages.
Juries—or any other fact finders—inherently have discretion concerning interpretation of any evidence. But two sources of discretion seem especially important in our context. These are scientific uncertainty about injury causation and doctrine concerning punitive damages.49

Scientific Uncertainty. When a person seriously injures a foot under a lawn mower, there is little doubt that the blade was instrumental in causing the injury. But when a person using a prescription drug suffers a stroke or develops cancer, or her child has a birth defect, it can be quite unclear whether the injury is causally connected to use of a drug.50 While injury causation may more often be obvious with devices, uncertainty can be important here as well. Even undoubtedly qualified experts may disagree on the strength of the evidence linking a drug or medical device to a specific type of injury. Fact finders can hear sharply conflicting testimony by seemingly credible experts, and thus may find themselves with substantial discretion.51

Punitive Damages. Even if the facts of a case are very clear, it can be quite unclear whether punitive damages are appropriate under the prevailing doctrine. This is because words like outrageous, wilful, and reckless involve inherent ambiguities. In addition, when punitive damages are assessed, juries are given very little guidance concerning how to determine the amount. In short, the doctrine of punitive damages leaves juries with substantial discretion in making such judgments.

Some Effects of Discretion. When central facts or the law itself is unclear—and the stakes are large—there is considerable scope for controversy. Scientific disagreements about injury causation and the application of the doctrine of punitive damages—and sometimes their combination—have given rise to major

49 Another source of discretion that gets considerable attention in discussions of product liability generally is compensation for “pain and suffering,” particularly the lack of clear legal standards for determining dollar figures. See, for example, American Law Institute (1991b, pp. 199–203). For reasons that are not clear, damages for pain and suffering are not nearly as prominent in discussions of liability for drug and device injuries as the two issues emphasized here.

50 Brennan (1989) categorizes scientific uncertainties that can arise in cases involving drugs and other toxic substances. Ceci et al. (1991, pp. 740–742), who argue generally that juries perform their fact-finding roles more capably than is often claimed, discuss expert testimony in cases involving exposure to drugs and chemicals as particular sources of “uneasiness over the role of the civil jury.” (p. 740.)

51 A particularly prominent legal issue was argued before the U.S Supreme Court in 1993 in Daubert v. Merrell Dow Pharmaceuticals, No. 92–102: the conditions under which scientific testimony is sufficiently reliable to be admitted as evidence (under federal rules of procedure). (See Greenhouse, 1993a; Marshall, 1993; Yang, 1993, and PWA, 1993.) The Court’s June 1993 ruling rejected the requirement of general acceptance within the scientific community and directed judges to consider the methods and procedures underlying the testimony to decide whether it should be presented to the jury. Early commentaries on the decision conflicted on whether this was a victory for plaintiffs or defendants. (Barrett, 1993b; Greenhouse, 1993c.)
controversies surrounding product liability for drugs and devices. After discussing some of the controversies, we turn to another source of controversy: sympathy and how discretion is exercised. The attention generated by such controversies and the consequent effects on decisionmaking are issues revisited below.

**Injury Causation.** It is unknown how often the issue of injury causation is contested in drug and device cases, but disagreements are not rare. It also seems obvious that when the facts are unclear, sometimes the plaintiff fails to convince the jury, and sometimes the plaintiff prevails. It is impossible to say which side is favored on balance by difficulties in determining injury causation.

Some disagreements about injury causation have become very widely known. Very prominent is whether Bendectin—a drug that was widely prescribed for the morning sickness accompanying pregnancy—does, in fact, cause birth defects. Perhaps the most well-known case of all—and a cause célèbre among advocates of tort reform—is *Wells v. Ortho,* which involved birth defects and a spermicide. It has come to symbolize the possibility of major financial liabilities based on findings of causation in the absence of scientific evidence. Finally, two very prominent cases involving the Sabin oral polio vaccine have also involved disputes over injury causation.

**Punitive Damages.** There have been several punitive damage awards in drug and device cases. Although there is great controversy about the effects of punitive damages, it seems widely agreed that they play an important role in shaping the incentives associated with product liability. A complete picture concerning the incentive effects of punitive damages cannot be developed. Even the actual frequency and amounts of punitive damage payments cannot be determined, because there is no comprehensive information source. Even more fundamentally, many of the issues of interest—e.g., how the potential for

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52 Besides those discussed presently, examples include the swine flu vaccine (see, for example, Institute of Medicine [1985, pp. 93-114]), and pertussis vaccines. Controversies arising relatively recently involve injuries allegedly caused by silicone leakage from breast implants and the drugs Proscar and Halcion. (See Section 6.)

53 See Lasagna (1991, pp. 337-341), Sanders (1992, pp. 331-348), Skolnick (1990), and Section 6. The Daubert case decided by the U.S. Supreme Court in 1993 (see above) involves Bendectin.


55 See, for example, Mastrianni et al. (1990, p. 134), and Mills and Alexander (1980). The Supreme Court let stand a $4.5 million award (reduced by a federal appeals court from the $5.1 million awarded—by a judge, not a jury—at trial). (Giannelli, 1986.)

56 In *Reyes v. Wyeth* (cited above), the company was found liable "even though evidence introduced during the trial showed that the disease was caused by an unrelated wild poliovirus." (Iglehart, 1987, p. 1285.) See also Institute of Medicine (1985, pp. 89-95). In *Johnson v. American Cyanamid* (discussed below), "Diagnosis of the plaintiff's condition proved difficult and Lederle offered evidence at trial that he had not had polio at all." (Kitch, 1983, p. 15.)
punitive damages affects claiming and settlement behavior, what standards are actually used by juries—could not be assessed even if comprehensive data on trial outcomes were available. But considerable perspective can be pieced together from previous studies and published accounts of individual drug and device cases.57

First consider trial awards of punitive damages. No study of this issue has focused on drugs and devices, but Rustad (1991) provides much useful information. His unusually extensive search located 355 trial awards of punitive damages in personal injury product liability cases between January 1965 and August 1990. Of these, 260 involved products other than asbestos, and 76 percent of the nonasbestos awards occurred during the years 1981 to 1990.58 “Medical products”59 were involved in 53 cases, or 20 percent of those not involving asbestos.60 Finally, 42 percent of the trial awards of punitive damages in medical product cases exceeded $2.8 million.61

Rustad (1991) considered only cases resulting in punitive trial awards. Thus, he tells us nothing about the fraction of trial verdicts that include punitive awards. It appears that no such data have been reported for drugs and medical devices, but a recent study by Daniels and Martin (1990) seems instructive. Their data included 967 product liability cases.62 Of these cases, 34 had punitive awards, which account for 8.9 percent of the cases in which the plaintiff won.63

57Khalil and Kingham (1990) review several cases involving awards of punitive damages against pharmaceutical manufacturers.
59These are defined by example in Rustad (1991, p. 26): “Drugs, breast implants, hospital equipment, contraceptives, prosthetic devices” —which suggests that this category is for all practical purposes coincident with our definition of pharmaceutical and medical devices.
61Rustad (1991, p. 30). It is not clear whether Rustad adjusts dollar amounts for inflation. The $2.8 million figure is the cutoff for the top quartile of punitive trial awards (p. 26), so the $2 percent figure indicates that a higher fraction of medical products cases had awards above $2.8 million than the other cases. In contrast, 28 percent of the medical product cases involved compensatory trial awards over the top-quartile cutoff of $1.34 million (p. 29).
62Of a total of 25,627 civil jury verdicts involving money damages from state trial courts of general jurisdiction in forty-seven counties in eleven states for the years 1981 to 1985.” (Daniels and Martin, 1990, p. 28.)
63Daniels and Martin (1990, p. 38). Some indication of the portion of product liability cases that involves drugs and medical devices is provided by General Accounting Office (1989, p. 90). Specifically, of 309 verdicts in five states—split roughly evenly between state and federal courts—thirteen involved medical devices and ten involved drugs.
But trial awards and damages paid are not the same thing. Trial awards can be reduced or overturned on appeal, and cases are often settled while on appeal. Rustad (1991) does not provide information about such post-trial events for medical products separately, but what he does report is likely to be informative for our purposes. Of the 355 cases, 128 were settled and collected while an appeal was pending, and in roughly half of the appeals that had reached a ruling, the decision was reversed or the award was reduced.

The circumstances under which punitive damages are and are not assessed in drug and device cases cannot be addressed in a quantitative manner. Rustad (1991) discusses reasons for punitive verdicts relying on questionnaires and interviews administered to attorneys representing both sides of many of his 355 cases. Not surprisingly, the views of the two groups are very different.

Additional information is available from published accounts of drug and device cases in popular media, the business press, trade publications, law journals, and policy discussions. Such accounts tend to focus on cases in which punitive damages were awarded: Even though instances in which juries do not award punitive damages are much more common, published accounts of such instances seem rare. Many accounts focus on cases in which punitive awards are of questionable appropriateness. The examples discussed presently provide essential background for the analysis—an analysis that emphasizes that such instances may be atypical and considers implications.

Punitive damages can be awarded only where liability is found. One class of situations in which punitive awards are inappropriate, then, is when any liability is inappropriate. Several widely discussed cases of punitive damages in drugs and devices are claimed to fall in this category. For example, punitive damages have been assessed in cases where there is considerable doubt about injury

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64 Note, however, that punitive damage awards that are never paid by the defendant may be costly nonetheless: Defending claims for punitive damages and appealing punitive awards involve direct legal costs, even punitive awards that are eventually overturned may generate substantial publicity, lead to the filing of additional suits, and impose indirect costs, such as lost sales.


66 Rustad (1991, p. 32) refers to “the 161 cases that were appealed.” But the table (Rustad, 1991, p. 31) suggests that these are actually the appealed cases that were not settled before the appeals court had ruled. While defenders of punitive damage doctrine point to the frequency with which such cases are overturned or reduced to support the view that their costs to business are often exaggerated, critics of punitive damages doctrine point to the same facts to argue that something is amiss.

67 The determinants of what cases attract attention of this sort and the implications for our analysis are discussed extensively below.

68 An exception is Rustad’s (1991, p. 24) discussion of the Dalkon Shield. He reports that the product was responsible for roughly 200,000 injuries, notes that only 51 cases came to trial, and writes: “Despite evidence of inadequate testing, a design defect known to the manufacturer, and a pattern of misrepresentation, there were only eleven punitive damage awards.”
causation. The most prominent examples may be punitive damages assessed against Bendectin.69

Another situation in which many have argued that punitive damages are inappropriate is where the behavior in question was required by FDA. A case in which this interpretation is widespread is Wooderson v. Ortho Pharmaceutical Corp.70 In particular, the company was held liable "for not providing a warning that FDA had in fact previously prohibited from appearing."71 Mastroianni et al. (1990, p. 132) report: "This is one of the very few oral contraceptive cases in which punitive damages were awarded and the award was upheld on appeal."

Another cause célèbre of advocates for restricting liability is Johnson v. American Cyanamid Co.72 in which a jury found the Sabin live polio vaccine defective because the alternative Salk killed-vaccine was safer.73 Brody (1987, p. 3) recounts:

In 1983, the Lederle Laboratories division of American Cyanamid, the only manufacturer of Sabin vaccine in the United States was assessed a $10 million jury verdict—including $8 million in punitive damages. . . . Although the verdict was finally reversed on appeal, similar verdicts have been upheld in the past and may be upheld in the future.

Pharmaceutical Manufacturers Association and American Medical Association (1990, pp. 17–18)—while also noting that the verdict was overturned on a 4 to 3 vote of the Supreme Court of Kansas—refer to Johnson as "an illustrative case."74

Sympathy. Besides such examples, controversy is fueled by claims that discretion is exercised—in interpreting the law and in fact-finding—in a biased fashion. Many assert that a desire to compensate an injured individual creates a tendency

73See, for example, Institute of Medicine (1985, p. 115) and Hershey (1988). Kirsh (1985, p. 15) writes: "[T]he court in Johnson was invited to, and did, impose punitive damages for the purpose of forcing the United States to change its polio vaccination policy." Institute of Medicine (1985, pp. 115–116), which was published before the award was overturned, expresses great concern about the potential effects of punitive awards in vaccine cases, emphasizing unpredictability for manufacturers.
74However, neither Brody (1987) nor PMA and AMA (1990) discusses a similar case.
to favor at least some plaintiffs.\textsuperscript{75} Even if case outcomes driven by desire to compensate are not frequent, their effects on company behavior may be pronounced. This is because individual instances can be quite costly to companies, and—as discussed in Section 5—their frequency may be overestimated because they are highly publicized.

\textbf{The Potential for Mass Torts}

Since no drug or medical device can be made perfectly safe, companies presumably accept the fact that most products will generate some suits and involve some direct liability costs. But an unusually large number of cases associated with a particular product can be extremely costly, and even threaten a company with bankruptcy.

Of the five products identified by Rheingold (1989) as involving the largest numbers of product liability claims, two have involved drugs (Bendectin and DES) and one a medical device (the Dalkon Shield).\textsuperscript{76} Accordingly, the aspect of the liability environment that has perhaps the largest effect on company decisions in drugs and devices is the possibility that a product will trigger a mass tort, disrupt the operations of the company, and potentially cause financial disaster. As discussed in Section 5, much literature in psychology and management reinforces the view that the potential for disastrous consequences is likely to have major effects on decisions when such a possibility commands the attention of decisionmakers.

\textbf{A Recent Legislative Reform}

Widespread concerns about the economic effects of product liability involving some vaccines have led to federal legislation. The program established by this legislation is of interest here for three reasons. First, the program may have already affected product pricing; this is discussed in Section 7. Second, the act is

\textsuperscript{75}For example, Richard M. Cooper—chief counsel of the FDA from 1977 to 1979: “It is hard to read the judicial opinions in this field without being drawn to the conclusion that many courts appear to be willing to make new law whenever that may be necessary to uphold or permit a verdict for an injured plaintiff.” (Cooper, 1986, p. 237.) Such an instance may be 	extit{Rayes v. Wyeth Laboratories}, 496 F.2d 1264 (5th Cir. 1974)—the second landmark case rejecting the learned intermediary defense in a mass inoculation program. In finding for the plaintiff in that case, the court wrote:

\begin{quote}
Until Americans have a comprehensive scheme of social insurance, courts must resolve by a balancing process the head-on collision between the need for adequate recovery and viable enterprise. This balancing task should be approached with a realization that the basic consideration involves a determination of the most just allocation of the risk of loss between members of the marketing chain. (OTA, 1979, p. 92.)
\end{quote}

\textsuperscript{76}Of these three, only DES involves multiple defendants, one of the elements that contribute substantially to the complexity of many mass torts.
viewed by some as a promising model for more widespread reform of the product liability system. Third, the surrounding politics seem revealing about the prospects for further reform.

The National Childhood Vaccine Injury Act of 1986 (NCVIA) was enacted in response to the perception that the tort system was not performing satisfactorily in the domain addressed by the act.\textsuperscript{77} It applies only to seven childhood vaccines whose administration is required for school enrollment in most states: polio, diphtheria, pertussis, tetanus, measles, mumps, and rubella.\textsuperscript{78} The proponents of the legislation argued that alternatives to the tort system were appropriate in these cases because of the fact that children are required by law to be vaccinated, the great social benefits of vaccination, and the threats posed to the vaccine supply by liability.\textsuperscript{79} All of these arguments seemed important to the viability of the legislation.\textsuperscript{80}

The program created by the act, which went into effect in January 1988, is generally described as providing a no-fault compensation mechanism for injuries attributable to these vaccines. Compensation\textsuperscript{81} is available to injured people who meet various criteria established by the program. For each covered vaccine, particular adverse conditions are identified that are presumed to be related to the vaccine if they occur within specified periods of time after vaccination.

For vaccinations prior to October 1, 1988 (the so-called “retrospective cases”), compensation is funded by general tax revenues.\textsuperscript{82} Compensation for later (“prospective”) cases is funded by an excise tax on the seven vaccines that went into effect on January 1, 1988.\textsuperscript{83}

If a claimant accepts compensation from the program in a prospective case, he or she forfeits the right to bring a civil action; if a tort action is brought, the injured party forfeits any right to compensation from the program. In addition, the act attempts to preempt state laws by prohibiting civil actions based on the

\textsuperscript{77} Unless otherwise noted, information on provisions of the act can be found in Mariner (1990).

\textsuperscript{78} Diphtheria, pertussis, and tetanus vaccinations are generally administered jointly as a “DTP” vaccination, and measles, mumps, and rubella vaccinations are generally administered jointly as “MMR.”

\textsuperscript{79} Vaccine availability is discussed in Section 6.

\textsuperscript{80} Nonetheless, the measure was controversial, passed only as part of an omnibus bill, and, according to Iglesias (1987, p. 1287), was “the most contentious proposal in the omnibus bill.”

\textsuperscript{81} The benefit in the case of death is $250,000; compensation for pain and suffering is limited to $250,000, and compensation for actual or projected lost earnings and for reasonable attorney’s fees is also available.

\textsuperscript{82} Funding of $80 million per year for five years.

\textsuperscript{83} The tax rates per dose for the most commonly administered vaccines are DTP, $4.56; MMR, $4.44; and polio, $0.59. The tax per dose for DT vaccine (i.e., DTP vaccine without the pertussis component, which is generally regarded as by far the most hazardous) is $0.06.
inadequacy of warnings complying with FDA requirements or inadequate direct-to-patient warnings; limiting design defect claims by codifying comment k; and prohibiting punitive damages unless the company is guilty of withholding information from the FDA or of other illegal behavior.  

The program is too new for its long-term effects to be assessed with any confidence. The prospects for reducing the rate of litigation appear quite good, but there are widespread doubts that the funding levels are adequate to sustain the program.

**Determinants of Liability Effects on Profitability**

To understand the economic effects of liability, we need to understand how liability doctrine and its application affect the incentives of companies. As discussed in the first subsection in this section, product liability affects profitability through direct costs of claims—i.e., costs of defense, settlements, and awards—and by decreasing sales and, hence, profits. Legal doctrine and its application are the fundamental determinants of direct costs. The indirect costs of liability stem from information or publicity generated by product liability suits. As we argue presently, these costs are driven by many of the same factors as the direct costs.

The information and publicity that generate indirect company costs result primarily from the efforts of plaintiffs' attorneys. Since these attorneys typically work on a contingency-fee basis, the potential dollar value of settlements and awards determines the attorneys' economic incentives to develop information or generate publicity. Thus, the fundamental source of indirect effects of liability on profitability is the potential direct costs net of defense costs. Accordingly, the

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84 See Hall and Treese (1991, p. 4)
85 For example, the total amount paid for the 66 post-1988 awards paid through March 8, 1993 was $27.6 million or about $420,000 per case. (Weekly Status Report for March 8, 1993, of the Vaccine Injury Compensation Program, received from Division of Vaccine Injury Compensation, Health Resources Services Administration.) Moreover, cases judged ineligible for awards would tend to be relatively weak ones.
86 Almost 4,100 retrospective claims have been filed. The 645 awards paid through March 8, 1993 ranged from $120 to $4 million and averaged $1 million. (Weekly Status Report for March 8, 1993, of the Vaccine Injury Compensation Program, received from Division of Vaccine Injury Compensation, Health Resources Services Administration.) According to FDC Reports (1991), estimates of the cost of compensating the 3,200 retrospective claims filed by November, 1990 were $1 to $3 billion (compared with $400 million of authorized funding), and the Assistant Secretary of Health told a January 8, 1991 meeting of the Advisory Commission on Childhood Vaccines that "money was not in sight" beyond 1994.
87 This is not to suggest that plaintiffs' attorneys are motivated solely by economic goals, but merely that focusing on economic incentives is the most promising basis for interpreting their behavior. This view is consistent with our emphasis on profits as the fundamental determinant of company decisions.
analysis of the determinants of liability effects on profitability focuses on the determinants of potential direct liability costs.

We consider the issue on a product-specific basis, because decisions are made at that level and liability potential differs greatly across products. The direct liability costs associated with a particular product depend on many factors. For purposes of analysis, they are broken down as follows:

\[
\text{Direct liability costs for a product} = (\text{Number of suits}) \times (\text{Cost per suit})
\]

\[
\text{Number of suits} = (\text{Number of product users}) \times (\text{Rate of adverse outcomes}) \times (\text{Rate of filing suits})
\]

\[
\text{Rate of adverse outcomes} = \text{Injury rate from product} + \text{Background injury rate}
\]

First consider the three indicated determinants of the number of suits.

The number of product users is a critical determinant of the potential absolute amount of liability exposure. Product users who are injured are potential plaintiffs. The fraction of product users who fall into this category—i.e., the rate of adverse outcomes—is usefully broken down by reference to the cause of their injuries. Specifically, some adverse outcomes are caused by the product and others would have occurred even if the product had not been used. The rate of causally unrelated injuries is referred to as the "background injury rate." Injuries of both types may well lead to suits, because there can be considerable uncertainty about the cause of injury. Both rates of injury vary systematically with the type of product.

The injury rate from the product is inversely related to the safety of the product. Product safety depends in large measure on the design of the product, and the design is under the control of the company. Indeed, a major rationale of the liability system is providing incentives for firms to pay particular attention to safety as they design products. But, as detailed in Section 3, considerable uncertainties are inherent in the process of product design.

Turning to the background injury rate, some causally unrelated injuries are much more plausibly blamed on the product than others. For example, courts are relatively unlikely to attribute to the product adverse consequences commonly associated with the condition under treatment (e.g., heart attacks in cardiovascular patients, infections among AIDS patients). At the other extreme,
it seems, are birth defects among healthy women. While birth defects are relatively common, many are not obviously attributable to any particular cause.89 For patient populations in which poorly understood injuries are common, injuries that are not caused by a product may well lead to liability costs.

Unlike injuries that are caused by the product, injuries that are not caused by the product are not under the control of the company marketing the product. But the threat of liability in such situations may well affect company behavior. For example, companies may warn that pregnant women should not use a product even if there is no evidence of danger to the fetus.

The rate of filing suits depends on a host of factors, the most important of which may be the patient’s perception of the prospects for receiving substantial compensation. Clearly, awareness of previous cases in which companies were held liable in similar situations could form the basis of optimism in this regard. Media accounts of such cases and activities by plaintiffs’ attorneys are often mentioned as important in this context.

Costs per suit also varies systematically across products. The filing of any suit imposes some costs on the defendant. But the major liability costs are associated with cases in which the company is likely to be held liable for substantial damages.90 The likelihood of being held liable depends on various factors including (a) the evidence linking the product and the injury, (b) whether some other explanation for the injury is available, (c) whether the product labeling was adequate, (d) the availability of the learned intermediary defense, (e) evidence concerning the company’s dedication to safety and honesty, and (f) the sympathy with which a judge or jury might view a plaintiff.

If a company is held liable in court or agrees to settle a case, various factors determine the size of the compensation payment. Awards may be designed to compensate for economic losses, such as lost earnings and medical expenses, as well as for pain and suffering. The seriousness of the injury is important in both regards. The extent of economic losses may also depend on the age, prior health status, and earnings ability of the plaintiff. For example, seriously injured, young patients who were healthy prior to their injury would be expected to pose especially stark liability concerns. Damages and settlements for economic losses and for pain and suffering can amount to very large sums per patient. Even larger stakes can be involved when punitive damages are awarded.

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89See, for example, Lasagna (1991).
90Massive numbers of cases successfully defended can be very costly to a company, but for large numbers of cases to be brought, plaintiffs’ attorneys require some reason to be optimistic about obtaining substantial settlements or awards.
In sum, the liability costs that may come to be associated with a product depend on numerous factors. Many of these differ substantially from one product to the next because of attributes of the conditions and patients for which the products are intended and because of actions of the company in such areas as product design, labeling, and marketing. But no matter how refined one's analysis of the determinants of liability costs, actual liability costs for a product cannot be forecast with much confidence. Inevitably, substantial uncertainties will remain. These uncertainties are the focus of the next subsection. The fifth subsection takes up the issue of how the potential effects of product liability on profits are likely to differ across products.

Aspects of Uncertainty and Risk

The liability consequences of a company decision cannot be known at the time the decision is made. Often they can be predicted with very little precision or confidence. But if the potential liability consequences are to be factored into decisions, they must be assessed somehow.

Uncertainty is almost always mentioned in discussions of the product liability environment in the United States. Discussions of the fairness of the liability system emphasize uncertainty. It is often identified as the source of great difficulties in making litigation and business decisions and may be a key factor determining the effects of liability on business decisions.\textsuperscript{91}

Various concepts related to uncertainty must be distinguished for our purposes, and terminology is not standardized. A distinction of the following sort is often made:\textsuperscript{92}

- \textit{Uncertainty} is a general term connoting lack of predictability.\textsuperscript{93}
- \textit{Risk} is a general term connoting potential for loss.

The concept of risk—which would not arise in the absence of uncertainty—focuses on possible consequences that are particularly undesirable. In our

\textsuperscript{91}For example, both OTA (1979) and Institute of Medicine (1985) emphasize the unpredictability of liability costs in discussing the effects of liability on vaccine availability and innovation. Similar emphasis is placed on liability uncertainty by Mastroianu et al. (1986) with regard to contraceptive availability and innovation.

\textsuperscript{92}In some fields—such as economics and statistics—these terms are often used interchangeably. The distinction made and employed here is broadly consistent with common usage and usage in many technical fields.

\textsuperscript{93}In terms of probability distributions, uncertainty refers to the dispersion among all potential outcomes. It might be measured—i.e., its degree quantified—for example, by the variance of a distribution or the range between the highest and lowest possible values.
context, these are liability costs that are especially large. But the term potential for loss is quite imprecise, and the term risk has various meanings in various settings. Here we will use the term (admittedly imprecisely) to encompass both the likelihood and the magnitude of especially large liability costs: Liability risk is higher the more likely large liability costs are and the larger their likely size. When a more precise concept is required, this is made explicit.

The sources of uncertainty and risk are numerous, and many are largely beyond the control of the company. Most fundamental is injury risk: true product safety cannot be known from clinical trials, and the possibility of latent injury contributes substantially to injury risk. Other sources of uncertainty for companies are the complexity and interjurisdictional variation in doctrine; lack of doctrinal precision and the potential for doctrinal change; the inherent unpredictability of the behavior of injured product users, attorneys, judges, and juries; evolution of social attitudes towards litigation and compensation; and future capabilities for determining injury causation.

This subsection explores issues pertaining to uncertainty that seem particularly important for understanding the effects of product liability on the decisions of interest. It focuses on three aspects of liability uncertainty: the unlimited nature of potential liability costs, the links between the degree of uncertainty and the time horizon for decisions, and the information that decisionmakers have about the liability environment.

**Unlimited Potential Liability Costs**

Liability risk is fundamentally different from many other risks facing drug and device companies. While the development and marketing of drugs and devices are fraught with uncertainty and risk, liability seems unique in that potential liability costs can be effectively unlimited. For example, the innovation process involves major uncertainties associated with technology, regulation, and the market. An R&D project could fail to generate a product worth testing on humans. In this case, the entire investment in that product may be lost. Moreover, even if a product looks promising to a company after clinical trials, it may fail to obtain regulatory approval in the United States and other major markets. Again, this outcome might mean that the entire investment is lost. But only the entire investment would be lost.

\footnote{For example, the term is commonly used to denote the probability of loss, the size of the potential loss, or a combination of the two.}

\footnote{Under current liability arrangements, patents and companies both bear considerable shares of this risk.}
In the case of product liability, the worst-case scenario is much worse. There is no particular link between the maximum liability cost and any amount a company chooses to invest. A particularly bad liability experience with a product can bankrupt a company no matter how small a portion of its assets was invested in it. This worst-case scenario for companies is more plausible because of the salience of mass torts and the potential for punitive damages, which are not limited in amount and can be assessed in multiple cases.96 The potential for unlimited liability costs seems to set liability risk apart from the more ordinary business risks confronting decisionmakers in drugs and devices.

The Time Horizon and the Degree of Uncertainty

Liability uncertainty is likely to be larger the further into the future one looks. This is particularly important when considering the legal environment. Legal doctrine has changed substantially over the last few decades, and further dramatic, but unpredictable, change might be expected.97 But it is not possible to say how legal doctrine will change over the next ten or twenty years, or the even longer time horizons relevant to the drug development process or the time that might elapse between use of a product and the appearance of injuries.

The chemical composition of a drug is generally determined a decade or more before the drug might be marketed in the United States, and cannot be changed without returning to the preclinical stages of product development. A company can anticipate that, if the development effort is successful, the drug will not be

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96 Although he views punitive damages as a major source of uncertainty, Viscomi (1991b, p. 94) argues that they are not a major source of compensation in product liability cases generally, because a computer search of cases from 1970 to 1989 located less than 252 million in payments of punitive damages to plaintiffs. However, this analysis does not account for the possibility that potential punitive damages have major effects on settlements.

97 Most discussions of changes in the product liability environment in general have emphasized expansion of liability — i.e., pro-plaintiff trends — since the 1960s. Henderson and Eisenberg (1990, pp. 485–486) indicate that a pro-plaintiff trend in drug cases emerged only in the late 1970s. Henderson and Eisenberg (1990) present broad-based, systematic evidence that, by the mid-1980s, pro-plaintiff trends in product liability doctrine had undergone a reversal, but note (p. 496) that a reversal in favor of defendants was not evident in failure-to-warn cases (which are the bulk of drug, and perhaps also device, cases). See also Henderson and Twerski (1980, fn. 195) and Henderson and Twerski (1991, p. 1337). Schwartz (1992, p. 666) argues that the appeals court rulings documented by Henderson and Eisenberg (1990) primarily involve “not the overturning of precedents but rather the rejection by the judiciary of further expansions of products liability doctrine,” and Henderson (1992, p. 777) accepts Schwartz’s interpretation. Schwartz (1992, p. 666), however, also reports on a recent, pro-defendant counter trend concerning failure-to-warn cases. Eisenberg and Henderson (1992) extend the analysis of Henderson and Eisenberg (1990) in various ways and provide quantitative information specific to drugs and medical devices. They present data on published opinions for various product categories separately for the years 1979 to 1985 and 1985 to 1989. For prescription drugs, there were 122 such cases in the earlier period, and plaintiffs succeeded in 48 percent of these; in the later period, there were 217 cases, and plaintiffs succeeded in 38 percent. For medical equipment, in the earlier period, there were 32 cases with a plaintiff success rate of 53 percent, compared with 56 cases and a 38 percent plaintiff success rate in the later period. (See Eisenberg and Henderson, 1992, p. 801.)
marketed for a decade or more after its chemical composition is set. For the development effort to appear worthwhile to the company at the time this decision is made, it must be anticipated that the drug has the potential to generate sales for roughly ten to twenty years after introduction. Thus, at the stage at which this element of drug design is determined, the relevant liability environments are those that will prevail at least ten years and as much or more than thirty years in the future. Long lead times may also apply to those medical devices requiring clinical tests and premarketing approval. Decisions affecting the general R&D capabilities of a company are made perhaps decades before an eventually successful product results from that decision.

As for the product itself, a drug that is intended for chronic conditions or a device remaining in the body indefinitely will be used by patients for periods longer than the duration of clinical trials or experience overseas prior to U.S. marketing. If injuries appear, say, only after twenty years of use, then the relevant liability environments for development decisions are those prevailing thirty to fifty years later. By the time that suits appear, the number of people exposed to the product can be very large, raising the specter of mass torts tried under legal conditions that are especially difficult to predict.

**Decisionmakers’ Information About the Liability Environment**

Many factors determining the ultimate liability costs associated with a product involve intrinsic uncertainty. Decisionmakers’ uncertainty also reflects the fact that only some of the information useful in understanding the liability environment is available to them. For example, potentially useful information about litigation is unlikely to be available to those outside the companies involved. Terms under which cases are settled seem very important in this regard, because confidentiality is often a condition for settlement.

The experience of one’s own company is a small fraction of the experience of all companies with liability and may present a distorted view of the general liability environment. Some information is publicly available about the liability experiences of individual companies. Sources include mass media, law journals,
trade publications, writings of reform advocates, judicial decisions, and bar association meetings.

The information available from many sources seems rather unrepresentative. For example, mass media seem to provide more complete coverage of plaintiff victories and large and punitive awards than defendant victories, small awards, damages reduced by the judge, or cases overturned on appeal. Readers of law journals and trade publications are likely to be particularly interested in groundbreaking cases, and the content of such publications seems to reflect such interests. Advocates of pro-defendant liability reforms emphasize—for obvious reasons—costs of liability to companies and plaintiff victories that appear inappropriate and awards that appear excessive.

In short, it seems that much of the readily accessible information tends to make the liability environment seem more hostile to companies than it actually is. Evidence consistent with this view is provided by Henderson and Eisenberg (1990), who conducted an extensive systematic analysis of (relatively inaccessible) judicial decisions. Henderson and Eisenberg (1990, p. 480) suggest that—in stark contrast to “the pro-plaintiff revolution in products liability in the early 1960s”—a major reversal in pro-plaintiff trends through 1989 had “gone all but unnoticed.” Potential implications for the economic effects of liability of unrepresentative information and consequent misperceptions are analyzed below.

**Differences in Liability Potential Across Products and Patients**

Product liability may pose much greater threats to company profits for some products than for others. To the extent that such differences are perceived by decisionmakers, the economic effects of product liability should be very different for different products.

Much of what is written about liability in drugs and devices leads people to believe that the products that are especially hazardous from a liability point of view are vaccines, products for conditions specific to pregnancy, and contraceptives. As discussed in Section 6, this characterization seems to have

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101 This is discussed further in Section 5.

102 For example, Viscusi (1991a, p. 88) reads: “An avalanche of anecdotal evidence, primarily involving vaccines and pharmaceutical products pertaining to contraception or birth...” Among the many other examples are Weaver (1995)—where only the possibility of liability for biotech products is also mentioned. See also Viscusi (1991b, p. 66) and OTA (1993, Ch. 7).
been developed from observation and induction. In particular, many of the most visible and costly product liability episodes in pharmaceuticals and medical devices include various vaccines, contraceptives, and products to prevent miscarriage and treat morning sickness.\textsuperscript{103}

Is this standard characterization of liability potential adequate?\textsuperscript{104} After all, there are other products with visible liability problems that do not conform to it.\textsuperscript{105} Are there generic characteristics of products or patients that explain what has been observed? What do these suggest about other types of products that involve especially large liability potential but have yet to experience substantial litigation?

In this subsection, we use the perspectives developed above to analyze such questions. This analysis emphasizes the determinants of potential liability costs for different types of products. Potential liability costs and incurred liability costs are not the same thing, and the extent to which company decisions respond to potential costs is a difficult and important issue, to which we return.

Potential liability costs or (more simply) liability potential involves three aspects:

- **Expected liability cost** refers to a best guess about the eventual value.\textsuperscript{106}
- **Uncertainty** refers to the degree of unpredictability of liability costs.
- **Liability risk** refers to the potential for large liability costs.\textsuperscript{107}

In general, differences across products in these aspects are the same qualitatively. When this is the case, the discussion refers simply to liability potential to refer to all of them. It is helpful once again to use the distinction between legal doctrine and its application.

**Doctrinal**

Recall that companies may expect to be held liable when (a) a product causes an injury and the company failed to warn physicians in a legally adequate manner; or (b) a product causes an injury, the company owes a duty to warn patients.

\textsuperscript{103}DES and various cases discussed in Section 6.

\textsuperscript{104}Section 6—once details have been reviewed—further considers what this characterization indicates about information and risk perception.

\textsuperscript{105}Very recent examples include Haloxon, Prozac, heart valves, and breast implants. These are discussed in Section 6.

\textsuperscript{106}More technically, this can be thought of as the mathematical expectation of liability costs.

\textsuperscript{107}Which, as discussed above, reflects both the likelihood and size of such outcomes.
directly, but fails to meet the requirements of that duty. What do these instances suggest about differences in liability potential across products?

Most obviously, instances of liability are more likely—other things equal—the larger the number of product users. Consider first the prevalence of the two types of instances, holding both this number and the level of damages per case constant.

From the standpoint of legal doctrine, the prevalence of damages associated with instances of type (a) appears not to be systematically related to the nature of the product or patient involved. But the prevalence of instances of type (b) should be related to product and patient characteristics affecting the likelihood of a company having a duty to warn patients directly.

As discussed above, a company currently has a duty to warn patients directly only in some special circumstances. One of these is when products are administered without individualized interaction between patient and physician. The obvious, and perhaps only, example of this is mass inoculation programs. Here many are exposed to the product, and many of them are young or healthy. The other major exception to the learned intermediary rule is for oral contraceptives. However, as discussed above, companies are more likely to be found to have a duty to warn patients directly if they advertise a product directly to consumers, which was almost never done a few years ago but has become quite common. Companies might advertise directly to patients when the potential gains in profits are sufficient to compensate for the extra liability potential involved. As developed in Section 8, direct-to-consumer advertisements are likely to be especially profitable for products for healthy patients, products for relatively minor conditions, and products recently introduced for previously untreated conditions (where potential product users may fail to consult a physician unless they are aware of the existence of the product).

Interpretation and Application of Doctrine

Recall that when causality of injury is controversial, trial evidence can leave room for a legally defensible finding for either side. In such circumstances, companies may be held liable for injuries that would have occurred even without the use of

\footnote{The attributes of vaccines that lead to administration in the absence of physicians seem to be that these products are viewed as potentially valuable to all and that nothing about the patient could be used to predict the rare cases of injury.}

\footnote{See Section 8.}
the product.\textsuperscript{110} Hence, products for patients with high rates of unexplained background injuries appear especially hazardous from a legal point of view—birth defects are the most prominent example. In addition, the likelihood that difficult and controversial issues will be resolved in favor of the plaintiff is higher when the desire to compensate is unusually strong. The desire to compensate would seem strongest when the injured patient evokes an unusual degree of sympathy, as when the patient’s condition was much worse after the therapy than before—for example, severe injuries or deaths of young patients who were healthy prior to use of the product. Examples of products often used by young, healthy patients are contraceptives; sleeping aids; cosmetic products, such as treatments for baldness or breast implants; and products used for disease prevention, such as vaccines.

\textbf{Potential for Mass Torts}

A potential for a mass tort is particularly likely to have important economic effects, because this suggests especially large liability potential. Clearly, a fundamental reason that mass torts can occur is the potential for mass injury. But mass torts can—at least in principle—emerge without mass injury.\textsuperscript{111} What kinds of products are most likely to trigger mass torts?

The most obvious sources of mass torts are product hazards coupled with widespread product use. First consider product hazards that are known at the time the product is marketed. If significant safety hazards are known to the company and reported to the FDA, either the product will not be marketed or explicit warnings will be provided. Warnings serve to reduce liability potential, but cannot eliminate it. The possibility of mass liability because an explicit warning is found legally inadequate does not seem predictable on the basis of product type. Mass torts can also emerge if a company chooses not to reveal significant hazards of a widely used product.\textsuperscript{112} Such courting of a mass tort does not seem predictable on the basis of product type.

Besides such scenarios, two distinct factors come to mind as sources of mass tort potential. First is the possibility of especially wide exposure to a product before safety problems become known. Second is the extent to which patient characteristics contribute to publicity that fuels the dynamics of mass tort.

\textsuperscript{110} The converse possibility—that causation will not be found when it should be—is ignored here because the current concern is on circumstances leading to liability.
\textsuperscript{111} Many would cite Bendectin as an example.
\textsuperscript{112} Many would cite the Dalkon Shield as an example.
The first case may occur when a product gives rise to latent injuries or to injuries that result only with long-term use. Injuries that remain latent for many years after use of the product might not become apparent until a very large number of patients have been exposed to it. This kind of possibility can lead to mass tort, but in principle can pertain to any product. Mass-tort possibilities associated with long-term product use do, however, provide a basis for distinguishing products.

In the past few decades, many drugs have become available for chronic conditions that are effective only if used for long periods or only as long as they are used. Examples include anti-cholesterol drugs, drugs for hypertension, birth control pills, and the only drug on the market for baldness. In addition, many medical devices—such as heart valves, pacemakers, breast implants, and artificial joints—may be implanted in the body permanently. Injuries from products that result only if they are used for long periods would not be apparent from preapproval clinical trials, and many patients may use such products for long periods before any safety problems become apparent.

Mass torts are fueled by publicity, and some types of liability events appear to be more newsworthy than others. Aspects that seem to be of most interest in mass media include large awards, punitive awards, and serious injuries to patients evoking particular sympathy. Also, cases involving a product that is especially widely used might attract media attention precisely because users of the product (or people who know them) would find the information especially interesting.113

**Differences Across Products: Summary**

The analysis here rationalizes the stereotypical list of products that involve exceptional degrees of liability potential: vaccines, contraceptives, and products for conditions specific to pregnancy. But it also points to other characteristics of products or patients that seem to contribute substantially to liability potential: healthy patients, relatively minor conditions, a treatment for a condition that had until recently been untreatable, products used by patients with a high rate of unexplained injury, products for chronic conditions, and products used by exceptionally large numbers of individuals.

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113Halcion—discussed in Section 6—is an example.
Conclusions

Liability threatens profitability and influences decisions through direct costs of liability and indirectly by generating or publicizing information that affects the behavior of the FDA and product buyers. Legal doctrine provides substantial protection against findings of liability for design defects, especially for drugs. The central legal issues are generally whether the injury was caused by use of the product and, if so, whether the manufacturer's warnings were legally adequate. These scientific and medical questions often involve issues that are complex and unsettled. Doctrine regarding punitive damages is often especially ambiguous. As a consequence, juries often have wide discretion in deciding whether a company is liable, whether punitive damages are appropriate, and, if so, the appropriate amount. Published accounts—particularly of cases with large damages, punitive damages, and arguably inappropriate outcomes—appear to have disproportionate effects on information about the liability environment.

The liability potential associated with a particular product is subject to numerous sources of uncertainty. While there are other major sources of uncertainty in the decision environments of interest, liability uncertainty is unique in that liability costs can be effectively unlimited. A mass tort could threaten the financial viability of even large pharmaceutical companies. Depending on product and patient characteristics, the liability potential associated with different products ranges from the almost trivial to the potentially disastrous.
5. Decisionmaking in the Presence of Liability Potential

To recap, many decisions of concern are made by profit-seeking companies; liability can pose very substantial threats to profits; and the eventual liability consequences of decisions can be very unpredictable. To understand or predict decisions, it is essential to take explicit account of uncertainty.

Decisionmaking under uncertainty is the subject of much research in various scholarly fields. Two very different perspectives are prominent in the literature: one emphasized in economics and statistics, and another emphasized in management and psychology. These perspectives differ in two major respects: how uncertainty is perceived and how decisions are made. Both perspectives should be taken into account in assessing the economic effects of liability, because relying on one of them would sacrifice potentially valuable insights suggested by the other. It is also useful to consider how decisions of interest would be predicted to differ under the two perspectives. We should have additional confidence concerning the validity of predictions that are common to the two perspectives and should be more circumspect about predictions that conflict across them. The two perspectives are discussed in turn.

Maximization of Expected Utility

In economics and statistics, the most common perspective used to interpret or predict decisions assumes optimal decisions in the face of precisely specified prospects. The approach is often referred to as maximization of expected utility. A decision problem is generally expressed and analyzed mathematically, which requires that all of its features be specified precisely. This abstract approach requires extensive simplification of reality to enable mathematical analysis of implications. Nonetheless, it has proved very useful in various settings. In fact, it is widely applied—and provides many useful insights—in the theory of economic effects of liability in general and product liability in particular.¹

¹Shavell (1987), Cooter and Ulen (1988), Polsky (1989), and Cooter (1991) provide very useful accounts of the literature and insights developed from this approach. It is used in Section 10 to guide consideration of policy implications of the analyses in Parts I and II.
First, the objectives or goals of decisionmakers are represented as mathematical functions of their decisions (or actions) and of quantities that are unknown to them (i.e., subject to uncertainty) at the time their decisions must be made. For example, the goal of a business is generally assumed to be the attainment of the highest possible level of profits. The pursuit of this objective is complicated in our context by uncertainties concerning features of the market, research process, and regulatory and liability environments.

To approach the decision problem mathematically, the uncertainties must also be specified precisely. This is accomplished by assuming that the decisionmaker has precisely defined beliefs about the probabilities associated with all possible values of the uncertain quantities. These beliefs are represented by a probability distribution. For example, for any product design or labeling decision made by a pharmaceutical company, the eventual liability costs cannot be predicted precisely at the time that the decision is made. But the decisionmaker has beliefs about the likely values of these costs for any set of decisions he or she makes, and for analytic purposes, it is assumed that these beliefs can be represented by a probability distribution.

Thus, the company's objective function specifies how company actions and the values of the uncertain quantities determine profits, and a probability distribution specifies the laws of probability that apply to the unknown quantities that affect profits. These pieces can then be combined to determine for each contemplated action the implied probability distribution of profits. The optimal decision is the one that results in the distribution of profits that is most attractive to the decisionmaker.

Since the decisionmaker is typically choosing among distributions involving different degrees of uncertainty, the action that is chosen depends on the decisionmaker's attitude toward uncertainty. In the simplest case, the decisionmaker is assumed not to care about uncertainty one way or the other. Such a decisionmaker is called risk neutral and would always be willing to gamble at "fair odds." For example, such a decisionmaker would always be indifferent between receiving $10 with certainty or the uncertain prospect of receiving $20 with a probability of 0.5 and receiving $0 otherwise. For such a decisionmaker, the only feature of the distribution of profits that is relevant to

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2This very common pargon reflects the fact that the terms risk and uncertainty are often used interchangeably in economics. Recall that we use the term risk to connote potential for loss, which is not the same thing as uncertainty.
choice is its average or expected value. In particular, a risk-neutral business decisionmaker will choose the action(s) yielding the distribution of profits that offers the highest expected level of profits, regardless of the amount of uncertainty involved. Such decisionmakers are said to choose actions to "maximize expected profits."

The hypothesis that companies act as though they maximize expected profits has been generalized to take account of the possibility that the degree of uncertainty does affect choices among distributions. Most plausibly, if decisionmakers care about uncertainty, it is because they would prefer less uncertainty to more uncertainty, all other things being equal. Decisionmakers with such attitudes towards uncertainty are called risk averse. Such decisionmakers act as though they are willing, to some extent, to reduce expected profits in order to reduce the degree of profit uncertainty they face. Purchase of insurance by businesses exemplifies such an attitude: By paying a premium whose value exceeds the expected value of the losses that are insured, a company chooses to reduce its expected profits in order to reduce its exposure to uncertainty. Such decisionmakers will not necessarily maximize expected profits if doing so involves more uncertainty than is attainable from some other action.

In sum, in economics and statistical decision theory, decisionmakers are viewed as having precisely defined goals and beliefs and taking actions that maximize the expected value of their payoffs: profits or, more generally, utility. This perspective implies that, even if an action can lead to disaster, the action might be taken if the potential rewards are large enough and likely enough to outweigh the potential losses. Many view such behavior skeptically, as is discussed presently.

Behavioral Decisionmaking and a Model Emphasizing Liability Risk

The other leading approach to modeling company decisions is based on research in psychology and management. The strategy is to ground the analysis of decisionmaking on observation of actual behavior, in the belief that doing so will yield more instructive interpretations of observed decisions and more accurate predictions of unobserved decisions.

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3 The "expected value" or "mathematical expectation" of profits can be thought of as a weighted average of the possible profit levels in which the weights used in the averaging procedure are the probabilities with which each level of profit is assumed to occur.

4 Particularly useful surveys of the psychology literature upon which the present discussion relies are Kahneman and Tversky (1979, 1984); Tversky and Kahneman (1974, 1981); Machina (1987,
The behavioral perspective on decisionmaking emphasizes two considerations that are ignored in the expected-utility approach. First, real-world decisions are generally much too complicated for human beings to be capable of finding and implementing optimal solutions. Because of the limits of human problem-solving capabilities, decisions are based on simplified views of actual decision problems. In practice, decisionmakers (consciously or not) use simple rules to arrive at decisions. Such rules are called heuristics. Second, decisions reflect decisionmakers' perceptions of their environments, and such perceptions may not be accurate. For example, how a decision environment is perceived can be very sensitive to what information is possessed by the decisionmaker. Moreover, various systematic discrepancies have been documented between actual and perceived aspects of decision environments; these are often referred to as perceptual biases.

A sequential process for taking liability considerations into account in decisionmaking is diagrammed in Figure 5.1. In the figure, rectangles represent interim actions (actions that must be taken to arrive at a decision), judgments are indicated by ovals, and final actions (actions that end the process) are indicated by diamonds.

The model begins at the top of Figure 5.1 with a company faced with assessing the liability potential of a contemplated action. The possible final outcomes of the process (actions) are of three types: the contemplated action—referred to in the figure by take original action; a different action in the spirit of the original one—referred to as take modified action; and rejection of any action in the original spirit—referred to as reject this type of action. For example, for a company contemplating the marketing of a drug labeled in a particular way, a modified action might be to market the drug after revising the labeling; but the company might decide not to market the drug at all, which would be viewed as rejecting.

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Figure 5.1—Behavioral Model of Decisionmaking with Liability Risk
the type of action contemplated. The remainder of this subsection describes the paths from contemplated action to outcomes, step by step.\footnote{The contemplated action is determined outside the model, but to be of interest here, it must appear potentially profitable. Liability considerations are assumed to enter the decision process after a course of action has been identified as attractive considering market, regulatory, and technological factors, because product liability is typically not as fundamental as these other considerations. In unusual and extreme cases—such as products for conditions specific to pregnancy—decisionmakers may refuse even to consider developing or marketing a product. If so, there is nothing left to analyze here.}

**Assessing Liability Risk**

Assessment of potential liability costs involves—one way or another—magnitudes of costs and the likelihoods associated with them. As discussed above, the full complexity could be represented by a probability distribution of liability costs. But the psychology literature suggests that liability potential will be dealt with in a simplified form.

Liability potential has two aspects that are particularly salient to decisionmakers: a best guess about eventual liability costs, or a narrow range that is perceived as very likely, and the degree of uncertainty or lack of confidence about eventual liability costs. Sometimes, consideration of the first aspect alone will be sufficient to reach a decision: For example, if decisionmakers think it is very likely that liability costs will be larger than sales revenues, that decision will be rejected. In contrast, decisions are more difficult to make when it is very likely that eventual liability costs will be small compared to product profits, but there is concern that much higher costs might result. Here, uncertainty is an important consideration in deciding, because the decision looks risky. The potential for large liability costs—i.e., liability risk—may often be an important consideration in decisionmaking, and the model focuses on its effects.

The management literature and information about the product liability environment provide insight into how liability risk is likely to be perceived and handled. For example, March and Shapira (1987, p. 1407) write that “for these managers, risk is not primarily a probability concept” and report that when asked to evaluate risks, 80 percent of the executives interviewed for Shapira (1986) “asked for estimates of the ‘worst outcome’ or the ‘maximum loss.’” March and Shapira (1987, p. 1408) summarize this discussion by writing that “it is clear that these managers are much more likely to use a few key values to describe their exposure than they are to compute or use standard summary statistics grounded in ideas of probability.” Threats to firm survival are particularly important. For example, March and Shapira (1987, p. 1410) write:
"Over 90% of the executives interviewed by Shapira said they would not take risks where a failure could jeopardize the survival of the firm..."\(^8\)

Thus, the possibility of extremely bad outcomes is particularly salient in the decision process. Assume that a decisionmaker breaks up the wide range of potential liability costs into three ranges:

- **Small** liability costs—costs that would not make the company regret marketing the product
- **Moderate** liability costs—costs large enough to make the company regret marketing the product, but not to threaten overall profits
- **Disastrous** liability costs—costs high enough to threaten the overall performance or viability of the company.

But how might the decisionmaker form judgments (albeit rough ones) about the likelihoods of liability costs in the three ranges? Extreme cases are easy to analyze, and their outcomes easy to predict.\(^9\) For example, if moderate or disastrous liability costs were essentially unimaginable,\(^10\) then the risk would be judged as not substantial. At the other extreme, if a contemplated course of action would virtually guarantee liability disaster,\(^11\) the judgment is also easy.

In cases that are not so extreme, the so-called "availability heuristic" of the behavioral decision-making literature comes into play. As explained by Slovic, Fischhoff, and Lichtenstein (1987, p. 19):

> People using this heuristic judge an event to be likely or frequent if instances of it are easy to imagine or recall. Because frequently occurring events are generally easier to imagine or recall than are rare events, availability is often an appropriate cue. However, availability is also affected by factors unrelated to frequency of occurrence. For example, a recent disaster or a vivid film could seriously bias risk judgments.

These authors review research indicating that personal experience is very important in affecting what can be imagined or recalled, and that people who

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\(^8\)This consideration in a management context is so well accepted, it seems, that Schoemaker (1982, p. 548) uses it as his example of a decision rule that requires only a single comparison: "For example, Melvin W. Reder (1947) found that investment projects are often eliminated from consideration because the probability of ruin exceeds some critical level, ..."

\(^9\)In such cases, application of the expected-utility approach might also be easy and lead to the same predictions.

\(^10\)For example, marketing with extensive warnings a product to alleviate the pain of terminally ill patients.

\(^11\)For example, withholding information from the FDA to enable marketing a product to pregnant women that is known to the company to cause birth defects in a large percentage of cases.
have not suffered personally from some types of hazards "tend to view themselves as personally immune to certain kinds of hazards." (Slovic, Fischhoff, and Lichtenstein, 1987, p. 20.) As discussed by Slovic, Fischhoff, and Lichtenstein (1982, pp. 467-468), media accounts may also be very influential in affecting what can easily be imagined or recalled, and hence how people perceive various risks.

These observations suggest hypotheses about perception of liability risk. The perceived liability risk for a product may be expected to be substantial if a company has had extensive liability problems with this or a similar product. Such problems at other companies might also easily come to mind if decisionmakers have been exposed to extensive media coverage or other frequent or forceful information about them.

Consideration of the availability heuristic suggests that the perceived likelihood of moderate or disastrous liability costs is likely to be overestimated by decisionmakers in some contexts. For example, unusually large liability costs associated with the stereotypical products—namely, "vaccines, contraceptives, and products for pregnant women"—are seemingly well known to all decisionmakers in the industry and are very easy to recall or imagine. Similar comments apply to other instances that receive considerable attention: large jury awards, punitive damages, and large awards where the findings of causation are disputed by respected authorities. Potential liability costs for such products or from such sources are likely to be commonly perceived as substantial, and perhaps much more substantial than they really are.

But consideration of the availability heuristic also suggests that some risks may be underestimated. As discussed in Section 4, the stereotypical products are not necessarily the only ones with substantial liability risks. The lack of well-known instances of unusually large liability costs for other products suggests that their

\[12\] The bases of this stereotype and lessons for the psychology of perceived liability risk are discussed more extensively in Section 6.

\[13\] For example, American Law Institute (1991b, p. 225) refers to "the somewhat distorted perception one gets from reading only about the largest and most questionable punitive awards." Ruseid (1991) argues that overestimation of the sizes and frequency of punitive trial awards and lack of awareness of post-trial reversals or reductions of punitive trial awards are major sources of misconceptions about the liability environment. Daniels and Martin (1990)—who emphasize the influence of reform advocates—argue that the frequency, size, rate of increase, and jurisdictional scope of punitive damages are all less than is widely believed. Cecil et al. (1991, p. 743) write: "Publicity about occasional large verdicts may leave the incorrect impression that such awards are typical. Often repeated 'horror stories' about jury verdicts, many of which are unconfirmed or erroneous, encourage a misleading impression of the performance of the civil jury." (footnotes omitted) Finally, Viscusi (1991b, p. 1) writes: "Seemingly outrageous cases have come to epitomize the malfunctioning of the tort liability system."
risks are underestimated by many decisionmakers: Hypothetical costs cannot be recalled and seem harder to imagine than actual ones.\textsuperscript{14}

\textit{Mitigating Substantial Risks}

According to the model, if moderate or disastrous liability costs are perceived to be sufficiently implausible, the judgment is that the liability risk is not substantial and the original action is taken without considering other options.\textsuperscript{15} When the action is not taken, the next step in the process is to consider how the contemplated action might be modified to mitigate the liability risk. There is considerable evidence that managers typically seek to manage risk, rather than merely accepting it, and feel especially uncomfortable with risks that they do not believe that they can control. (March and Shapira, 1987, p. 1410.)\textsuperscript{16}

Depending on the nature of the action contemplated, the risk-management strategy may involve immediate actions or be largely a matter of making contingency plans. For example, the modified action might be the immediate action of strengthening the warnings on the labeling of a product that is generating a surprising number of adverse reaction reports or liability suits. Alternatively, if the contemplated action is proceeding with an R&D project for a product that is perceived to pose substantial liability risks, the company may plan to be especially diligent in complying with all FDA regulations, provide warnings or list contraindications in their initial labeling that they would not consider otherwise, and withdraw the product at the first sign of trouble.

If, after modifying the action, it is judged that the remaining liability risk is not substantial, the company takes the modified action. If the remaining risk is substantial, the process continues. Here, the distinction between acceptable and unacceptable risks is made explicit.\textsuperscript{17} If the remaining risk is unacceptable, the

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\textsuperscript{14} Evidence consistent with this view is reported in McGuire (1988, p. 19, Tables 28 and 29), who summarizes survey responses from corporate CEOs concerning responses to product liability. Regarding decisions of the types emphasized in the present study, much higher fractions of respondents reported taking the following actions in response to "anticipated liability problems" relative to "actual liability experience": discontinuing product lines (26 percent versus 1 percent respectively); not introducing new products (30 percent versus 9 percent); and discontinuing product research (21 percent versus 4 percent). As noted in Section 1, the reliability of such survey responses may be questioned, because respondents may have incentives to exaggerate the extent of their responses to liability. But there is no apparent reason that respondents would exaggerate their responses to actual liability experience more than their responses to potential liability problems.

\textsuperscript{15} This path of the model would pertain to a situation in which liability potential is not even considered, as well as situations in which it is considered and judged not to be substantial.

\textsuperscript{16} Managers tend to think of risks they cannot control as gambles, hence more troublesome.

\textsuperscript{17} In principle, this distinction is relevant to the risk assessment for the original action. This complication is ignored in the model to emphasize the fact that some risk mitigation measures are likely to be considered for any contemplated action perceived to involve substantial liability risk.
company would consider further actions to mitigate the risk or give up and reject this type of action. As an example of the latter possibility, if all imaginable changes in the product labeling would not make the likelihood of disaster acceptably low, the product might be withdrawn from the market without even considering the potential for gain.\textsuperscript{18}

**Comparing Remaining Risk with Potential Profits**

If, after modifying the action (perhaps several times), the remaining risk is acceptable, the decisionmaker compares the risk to the prospective gains. If a mitigated risk is not substantial, and the modified action still appears profitable, the modified action is taken. But if the remaining risk is substantial, the decision is more difficult. Since the perception of potential liability costs is quite vague and qualitative, this comparison is likely to require substantial guesswork.

At one extreme, a company would be willing to take a relatively large liability risk rather than withdraw a blockbuster product from the market. In such an instance, the comparison is favorable, and the company would take the modified action. At the other extreme, a company is unlikely to continue marketing a barely profitable product if the action under consideration is perceived to involve any substantial liability risk. Here, the comparison is unfavorable, and the company would either continue to seek ways to mitigate the risk or reject the continued marketing of the product.

While comparison of profit prospects with perceived liability risks is fundamental to the decision, the management literature suggests a final consideration that proves useful below: The decision may depend on the broader context. Specifically, March and Shapira (1987, pp. 1412) write:

\[\text{The acceptability of a risky alternative depends on the relation between the dangers and opportunities reflected in the risk and some critical aspiration levels for the decision maker. } \ldots \text{ The most frequently mentioned values are a target level for performance (e.g., breakeven) and a survival level.}\]

And they continue:

In general, if one is above a performance target, the primary focus is on avoiding actions that might place one below it. \ldots \text{ For decision makers who are, or expect to be, below the performance...} 

\textsuperscript{18}In contrast to the expected-utility approach, in the model here an action might be judged unacceptable on the basis of its potential for losses regardless of its potential for gains. The concepts of acceptable and unacceptable risks are meaningless in the expected-utility context.
target, the desire to reach the target focuses attention in a way that generally leads to risk taking. (March and Shapira, 1987, p. 1413.)

Thus, depending on the larger company contexts, two different companies might—predictably—make different decisions about, for example, continuing to market a product even if they had the same perceptions about the product’s profit and liability potentials. For example, a company that specializes in vaccines might be expected to continue vaccine research in a liability environment that induces more-diversified companies to discontinue vaccine research; a specialized company is unlikely to be able to meet its long-term performance targets if it ceases product development efforts in its core business.¹⁹

Conclusion

The two perspectives on decisionmaking provide a foundation for interpreting observed outcomes within the prevailing liability environment, predicting actual effects we cannot observe, and predicting the effects of liability reforms. At the core of both perspectives are the pursuit of profits, potential liability costs, and judgments about the likelihood of various outcomes. As a result, predictions under the two views will be similar in most instances, and they are difficult to distinguish empirically. The sharpest conflict between them stems from the concept of unacceptable risk. But when a risk is unacceptable according to the behavioral view, predicted behavior under the two views will often be the same despite the conceptual difference. In particular, a more than trivial probability of financial disaster—which would absolutely deter an action under the behavioral view—involves a heavy penalty in the calculation of expected profits or utility and hence would greatly discourage an action under the expected-utility view.

The two perspectives are complementary in many ways. For example, the psychological perspectives can be helpful for specifying the beliefs of decisionmakers who are modeled as maximizing expected utility, and the optimizing perspective provides an especially promising approach to understanding and predicting decisions where the potential for disaster is not large enough to enter decisionmaking. It seems more useful to treat the two perspectives as complements than as competitors. The following analyses are pursued in that spirit.

¹⁹This argument is distinct from more familiar—but also relevant—ones based on the sizes of firms. For example, if the less-diversified firm is smaller, it has less to lose (i.e., bankruptcy limits its worst-case scenario), and it is a less-attractive target for liability suits and can expect to have lower liability costs (i.e., the deep-pocket effect on claiming behavior).
Part II

The Prevailing Liability Environment and Economic Outcomes

In the next four sections, we review, synthesize, and interpret empirical information pertaining to the effects of liability on economic outcomes of policy concern. The empirical information is of many types, including descriptive accounts of company actions, time-series data on prices, the content of product inserts, and numerical simulations calibrated from pharmaceutical industry data.

Our major objective is to learn what we can about two broad questions:

- How have economic outcomes been affected by liability?
- How would policy reforms change these outcomes?

As discussed in Section 1, most analyses and discussions of the economics of product liability are focused on the first question, but the second—which requires us to understand company decisionmaking—is also critical.

Moreover, the first question is problematic because “economic effect of liability” is an ambiguous, albeit common, term: It has meaning only with reference to a particular alternative. Such an “effect” is the difference, all other things being equal, between an outcome that occurs within the current liability environment and a corresponding outcome that would occur under a different set of liability arrangements. To discuss meaningfully the effects of liability, then, we must consider alternatives.

The legal environment is a collection of statutes, common laws, and procedures. Policy can affect these directly. Company decisions also depend on factors that cannot be directly affected by policy, such as the fundamental safety hazards of drugs and devices; the potential for latent injury; difficulties in attributing injuries to causes; and the attitudes of judges, juries, attorneys, and company decisionmakers. We must consider such factors in interpreting what we observe. However, variations in such factors are not relevant when we are considering alternative liability environments, because they are not subject to policy control.
Policy discussions often consider changes in specific aspects of the legal system, separately or in combination. Thus, we seek to understand the economic effects of changing various components of the system, keeping the others in place. In short, there is no single alternative liability scenario of interest; there are many of them.

As a result, as we interpret the empirical evidence on economic effects, we attempt to identify how economic outcomes would be different if specific aspects of the legal environment were different. For example, in some instances, what we observe seems to be driven largely by particular aspects of the legal environment—e.g., comment k, the learned intermediary rule, how regulatory compliance is treated, or the possibility of punitive damages. If so, this is discussed.

However, what we observe often seems not to point clearly to specific aspects of the legal environment. For example, some outcomes seem best explained in terms of substantial liability potential—i.e., high expected liability costs, major degrees of uncertainty, or especially large liability risks—attributable to a combination of product and patient characteristics that are relevant because of numerous legal factors operating together. Moreover, these three aspects of liability potential often go hand in hand.

In many instances, then, effects of liability are discussed in Part II with reference to alternative liability environments with lesser degrees of liability potential. Such alternative environments could be achievable through several different alternative legal arrangements. For example, many alternative legal reforms might increase the predictability of the liability costs resulting from particular company decisions by roughly the same extent.

A final complication is that, if the liability environment were very different from the prevailing one, the market and regulatory environments might differ as a result. For example, suppose there were no product liability system at all. This would not eliminate the fundamental concerns to which product liability responds: protection from and compensation for product-related injuries. In the absence of any product liability system, injury compensation might be addressed by explicit contracts or warranties accompanying the product. In addition, the FDA might be stricter in promoting safety, especially if the market did not provide for much injury compensation. In response, in (the few) cases where the alternative liability scenario is sufficiently different from the status quo, the possibility of consequent differences in the market and regulatory environments is addressed explicitly. Unless otherwise indicated, however, the (implicit)
assumption is that, under the alternative liability scenario, the relevant market and regulatory environments are those that currently prevail.

Sections 6 through 9 consider liability and, respectively, the availability of existing products, pricing, safety and effectiveness of existing products, and innovation. Conclusions are of several types, including direct observations, interpretations of observations, deductions from empirical generalizations and theoretical premises, and results from numerical simulations. As an expository aid, various conclusions are set off and designated as "Propositions," a term that is used to refer to various types of generalizations offered to the reader for consideration and acceptance.
6. Product Liability and the Availability of Existing Products

This section considers the U.S. availability of drugs and devices that have already been developed. The analysis rests largely on published accounts about the liability experience of various drugs and devices and associated availability decisions. In attempting to generalize from these observations, it is critical to consider—as we do—why these cases generate public information, receive so much attention, and dominate the empirical base available to us.

The most fundamental perspective developed in this section is that it seems meaningful to say that product liability has reduced the availability of some products, but that many products are marketed despite substantial liability potential. Liability can affect product availability in various ways. This is illustrated by actions reviewed in this section: product withdrawal, delay or failure to market, and various ways to mitigate liability risks while marketing. Some apparent responses to liability—such as withdrawal of only some suppliers of a product, strengthening of warnings or informed consent procedures, and efforts to reduce product use by the patients most likely to generate lawsuits—have implications for other outcomes, such as pricing, product safety, and effectiveness.

The first subsection focuses on products with substantial liability potential that have become unavailable in the United States. Case histories are used first to consider what can be said about the effects of the existing liability environment and then to suggest lessons about company decisionmaking. The second subsection focuses on products that have remained on the U.S. market despite substantial liability potential. These cases illustrate responses to liability less extreme than refusal to market and suggest additional lessons about decisionmaking. The last subsection summarizes major conclusions from considering product availability.

Products That Have Become Unavailable

The first subsubsection considers observed cases of lack of product availability in the presence of substantial liability threats and what can be said about the role of liability in determining these outcomes. The last three subsubsections discuss
broader implications of these observations—for decisionmaking in the face of substantial liability risk and the possibility that liability has had unobserved effects leading to lack of availability of existing products.

**Outcomes Within the Prevailing Liability Environment**

This subsubsection begins by reviewing five cases in which liability may well have played an important role in product withdrawals: vaccines, intrauterine devices, Bendectin, the Shiley heart valve, and silicone-gel breast implants. It then reviews three cases in which liability concerns may have contributed to delays or failures to introduce products: the swine flu vaccine, thalidomide, and Oculinum. These discussions defer the issue of what can be said about the role of liability in determining the events described. This issue is addressed after the eight cases are reviewed.

**Product Withdrawals.** The first three examples of product withdrawals are prominent and widely accepted as being attributable to product liability. In fact, these are the only three instances of problematic product withdrawals due to liability cited by the Board of Trustees of the AMA in a 1988 report¹ that was critical of the liability system.² The last two cases reviewed here—the heart valve and breast implants—are more recent. Future developments regarding them may have major effects on perceptions of the liability environment.

**Vaccines.**³ The effects of product liability on vaccine availability are a leading source of concern about the economic effects of product liability. The reasons include the following: (a) vaccines are among the most socially valuable medical products; (b) continued availability of vaccines is a major concern; and (c) product liability is one factor that has discouraged vaccine availability.

Concerns about vaccine availability in the late 1970s and early 1980s led to inquiries by both the Office of Technology Assessment (OTA) of the U.S. Congress and the Institute of Medicine (IOM) of the National Academy of Sciences. Their reports—OTA (1979) and IOM (1985)—documented decreasing numbers of vaccine producers. For example, IOM (1985, p. 5) reported:

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¹Weaver (1988). The only other specific concerns raised are Oculinum (p. 11), which is discussed below, and the effects of liability on incentives to develop biotech medical products, an issue taken up in Section 9.

²For example, the opening paragraph reads: "...product liability lawsuits are having a profound negative impact on the development and utilization of potentially life-saving medical technologies. The AMA supports continuing the efforts of tort reform."

³The discussion here relies heavily on OTA (1979) and Institute of Medicine (1985).
The United States is heavily dependent on sole suppliers (either sole manufacturers or distributors). Two commercial companies (who do not compete with each other) dominate the markets for the major pediatric vaccines. The withdrawal, during 1984, of two manufacturers from the distribution of DTP vaccines and technical problems encountered by the one remaining producer resulted in a shortage of it in early 1985.

The decline in the numbers of producers of various vaccines is summarized in *New York Times* (1984).

Both the OTA and IOM studies pointed to various factors contributing to these decreases in the numbers of vaccine suppliers, including relatively small markets, low profits, large capital requirements, federal regulation, limited funding for basic research, complexity and cost of development and production, and liability. Nonetheless, both groups concluded that liability may have played an important role in some instances and was a serious concern. The belief that liability has played an important role in reducing the availability of some vaccines is widespread and appears largely uncontroversial.

**Intrauterine Devices.** In general discussions of economic effects of liability, contraceptives also receive considerable attention. For the narrower issue of product withdrawals, intrauterine devices (IUDs) have been the focus. The first, and most well-known, episode involves one of the largest mass torts ever: the Dalkon Shield. It was marketed nationally in the United States beginning in January 1971. Because it did not rely on chemical action, it was considered a device (rather than a drug) and hence was not subject to FDA premarking approval requirements (which were not instituted for devices until 1976). As documented in a May 1974 report of the Centers for Disease Control, a survey of physicians suggested serious safety problems with the Dalkon Shield. Shortly thereafter, sales were voluntarily suspended, and in January 1975, all unsold Dalkon Shields were recalled.

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4While at the end of 1984 there was only one producer of each childhood vaccine, in the 1960s there were eight producers of DTP vaccine, six of mumps vaccine, three of rubella vaccine, and three of live-virus polio vaccine. There had been only one producer of mumps vaccine for the previous twenty years. In addition, there were three producers of influenza vaccine at the end of 1984, compared with seven in the 1960s.

5For example, OTA (1979, p. 3) pointed to "unpredictable liability risks" and IOM (1985, pp. 6-7) to "apprehension over the liability situation."

6For example, IOM (1985, p. 2): "... the committee's analysis identified a variety of deterrents to commercial interest in vaccines. ... Paramount among current concerns is the pressing need for a consistent and just approach to the issues of liability for vaccine-related injury and of compensation for those who are injured."

7IOM (1985, pp. 117-119) summarizes the basis for this view.

8Information about the Dalkon Shield reported here can be found in Mastroianni et al. (1990, pp. 126-128).
It is generally agreed that liability exposure was a major consideration leading to the withdrawal of the Dalkon Shield. It is also widely agreed that this product was better unavailable than available. According to Mastroianni et al. (1990, p. 128):

The history of the shield illustrates the operation of the legal rules of product liability, functioning in the absence of premarketing review of FDA, to achieve the objectives of compensation, deterrence, and dispute resolution by causing a defective device to be taken off the market and by providing a mechanism for compensating thousands of women injured by it.

By the mid-1980s, there were two major manufacturers of intrauterine devices: Ortho and G.D. Searle. Ortho stopped producing its IUD—the Lippes Loop—late in 1985, citing low profitability. On January 31, 1986, the last major pharmaceutical company marketing IUDs—G.D. Searle—withdrew the Copper-7 and Tatum-T, citing liability suits and lack of insurance on acceptable terms. (Mastroianni et al., 1990, p. 130.) This left one small company—Alza Corp.—as the only company marketing an IUD in the United States. The result was generally regarded as an availability problem for U.S. women wanting to use this form of contraception, which is viewed as medically valuable for many women.

Bendectin. Introduced in 1956, Bendectin is the only prescription drug ever approved in the United States for the morning sickness accompanying pregnancy. It was very widely prescribed. The product was withdrawn voluntarily in 1983, and there is little—if any—dispute that product liability was a key factor. Suits against Bendectin increased for the next two years, but

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9. Skrzynski (1986, p. 42) reports that Ortho’s parent—Johnson & Johnson—had warned in its 1985 annual report that it was facing many liability cases involving contraceptives and was “substantially uninsured” for injuries after 1985.

10. The Copper-7 was regulated as a drug and introduced in 1974 with FDA approval. Searle had faced several hundred Copper-7 suits by the time it was withdrawn. (Skrzynski, 1986.) Information about Copper-7 litigation can also be found in Rust (1986), Blum (1986), Mastroianni et al. (1990, p. 130), and 1990 Securities and Exchange Commission Form 10-K of Monsanto—Searle’s parent.

11. See, for example, Los Angeles Times (1986).

12. See, for example, Mishell (1985).


14. The Wall Street Journal (1983) reports that it had been used in about 35 million pregnancies. Lasagna (1991, p. 338) suggests that it was used by roughly one quarter of pregnant American women during the period it was marketed.

15. As Lasagna (1991, p. 338) recounts: “...the demise of Bendectin... was traceable to a flood of legal actions...” The Wall Street Journal (1983) indicates that more than 300 U.S. suits had been brought by the time Bendectin was withdrawn, and that liability insurance for Bendectin was costing the company an amount roughly equal to the sales of the product (and, by implication, substantially more than its profits).
decreased thereafter as the plaintiffs failed to prevail on the issue of a causal link between Bendectin and birth defects. To date, the legal defense of Bendectin has been very successful, but the product remains unavailable.

Shiley Heart Valve. The Bjork-Shiley Convexo-Concave 60-degree heart valve was approved by the FDA for marketing in April 1979. By the time it was withdrawn in 1986—amid widespread safety concerns—about 85,000 of them had been sold worldwide. By late 1991, roughly 450 of the valves had fractured, causing almost 300 deaths. Determining the cause(s) of the fractures is more difficult than might be anticipated, but they have been widely attributed to weld failures.

Liability actions have been brought both for instances in which the valve has fractured and for anxiety associated with valves that have not fractured. For years the company pursued a policy of settling cases involving broken valves, while refusing to settle anxiety claims. In January 1990, a California appeals court ruled in Kahn v. Shiley that the company could be held liable for anxiety associated with a possible future valve failure if the company had fraudulently represented the risks associated with the product. The liability threat associated with the anxiety claims thus became much more substantial. Settlements involving tens of thousands of these claims have been agreed upon, but several hundred suits were still pending in California in mid-1993.

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16 General Accounting Office (1988, p. 35) indicates that a total of about 1,650 cases were brought against Bendectin between 1977 and 1986; filings in state and federal courts were much higher in the two years after Bendectin’s withdrawal than in earlier years; and filings fell off dramatically in the year ending June 30, 1986. Sanders (1992, p. 319) reports that more than 2,100 suits have been filed.

17 See, for example, Henderson and Eisenberg (1990, pp. 491, 534). Cecil et al. (1991, p. 741) discuss Bendectin in the context of “the trend toward removal of difficult cases from jury consideration.” Bendectin was at the center of the Daubert case decided by the U.S. Supreme Court in 1993 (see Section 4) concerning standards for allowing scientific evidence to be presented to a jury. Marshall (1993) discusses the legal issues and summarizes scientific literature on Bendectin. Sanders (1992, pp. 321–348) provides an extensive review of the scientific studies of Bendectin.

18 See the discussion of Proposition 65 below.

19 Useful accounts include Schroeder (1990), Rushford (1990a,b), Weber (1990), and Bailey (1990), upon which the description here of events through early 1990 is based.

20 The 70-degree valve was never marketed in the United States, but about 4,000 were sold abroad.

21 See, for example, U.S. House of Representatives (1990, pp. 205, 300).

22 Carley (1991) details alleged quality control problems in the manufacturing facility.

23 See Meier (1990) and Erickson (1992). Settlement terms are confidential, but might have been in the range of $1 million per death case. (Rushford 1988, 1990a; Weber, 1990.)


25 See, for example, Weber (1990) and Schwartz (1992, p. 677), who also details related court rulings in several other jurisdictions.

26 In August 1992 a Federal district judge in Cincinnati approved a settlement affecting roughly 80,000 people whose valves had not fractured. About 1,000 claimants—half of whom were bringing anxiety cases in California—chose not to participate in the settlement and were given until October 1 to change their minds. (Geyelin, 1992.) About 330 of the claimants who opted out accepted a
Silicone-Gel Breast Implants. More recently, silicone-gel breast implants have been withdrawn from the market in the wake of a large number of product liability suits.\textsuperscript{27} As many as two million American women have had them implanted.\textsuperscript{28} The devices came on the market in the late 1960s—before medical devices required FDA premarketing approval. The FDA first required safety data from manufacturers in 1991. Quite recently, concerns have been widely publicized that leakage from the implants may cause serious health problems. The Markham implant—about 200,000 have been sold in the U.S.—involves additional health concerns because it was coated with a material suspected of releasing a carcinogen.\textsuperscript{29}

So far, few liability cases involving these products have come to trial, but awareness of the issue became widespread during 1991, apparently because of such trials. In that year, three multimillion-dollar jury verdicts were announced against different manufacturers.\textsuperscript{30} In December 1992, a jury awarded $25 million—including $20 million in punitive damages—in another case.\textsuperscript{31} The Markham implant was removed from the U.S. market when safety data were requested by the FDA. In early 1992, two other manufacturers—Bioplasty and Dow Corning Wright—withdraw their products from the market. Two small companies continue to market silicone-gel breast implants.

Delay or Failure to Introduce a Product. U.S. market introduction of at least a handful of already-developed pharmaceutical products has reportedly been delayed or forestalled by product liability concerns.\textsuperscript{32}

In the well-known case of Swine flu vaccine, companies refused to distribute the product without federal legislation shielding them from liability.\textsuperscript{33}

Thalidomide\textsuperscript{34} was marketed as a sleeping pill in 46 countries by 14 companies, but withdrawn from almost all world markets in 1961 amid widespread concerns about birth defects. It was never approved by the FDA for marketing in the

\textsuperscript{27} See, for example, Duncan (1988).
\textsuperscript{28} The Markham implant is discussed at length in Burton (1992).
\textsuperscript{29} Lewin (1992) details these.
\textsuperscript{30} Smeltzer (1992).
\textsuperscript{31} An example not discussed below is "a computer controlled pump that would dispense medicine for transplant patients." (U.S. Senate, 1991, p. 8–9.)
\textsuperscript{32} See, for example, OTA (1979, pp. 98–131) and IOM (1985, pp. 93–114).
\textsuperscript{33} This discussion is based on Lasagna (1991, pp. 345–347). See also Sanders (1992).
United States. Lasagna (1991) reports that thalidomide appears to have promise in treating various serious conditions and argues that liability concerns attributable to its well-known history have prevented any manufacturer from introducing it in the United States.

Oculinum is a drug for severe vision problems "made from botulism A toxin, the same deadly substance that poisons improperly canned food." In 1986, its manufacturer curtailed its supply to participants in clinical trials, citing problems in obtaining liability insurance at an acceptable cost. This led to severe problems for the patients whose treatment was suspended and much outcry to the FDA. But Oculinum is now available on the U.S. market. While this episode is dramatic, it also appears to be unusual.

Attributing Outcomes to Liability. All of the product withdrawals discussed above involve products experiencing liability problems. This does not imply that they were withdrawn because of liability. A fundamental complication in attributing withdrawals to liability is that products can also be driven off the market by market forces, regulatory activity, or their combination.

The market and regulatory systems may not be capable of weeding out all products whose benefits do not justify their injury and other costs. But both institutions involve powerful forces working in that direction. Holding effectiveness benefits constant, products believed to involve larger injury risks are less attractive to physicians and patients and are less likely to be approved for marketing by regulators. But product-safety information available to physicians, patients, and regulators is quite incomplete, and information that would not be available under some alternative liability arrangements can play a major role in market and regulatory decisions.

All withdrawals of products experiencing liability problems are reasonably viewed as resulting from some combination of market, regulatory, and liability forces. The issue before us, then, is not which product withdrawals were caused by liability, but in which cases liability seems to have played more and less important roles.

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35 Unless otherwise noted, this discussion is based on Bofey (1986). See also Weaver (1988, p. 11).
36 Bofey (1986).
37 It was approved by the FDA late in 1989. (New York Times, 1990: Scrp, 1990.)
38 For example, Bofey (1986): "... researchers testing the drug said they were unaware of other cases in which patients were suffering because a drug had been withdrawn from use as a result of insurance problems.
39 Withdrawal of products alleged to pose unacceptable safety hazards is not uncommon. See, for example, Bakke, Wardell, and Lasagna (1984).
Moreover, when it is meaningful to ascribe to liability substantial roles in withdrawals, delays, or failures to market, it is important to be clear about the alternative scenario. As discussed in the introduction to Part II, this refers to the alternative liability environment and any differences in the market or regulatory environments.

Thus, attributing events to liability is complicated, and the evidence cannot be definitive. But understanding the role of liability in determining outcomes, such as product withdrawals, is fundamental to evaluation and formulation of liability policy. The first proposition offers a summary interpretation of the cases of withdrawal reviewed here, and its discussion points to specific aspects of the liability environment.

**Proposition 6.1:** Aspects of the liability environment played a central and perhaps crucial role in some of the product withdrawals. The role of liability in other withdrawals is much more equivocal. The former cases involve products that had relatively strong support in the medical community, and the latter cases are products that are much more controversial in the medical community.

First consider the childhood vaccines, IUDs other than the Dalkon Shield, and Bendectin. The withdrawn vaccines seem to have had virtually universal support in the medical community. While this cannot be said for Bendectin\(^{40}\) and the IUDs,\(^{41}\) it is clear that these products had much support in the medical community.\(^{42}\) Not coincidentally, FDA action to limit product availability was apparent in none of these cases.\(^{43}\) The support among physicians indicates that the market for none of these products had largely disappeared. Thus, it seems meaningful to say that aspects of the liability environment played a central role in these withdrawals.

It is not possible, however, to say which elements of the liability environment were most important in these decisions. For products that were not especially profitable—vaccines are often claimed to be examples—even moderately large expected liability costs might have sufficed to induce product withdrawals. It is

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\(^{40}\) Skolnick (1990) recounts some of the reaction in the medical community to the withdrawal of Bendectin.

\(^{41}\) Connell (1987, pp. 50-52) discusses some of the medical implications of the withdrawals of the IUDs.

\(^{42}\) Weaver (1988)—a report of the Board of Trustees of the AMA—laments the withdrawal of all these products.

\(^{43}\) The FDA had reviewed Bendectin in 1980, and "...consistently maintained that the medicine deserved to stay on the market, but restrained (quite correctly) from giving Bendectin a complete bill of health..." (Lasagna, 1991, p. 340.)
safe to say that, in all of the cases under consideration, companies would have viewed eventual liability costs as highly unpredictable and might have viewed disastrous liability costs as plausible.

The Dalkon Shield, the Shiley heart valve, and the silicone-gel breast implants seem to have much less support in the medical community than the other withdrawn products. Not coincidentally, it is considerably more plausible that the market and regulatory systems would have eliminated these products—perhaps less promptly—even in the absence of a liability system.

Safety concerns about the Dalkon Shield were widespread at the time of its withdrawal (when the FDA did not have authority to remove it from the market). Failures to comply with FDA regulations are widely alleged in the cases of the heart valve and at least some of the breast implants. The Shiley heart valve was withdrawn after the FDA had announced an investigation. Silicone-gel breast implants were withdrawn by three manufacturers after the FDA requested safety information (in 1991) or held hearings to consider restricting their use (1992), but before the FDA acted to do so. While liability may have been unnecessary to induce these withdrawals, information and publicity attributable to liability may have played an important role in each case.

Proposition 6.2: When a company publicly attributes the withdrawal of its product to liability, this might reasonably be accepted at face value. But the absence of such an attribution accompanying a product withdrawal is not strong evidence of the absence of a link to liability.

Public announcements blaming liability for product withdrawals appear to be rare. The leading examples are Bendectin, Wyeth's DTP vaccine, and the Copper-7—all products with substantial support in the medical community. Other withdrawals in which no FDA action was impending that have been attributed to liability by outside observers appear not to have been accompanied by such announcements (e.g., some vaccines, the Lippes Loop).

The costs to a company of pointing to liability while withdrawing a product seem typically to be high and the benefits low. Discouraging such announcements is

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46See the discussion of Proposition 6.4.
the danger that additional attention will lead to more suits. The benefits of such announcements seem less tangible and quite small by comparison: face saving, venting frustration, and seemingly minor effects on tort reform efforts. Thus, announcements attributing withdrawal to liability should be taken more seriously than the lack of them.

**Implications for Views of Decisionmaking.**

To evaluate proposals for policy reform, one must predict company decisions for liability environments that have never existed. Company behavior under the prevailing liability system contains useful information to the extent that it is revealing about decisionmaking in response to liability potential. What lessons can be drawn from the decisions reviewed thus far?

The Stakes: Direct and Indirect Liability Costs

*Proposition 6.3:* Many of the products whose withdrawals are typically linked to liability have experienced very large direct liability costs. The potential for future mass torts is apparent.

The most extreme example of liability cost is the Dalkon Shield. The direct costs involved more than 200,000 claims, various instances of punitive damages, and the bankruptcy of A. H. Robins. More than $2.5 billion were allocated in the bankruptcy reorganization to compensate injured users of the Dalkon Shield.48

The cases of DES and Bendectin are also generally considered mass torts, but they each involve only about one percent as many claims as the Dalkon Shield.49 The direct costs involved are not known; in the case of Bendectin, they are almost entirely defense costs. But no one disputes that they have been very substantial.

The Shiley heart valve is likely to be included in future lists of mass torts. Tens of thousands of anxiety cases now appear to be settled. Hundreds of anxiety cases are still pending in California. Future valve fractures may trigger more claims.

Mass torts may be emerging in the cases of the various breast implants. By early 1992, there were reports of 800 to 1,000 suits filed against various manufacturers,

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47 For example, by product users who had experienced injuries but had not considered that the injuries were linked to the product or had not considered it likely that a successful suit could be brought.

48 See, for example, Geyelin and Marcus (1990).

49 For example, Rheingold (1989, p. 15e) indicates there were roughly 210,000 Dalkon Shield claims and 2,000 claims for each of DES and Bendectin.
with about one-third involving Dow Corning Wright, the largest manufacturer. Some have suggested that the eventual liability of Dow Corning Wright could be over $1 billion.\footnote{For example, Redenstein (1992) suggests an eventual liability of $2 billion.} Some suits seek payments to allow removal of devices based on fears of health problems that have yet to materialize. Key aspects of the future litigation are the extent to which judges and juries will find links to various ailments alleged to have been caused by the implants, whether silicone leakage is considered a manufacturing defect, whether comment k is accepted as applicable to a medical device that does not involve lifesaving, and what the company knew or should have known about the risks involved.

Proposition 6.3 highlights the fact that liability can provide enormous financial incentives to change behavior. Direct liability costs can be much larger than lost profits from the product and represent a financial threat much larger than any penalties that may be imposed by the FDA.\footnote{Forcing product withdrawal seems often to be the most costly financial penalty that can be imposed by the government. For example, Galen (1992, p. 36) reports that the fines on Dow Corning Wright for various alleged violations involving the silicone-gel implants could be as high as (only) $1 million.} But the possibility of criminal sanctions may also have major effects on company behavior even in the absence of a product liability system.\footnote{Criminal charges for regulatory violations seem rare but are not unheard of. See, for example, The Wall Street Journal (1985) and Koenig (1984).}

The record also suggests that very large liability costs can fall on companies that comply with FDA regulations, even for products that many experts contend are socially valuable. The obvious example in this regard is Bendectin. Whether other products that are widely believed to be socially valuable—e.g., DTP vaccines and some IUDs—have incurred liability costs nearly as large as those of Bendectin is unclear. Such a possibility can create enormous uncertainty for companies no matter how responsible their behavior.\footnote{It is difficult to assess the extent to which the liability environment has become less threatening to socially valuable products since the early 1980s. While Henderson and Eisenberg (1990) provide evidence suggesting such a turn of events in the context of product liability generally, they acknowledge failure-to-warn cases as a major exception to the pattern they find.} Moreover, these events are repeatedly recounted by advocates of tort reform, and the resulting attention to them suggests long-lived effects on perceptions of company decisionmakers.

Proposition 6.4: Indirect liability costs—operating through reactions of the FDA, physicians, patients, attorneys, and insurers—can also be very costly to a company.

Various products exemplify the phenomenon of indirect liability costs discussed in Section 4. These include silicone-gel breast implants and the Dalkon Shield.
In January 1992, the FDA requested a moratorium on use of silicone-gel implants while its advisory panel considered the safety of the devices and formulated recommendations. The panel concluded that the safety of the devices was in doubt and recommended limiting their use until an informed conclusion could be reached. In April 1992, the FDA essentially adopted the panel’s recommendation, limiting use of the devices to patients requiring reconstructive surgery—they will be available to others only as part of clinical trials. It seems clear that product liability activities played an important role in triggering FDA action. One apparent mechanism is the publicity generated by the large jury awards in 1991. Another is that a former employee of the leading manufacturer—serving as an expert witness for plaintiffs—provided a list of documents to the FDA and Congress, and this reportedly “prompted FDA to act.”

It is often suggested that the Dalkon Shield episode had far-reaching effects on other products. For example, many attorneys who became experienced with IUD litigation in Dalkon Shield cases later brought suits against other IUDs, particularly the Copper-7. Moreover, the availability heuristic (of the psychology literature) suggests the financial proportions of the Dalkon Shield episode may have made liability threats to company viability considerably more salient to decisionmakers.

Liability suits against Bendectin are likely to have been part of the impetus for FDA hearings on the product. The hearings led to stronger warnings and generated considerable publicity, but the FDA did not require removal of Bendectin from the market.

The behavior of physicians and patients is less visible than that of the FDA. But the cases in which lost sales seem reasonably attributed in part to publicity related to liability actions are the DTP vaccine, Bendectin, silicone-gel breast implants, and IUDs.

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54 Seligman (1992a).
55 Cummins (1992b).
56 Smart (1992).
57 See, for example, Rust (1986).
59 Nazario (1995) reports that preschool immunization rates for pertussis were falling toward 80 percent, largely because of concerns about the safety of the vaccine. The Wall Street Journal (1983) reported that negative publicity had taken a substantial toll on Bendectin sales. On the decline in sales of breast implants, see Seligman (1992b). Roan (1993) reported that publicity about the Dalkon Shield continued to discourage women from using IUDs even in mid-1993. An additional example is Prozac, which is discussed in the next subsection.
Differences Across Products. Recapping, major direct liability costs were apparent at the time of withdrawal for most of the withdrawn products reviewed, and major indirect liability costs were apparent for many of them. It has been argued that some drugs and devices involve much more substantial liability potential than others. What do the cases reviewed here reveal about this issue and associated perceptions of decisionmakers?

Proposition 6.5: *Ability eventually to defend suits successfully does not preclude liability costs large enough to trigger product withdrawal.*

Even successfully defending suits can be very costly. The Copper-7 and Bendectin provide examples. At the time the Copper-7 was withdrawn, eleven trials had been held, and the defendant had won in nine of these.60 As for Bendectin, Marshall (1993, p. 590) reports that according to a company lawyer, "... of about 2000 suits filed against the company ... so far only one has resulted in an unfavorable jury verdict, sustained on appeal. Most have been dismissed ... no damages have been paid as yet." Nonetheless, the insurance and litigation costs and the prospects of losing at least some fraction of the cases were apparently more than sufficient to make withdrawal of the product the rational response for the company.

Proposition 6.6: *Withdrawals of products with substantial support in the medical community reproduce the stereotype of products subject to unusual liability potential: vaccines, contraceptives, and products for conditions specific to pregnancy. These and other common characteristics of these episodes provide insight into sources of perceptions about liability potential.*

That attention focuses so heavily on such products provides a basis for probing and extending our view of perception formation. The stereotype is not a complete list of the types of products that have experienced large liability costs. What might account for their apparent dominance of perceptions? Answers to this question provide insight into the crucial—but inevitably murky—issue of the perceptions of actual decisionmakers.

To be convincing, a proposed explanation for the stereotype should involve the availability heuristic discussed in Section 5 and appeal to factors common to the three product areas and largely unique to them. Four such commonalities are apparent:

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60Rust (1986, p. 1).
• Liability is believed to have driven from the market products with substantial support in the medical community. 61

• Prominent withdrawals were accompanied by public statements pointing to liability. 62

• Availability crises were associated with liability. 63

• Trial outcomes for plaintiffs became causes célèbres of advocates of tort reform. 64

These commonalities appear to be closely related: Medically unimportant products seem unlikely to be withdrawn with public announcements; their lack of availability does not cause a sense of crisis; and findings of liability against them do not provide powerful ammunition for tort-reform advocates.

Finally, while trial awards of punitive damages are not unique to the stereotypical products, products in all three categories have involved such awards. Punitive awards against Bendectin, the oral polio vaccine, and an oral contraceptive were reported in Section 4. There has also been at least one punitive damage award against the Copper-7 intrauterine device. 65

Proposition 5.7: The extent to which perceptions of decisionmakers go beyond the stereotypes is unclear, but factors that seem likely to be widely appreciated are widespread use, patients evoking unusual sympathy, and background injury rates.

The Bendectin episode may be very influential in this regard. With over thirty million infants exposed to the product in utero, and a background rate of serious birth defects of perhaps 3 percent, it seems that Bendectin's potential liability was enormous. 66 Almost one million babies born to mothers who used Bendectin would be expected to have had serious birth defects even if Bendectin had no

61Recall that they are the three examples cited by the AMA in Weaver (1988).

62Wyeth's DTP vaccine, the Copper-7, and Bendectin—perhaps the only examples of such announcements.

63DTP, IUDs, and Bendectin.

64Examples are discussed in Section 4: the landmark exceptions to the learned intermediary rule for vaccines and oral contraceptives; the Johnson polio vaccine case; findings of causation of birth defects by Bendectin and the spermicide in the Wells case. In addition, DES—a product to prevent miscarriage—involves highly publicized and controversial legal decisions involving liability for latent injuries and proportionate or market-share liability. (For example, Simond v. Abbott Laboratories; see Section 4.)

65Kawakami v. C.D. Sante & Co., 707 F. Supp. 1317 (D. Minn. 1989), “the first case of punitive damages ($7 million) awarded against a manufacturer of an FDA-approved IUD.” (Mastroianni et al., 1990, p. 132.) This case was subsequently settled while an appeal was pending.

66The numbers used here are from Lasagna (1991, p. 339), which indicates that roughly 3 percent of infants are born with some malformation. See also Sanders (1992, p. 367, in. 278).
such effect. The arithmetic of Bendectin and the availability heuristic provide considerable support for the widespread notion that products to treat conditions specific to pregnancy are enormously risky from a liability point of view.

**Could Liability Have Caused Withdrawals Escaping Public Attention?**

The apparent, potential examples of liability-induced reductions in product availability have been reviewed. But a fundamental issue remains: Are these cases likely to provide a largely complete and accurate picture of the effects of liability on product availability? If not, are unobserved reductions in availability more likely to involve socially valuable products or the opposite? This subsubsection considers withdrawals and the next considers failures to introduce a product.

*Proposition 6.8:* Liability may play a substantial role in a product withdrawal without triggering a public perception of that fact.

Our view of decision making implies that companies withdraw products because of liability only if the threat is perceived be sufficiently large in relation to the profitability of the product. The withdrawals that have been discussed involved substantial and mounting liability costs. If a product is withdrawn under these circumstances, it is unlikely to escape public notice.

However, perceptions of substantial liability potential can develop without already-substantial liability costs. Perceived changes in the liability environment or in the cost of liability insurance could lead to such perceptions. For example, outcomes in trials involving other companies can signal changes in doctrine—such as the vaccine and contraceptive exceptions to the learned intermediary rule. These could lead to major changes in perceptions of liability potential for products yet to experience many claims.

It does not seem safe to presume that, whenever such perceptions develop and lead to product withdrawal, this will become public knowledge. Recall that companies withdrawing a product because of liability might often find it preferable not to call attention to that fact. Thus, we should not presume that companies will typically call attention to the kinds of situations we seek to identify.

*Proposition 6.9:* Except for some products involving long-term, latent injuries, all socially important product withdrawals are likely to be publicly visible.
The withdrawal of a medical product of major social value would not escape the attention of medical professionals. Moreover, given the energy with which advocates of tort reform seek evidence to bolster their cause, it is unlikely that such a case would go unpublicized. For example, it is hard to imagine that an AMA report advocating tort reform (such as Weaver [1988]) would fail to identify such a case.

Similarly, liability-induced withdrawal of a particularly hazardous product is likely to attract public notice if the injuries attributable to the product have already materialized. Here, both the FDA and opponents of tort reform can be expected to contribute to a public awareness of the hazards associated with the product. It seems safe to conclude that large numbers of deaths or very serious injuries would eventually trigger FDA action.

By the process of elimination, we are left with three types of products that might be withdrawn because of liability without generating public awareness: (a) products without major social value, (b) products without major hazards, and (c) products with major hazards in the form of latent injuries that have yet to emerge. The last possibility may involve major or minor social consequences. A plausible scenario, it seems, is a company discovering a reason to fear latent injuries and withdrawing the product without reporting its concerns publicly.

**Could Liability Have Prevented Product Introductions Without a Public Awareness of This Effect?**

In Section 4, we reported that the liability system provides strong incentives to comply with existing FDA safety standards. For example, a company that ignores a safety problem suggested by clinical tests or fails to report it to the FDA in its application for marketing could find itself with very serious liability problems as a result. Because of such incentives, a company may choose not to apply for marketing approval for an existing product or may decide to report such a problem, with the result that the FDA would fail to approve the product.

Such effects of liability cannot be observed, but neither can they be dismissed. Even with the threat of large liability penalties for doing so, some companies seem to ignore evidence of safety problems or fail to report it to the FDA. While perhaps only a minority of companies might consider such behavior, it is at least

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67 The market provides incentives for regulatory compliance—incentives that may be very powerful in at least some instances. See, for example, Jarrell and Peltzman (1985), who study the effects of product recalls in drugs and automobiles on the value of a company's stock.
plausible that liability has prevented others from doing so, with the result of preventing existing products from reaching the market.

**Marketing Despite Substantial Liability Potential**

Discussions of the effects of product liability on product availability almost always focus on lack of availability. To some extent, this reflects the fact that lack of availability is perceived as a problem. But if we want to understand availability decisions, we must understand decisions to market products that appear to pose substantial liability risks.68

**Behavior Within the Prevailing Liability Environment**

Company Actions to Mitigate Liability Potential. Here we consider oral contraceptives and five other products—manufactured by five different companies—embroiled in quite recent controversies: Accutane, Cytotec, Clozril, Halcion, and Prozac. These cases attest to the willingness of companies to accept substantial liability risks if there is sufficient profit potential and illustrate steps that might be taken to mitigate safety and liability risks when a legally hazardous product is marketed.

Product liability has not caused an availability problem for oral contraceptives, despite apparently extensive liability actions—some of them very prominent and very costly to companies.69 Mastroianni et al. (1990, p. 122) report that seven companies market oral contraceptives in the United States, explaining: “Despite litigation costs, these products continue to be profitable because the market is relatively large and the monthly cost of the pills is high.”70 The package inserts for oral contraceptives are especially extensive. It is unclear whether liability litigation has triggered product withdrawals, but it is quite clear that there has been no availability crisis for oral contraceptives.

Two other products—Accutane and Cytotec—are known to be particularly hazardous if used by pregnant women. Both appear to be uniquely effective treatments for serious conditions, and for that reason were approved by the FDA despite their hazards.

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68 Unlike most other discussions of liability effects, Swain (1991) does consider products that are marketed despite major liability threats.
69 See Mastroianni et al. (1990, pp. 126–135).
70 The U.S. market for oral contraceptives may exceed $1.5 billion annually. (Schrage, 1992.) Abelson (1990) reports a figure of $900 million.
**Accutane** was approved by the FDA in 1982—despite acknowledged links to birth defects—for treatment of a particularly severe form of acne in patients who do not respond to the other treatments.\(^{71}\) Subsequently, an FDA study estimated that by 1986 as many as 1,300 birth defects in the United States had been caused by use of this drug. Its manufacturer—Hoffmann-La Roche—has continued to market the product, but has also taken extensive, unusual steps to prevent birth defects, steps that may also be very effective in protecting the company from liability.\(^{72}\) These include a reminder to avoid pregnancy on each capsule of the product; eight separate criteria for prescribing; a requirement that a negative pregnancy test result be obtained within the two weeks before starting use of the drug; required consent forms for both patients and physicians; and educational material and a test that the patient must take prior to prescribing.

**Cytotec** has been marketed in the United States since 1989.\(^{73}\) It is the first product approved by the FDA for the prevention of ulcers in high-risk patients taking nonsteroidal anti-inflammatory drugs—such as aspirin and ibuprofen. However, as detailed on the package insert, it causes miscarriage in about 11 percent of pregnant users and abnormal bleeding in about another 40 percent. The package insert includes a boxed warning about the dangers of pregnancy for product users, and patients also receive written warnings.\(^{74}\) The prescribing instructions require that patients test negative for pregnancy and specify other criteria, such as the ability to practice effective birth control.

**Clozaril** was introduced in the United States in February 1990.\(^{75}\) It is widely acknowledged as a significant advance in treatment for schizophrenics. But the drug has potentially fatal side effects for roughly 2 percent of patients—effects that can be reversed if detected sufficiently quickly. Because of this risk, the company that markets it—Sandoz—established a U.S. distribution system in which patients were required to submit a blood sample every week to get a week’s supply of the drug—a requirement that is not used abroad. The company attributed the policy to various considerations, including liability concerns.\(^{76}\)

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\(^{71}\) Accutane is discussed by Shulman (1989), on which the discussion here is based.

\(^{72}\) It is unclear which of these actions would have been taken by the company without the influence of the FDA.

\(^{73}\) The discussion of Cytotec is based on Kolata (1988) and the package insert for Cytotec in the 1990 *Physicians’ Desk Reference*.

\(^{74}\) It is unclear to what extent these steps are attributable to the FDA. There is some indication that the company (C.D. Searle) sought to warn more strictly than was viewed appropriate by an FDA advisory committee. (See Kolata, 1988.)

\(^{75}\) This account of Clozaril is based on Wieslow (1990a, 1990b, 1991).

\(^{76}\) Other considerations cited by the company were: its concern for patients and their need for drug—the company has reported that, if a number of deaths were to occur, it would feel compelled to withdraw the drug; the company’s desire and ability to meet higher safety standards in the United States than it does abroad; and price controls and other policies abroad.
The price of the original program—roughly $9,000 per patient annually—led to intense pressure on the company to change the marketing system. By early 1991, the company relented and substituted other stringent safeguards.

Finally, two widely used products that lead their product classes in U.S. sales continue to be marketed despite substantial liability risks. These products—Halcion and Prozac—involves ongoing, heated disputes about their safety and the emergence of numerous lawsuits.

Halcion was approved by FDA in 1982. It is the most widely prescribed sleeping pill in the United States, with annual sales of about $100 million. But there is a history of reports of various troublesome behaviors among Halcion users, including personality changes and aggression. The most widely known Halcion case involved a woman cleared in 1989 of a murder charge on the basis that she acted involuntarily under the influence of the drug. In the course of her subsequent liability suit information was found that led to the FDA reconsideration of Halcion. In May 1992, an FDA advisory panel recommended that it be allowed to remain on the market with strengthened warnings.

Prozac, the leading antidepressant drug in the United States, was introduced in late 1987. By 1990, its annual sales had reached over $750 million and were expected to reach $1 billion in 1991. During 1990 and 1991, between one-half million and one million Prozac prescriptions were being written each month. But by early 1991, this blockbuster had also become the target of more than 50 liability suits claiming that it causes users to engage in violent behavior, including suicide and murder. With a very substantial background rate of suicide among potential product users, the arithmetic of Prozac is reminiscent of that of Bendectin. But Prozac’s manufacturer—Eli Lilly—has continued to market Prozac, which accounts for roughly 25 percent of its total sales. It has announced that it will not settle any cases, and—in an effort to bolster sales threatened by extensive publicity—has offered to indemnify physicians facing

77 Unless otherwise indicated, information reported on Halcion can be found in Cowley (1991b, 1991c, 1992).
78 Including indication that the application for marketing approval was misleading.
79 Information about Prozac presented here can be found in Waldholz (1990), Marcus (1991), or Cowley (1991a) unless otherwise indicated.
80 Fully 15 percent of all clinically depressed patients end up taking their own lives. (Cowley, 1991a, pp. 65–66.)
malpractice claims associated with Prozac\textsuperscript{81} and has mounted a vigorous public
defense of the product.\textsuperscript{82}

Withdrawals of Only Some Producers. In some cases, some manufacturers of a
type of product withdraw from the market because of liability, and others
remain. Examples include IUDs, DTP vaccines, and silicone-gel breast implants.
It is instructive to consider both causes and effects of the withdrawal of only
some producers. Consequences of such a reduction in competition may include
price increases; these are considered in Section 7.

As for causes, first consider that in principle some companies may withdraw and
others remain even if all were otherwise identical. Suppose a number of identical
companies were to perceive large identical increases in liability potential in a
market that was not very profitable. Absent some economic adjustment, these
changes in perceptions would make participation in the market unattractive to all
of them. One possible adjustment is that a subset withdraws from the market,
reducing competition, thereby making the market sufficiently attractive for the
others to be willing to remain.

But firms are not identical, and various differences across firms might explain
which withdraw and which remain. These include differences across companies
in the extent of the liability threat, perception of the liability threat, profitability
of the product, and how withdrawal affects the chances of achieving company
aspirations. These are discussed below in turn.

The extent of the liability threat can vary across companies marketing products
of the same type for several reasons. One is differences in product safety: For
example, injury rates may vary considerably for different DTP vaccines, different
IUDs, or different breast implants. Second, even if injury rates are the same,
liability threats can vary, because companies with more assets (i.e., “deeper
pockets”) can be more attractive litigation targets.\textsuperscript{83} Third, companies of very
different sizes can have similar profit prospects in particular product areas, but
smaller companies have less to lose, because the possibility of bankruptcy limits
liability risk. For example, in the case of a company with only one product.

\textsuperscript{81}Hersh (1991), Preuss (1991). The offer extends to physicians who prescribed Prozac in
accordance with FDA regulations and the product labeling.

\textsuperscript{82}Blum (1991).

\textsuperscript{83}For example, Alza has not had major liability problems. Alza’s apparent response to the
liability environment was to strengthen its informed consent procedure (Los Angeles Times, 1986) and
to resist the temptation to expand production (Gladwell, 1988). Abelson (1990) reports: “Alza and its
liability insurers have paid out total claims for its products, including its IUD, of less than $250,000 in
the last twelve years.” The hypothesis that smaller companies have advantages over larger ones in
coping with liability is explored empirically by Eingleb and Wiggins (1990) in the context of
industrial safety.
product withdrawal and bankruptcy may involve similar losses. Fourth, more-diversified companies may have more to lose in other product areas from publicity surrounding products subject to liability suits. Finally, a company's vulnerability to suit also depends on its ability to demonstrate compliance with FDA regulations, which can also vary from instance to instance.

Even if liability threats are equal, there may be major differences in perception of liability potential, because different companies have different information. As suggested in Section 5, companies may be expected to rely heavily on their own experiences in forming perceptions. Since liability can impose a handful of extremely bad outcomes even when a company prevails in most cases, one might expect that companies that have had worse liability experience to date are more likely to withdraw. Yet another consideration points in the same direction. Recall from Section 5 that decisionmakers are much less comfortable with uncontrollable "gambles" than "risks." Those companies that have experienced particularly bad liability outcomes may tend to view the liability environment as less controllable—and therefore more threatening—than those who have not.84

In addition, companies remaining in the market might have market advantages over ones that withdraw. If the product is more profitable for a particular company, all other things being equal, it is less likely to withdraw from the market. This possibility cannot be assessed empirically, because profitability figures for individual products are unavailable.

Finally, companies that remain may be those that cannot achieve their aspirations or target levels of earnings if they withdraw. For example, large, diversified companies for which IUDs and breast implants were of minor significance withdrew, and smaller, more specialized companies remained.85 Such a tendency for smaller, more specialized companies to remain and larger, more diversified companies to withdraw86 might be better explained, however, by the differences in potential liability costs discussed above.

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84 This seems more plausible in light of psychology literature suggesting that people who have not been victimized tend to think they are less vulnerable than others. See, for example, Perloff and Fetzer (1986).

85 When Searle withdrew its IUDs, Alza had roughly 10 percent of the U.S. market. (Hamilton, 1986.) The largest company in the silicone gel breast implant business had been Dow Corning Wright, for which breast implants represented less than 1 percent of sales. (Galen, 1992.) Bristol Meyers Squibb—a large pharmaceutical company—withdraw the Mammam implant, but this may be explained by an additional liability hazard associated with its foam cover. The two companies still selling silicone gel implants are Mentor Corporation and McGhan Medical Corporation. (Climon, 1992d.) Both are relatively small, with 1990 sales of less than $100 million and $200 million, respectively. (Dun and Bradstreet, Market Identifiers Database).

86 This is not a universal pattern; for example, the largest U.S. pharmaceutical company—Merck—which is also highly diversified, remains in the vaccine business.
Consider an effect of the tendency for large firms to withdraw and smaller firms to remain. Drugs and devices can involve potential for serious, mass injuries. The ability of the liability system to provide compensation for injuries is limited by the wealth of the company marketing a product. Thus, while willingness of small companies to market products involving substantial liability potential may play an important role in mitigating availability crises, another result is that substantially less injury insurance is bundled with the product.

Entry into Markets with Earlier Withdrawals. Companies may also enter markets that have apparently experienced availability crises due to liability. This suggests that markets are more resilient than commentaries tend to suggest in the midst of crises.

In 1988, GynoPharma—a small company specializing in contraceptive and gynecological products—introduced an IUD. There are two IUDs available in the United States today, both marketed by small companies. Apparently, GynoPharma has had no major liability problems. GynoPharma's entry may be part of a process by which markets for products with especially large liability risks adjust to be served by smaller, specialized companies.

Reviews of the Physicians' Desk Reference and corporate annual reports indicate that new vaccines for type b (Hib) meningitis were introduced by both Merck and Lederle in 1990, and both are approved for infants of two months and older. In addition, vaccines have been introduced for hepatitis B. Finally, there is indication that at least one major company that has not been marketing DTP is involved in a joint venture to market its vaccines in combination with DTP produced by another company. This possibility may be attributable both to the market advantages available to companies providing supershots and the effects of the National Childhood Vaccine Injury Act on the liability environment.

However, there is reason to doubt that all availability crises disappear given enough time. For example, there is no apparent indication that any company is interested in marketing a treatment for morning sickness or to prevent miscarriage.

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89. Abelson (1990, p. 268) reports: "GynoPharma hasn't had any claims," and Roan (1990) reports that no suits had been filed against GynoPharma's IUD as of mid-1990.
90. Merck's Recombivax HB, SmithKline Beecham's Engenix-B.
91. Merck and Corvantaed are pursuing a joint venture to combine some of their vaccines (Merck's hepatitis B and Corvantaed's DTP) and are attempting to develop a "super shot" that would combine vaccines for six or more diseases. (Zonana, 1991.)
Implications for Decisionmaking

These observations about products marketed despite substantial liability potential fortify and extend our views about decisionmaking. Most important, the willingness of companies to market some products with substantial liability potential supports the view that liability is weighed against potential profits in making availability decisions. Observed changes in the composition of producers are consistent with the view that liability risks are more likely to be taken if company aspirations cannot be achieved otherwise. But a rival explanation is at least as plausible: For a given product, smaller, less specialized companies face lesser liability threats. Finally, various measures taken to reduce liability potential illustrate the importance of risk-mitigation responses to liability.

Conclusion

Within plausible alternative liability environments, some withdrawn products might well have remained on the market. The least equivocal examples involve products with substantial support in the medical community that faced numerous liability claims and suits before withdrawal. Withdrawn products that did not enjoy such support might well have been weeded out—albeit more slowly—by market and regulatory forces even if there were no product liability system at all and if market and regulatory institutions were the same as in the prevailing environment.

Some products continue to be marketed despite substantial liability potential. Various extensive efforts to mitigate liability potential are involved. Only time will tell whether these measures will prevent liability potential from becoming liability problems large enough to trigger product withdrawals.

Liability can in principle affect the availability of existing products in publicly invisible ways. But if a product is especially valuable or especially dangerous, its withdrawal is unlikely to escape public notice. If a link between such a withdrawal and liability is plausible, this is unlikely to go unreported. The most plausible qualification is the possibility of a product being withdrawn before its potential for mass, latent injury is publicly recognized. Liability might also prevent existing products from reaching the market without public awareness. The most plausible mechanism here is deterrence of decisions to ignore safety problems or to conceal them from the FDA.

The difficulty of attributing observed behavior to liability and the possibility of unobserved responses imply that a reliable summary judgment about the net
social benefits of liability-induced changes in product availability is far out of reach. The analysis serves to narrow the plausible range and as a caution against oversimplifying.

The fact that some products are withdrawn in the presence of substantial liability potential and others are marketed despite such potential is comfortably explained by the view that companies weigh profit potential against liability potential. No product that is reasonably viewed as withdrawn because of liability seems to have been sufficiently profitable to cover liability costs of the magnitude that were being realized or could reasonably be anticipated at the time the product was withdrawn. Thus, these withdrawals might be rationalized simply by appeal to expected liability costs. But in each case, eventual liability costs were highly unpredictable, and extremely large liability costs were at least imaginable.

The behavioral model presented in Section 5 emphasized the distinction between risk mitigation and risk taking. Product withdrawal is an extreme and visible form of risk mitigation. But when a legally hazardous product is not withdrawn, there are various, albeit less extreme, responses that serve to reduce liability risk.

This section has focused on several aspects of the availability of existing products. There are additional ways that liability can affect what products are available to U.S. patients. Specifically, Section 9 considers how liability might eliminate products, including ones of major social consequence, by deterring their development.
7. Product Liability and Product Pricing

Companies often claim that liability costs must ultimately be passed on to consumers in the form of higher product prices, so companies do not bear the costs of liability—their customers do. In judicial opinions and scholarly analyses, it is also often presumed or predicted that liability costs are passed on to consumers. While liability-induced price increases would reduce the affordability of health care, such price increases are viewed in many discussions as also serving two socially useful functions: providing a pool of funds that can be used to compensate injured product users and providing price signals that guide consumers to more appropriate purchase decisions.

Does liability, in fact, affect the prices of pharmaceuticals and medical devices? If so, under what circumstances, and to what extent? What are the mechanisms by which this occurs, and what can we learn from them? Are price increases due to liability likely to provide roughly enough money to fund a compensation program? Would such price increases help consumers make more appropriate purchase decisions? These questions are considered here.

Price Effects of Substantial Liability Potential

The following conclusion is suggested by a record of product price changes coincident with major liability events affecting those products:

*Proposition 7.1:* Substantial increases in the perceived liability potential for a product can cause major increases in its price. Substantial decreases in perceived liability can lead to price declines.

For example, upon the withdrawal of Searle on January 31, 1986, Alza found itself to be the sole U.S. supplier of intrauterine devices. By April, the price of its IUD—which needed to be replaced annually—had increased from $38 to $84.

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1A statistical approach to estimating price effects would be preferable if it were feasible. This might entail a multivariate analysis of data on prices of many products, incorporating measures of factors believed to play major roles in pricing and measures of perceived liability potential. However, for many product prices, liability effects are subtle, and our ability to measure the factors driving pricing—e.g., demand conditions, production costs, strategic, political and goodwill considerations, expected liability costs and perceived liability risks—is extremely limited. Caves, Whiston, and Furwicz (1991) exemplify the state of the art in studying pricing in pharmaceuticals, and the difficulties they acknowledge (e.g., p. 3) are especially discouraging in the present context.
"largely in response to the litigation prone market." Also, at the time that Bendectin was withdrawn from the market, its price had reportedly increased by about 250 percent in response to growing legal costs.

The history of prices of childhood vaccines over the past 15 years is of particular interest. Like the cases just discussed, this history illustrates how prices may rise in response to a dramatic increase in perceived liability potential. But it also illustrates the potential for prices to fall in response to a perceived decrease in liability potential.

Annual data on price per dose for childhood vaccines from 1977 to 1992 summarize this history. The vaccines are combined diphtheria, tetanus, pertussis (DTP); oral polio vaccine (OPV); combined measles, mumps, rubella (MMR); and combined diphtheria, tetanus (DT). There are two price series for each vaccine, corresponding to two different conditions under which vaccines are sold. Roughly 50 percent of childhood vaccines are purchased by the CDC under contract for use in state immunization programs. "Contract" price data are, for the most part, prices under such federal contracts. "Catalog" prices pertain to sales to private parties (e.g., physicians), as listed in price catalogs.

The major patterns are easily seen graphically after adjusting for inflation to express them in 1983 dollars per dose. Figure 7.1 shows real prices for the DTP vaccine from 1977 to 1991. These prices were virtually constant in real terms for the early part of the period, but increased very rapidly starting in the mid-1980s. The catalog price of DTP increased substantially every year from 1983 to 1986—the year this price peaked—increasing roughly tenfold in three years. Contract prices for DTP followed a similar pattern. Real prices of DTP vaccine have fallen since 1988.

Figure 7.2 compares the catalog price series for DTP with that for DT—the DTP vaccine without the pertussis component. The real price of DT vaccine barely increased during the 15-year period. While the DTP vaccine was priced lower
Figure 7.1—Real Prices per Dose of DTP Vaccine, 1977–1991 (1983 dollars)

Figure 7.2—Real Catalog Prices per Dose of DTP and DT Vaccine, 1977–1991 (1983 dollars)
than DT through 1983, this ordering was reversed over the next few years. By 1986, the price of DTP was almost 18 times as high as that for DT.

During the early 1980s, liability suits involving DTP became much more common, and the pertussis component was typically singled out as the cause of injury. Thus, the dramatic increase in the price of DTP—while the price of DT vaccine barely increased—occurred during a period of rapid and publicly visible increase in liability involving the pertussis vaccine. Perceived liability potential seems clearly to have played a role.

The recent histories of other childhood vaccine prices display similar, but less pronounced, patterns. Figure 7.3 shows that the catalog price of OPV increased dramatically over the period, with the rate of increase rising from the early 1980s and prices peaking in 1986 after two years of particularly sharp increases. The OPV contract price increased during the same period, but much less. Both price series have leveled off since peaking in 1986, but neither is clearly declining.

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9For example, Kolata (1986, p. 1339) reports that only one DTP suit was filed in 1978, but there were 73 in 1984 and 219 in 1985.

10See, for example, OTA (1993, p. 177).

11This suggestion is not novel. See, for example, Kolata (1986) and Iglehart (1987).

12Price developments since 1988 are discussed below.
Figure 7.4 shows that the prices for the MMR vaccine increased steadily but moderately through 1987, with an especially large increase in 1988. There has been a slight downward movement since then.

Here, liability may also have played a role. The earlier erosion of the learned intermediary defense for vaccines combined with the Johnson verdict in 1984 involving OPV—reviewed in Section 4 in the discussion of punitive damages—could be central factors. The fact that OPV prices rose substantially more rapidly than MMR prices in the few years following 1983 would be consistent with the view that this case was of particular importance. The increases in MMR prices might reflect a perception of an increased liability threat on the part of its only manufacturer, perhaps due to litigation involving this vaccine or others.\textsuperscript{13}

Thus, there have been a number of cases of large price increases within environments characterized by substantial and highly visible product liability actions. It seems reasonable to accept the widespread belief that major portions of these price increases are attributable to product liability.

\begin{figure}[h]
\centering
\includegraphics[width=\textwidth]{figure7.4.png}
\caption{Real Prices per Dose of MMR Vaccine, 1977–1991 (1983 dollars)}
\end{figure}

\textsuperscript{13}No specific information concerning liability actions involving the MMR vaccine—e.g., major awards, numbers of suits—appears to be available.
It is more difficult, however, to gauge the significance of these observations. After all, the examples may be available because they are atypical: They correspond to well-known, dramatic liability events and hence have generated public information about price developments. Thus, the implications of these observations for other cases of substantial liability potential are quite unclear, and the observations may tell us nothing about the effects of liability on pricing in cases involving substantially less liability potential. The latter are addressed later in this section. First various mechanisms by which liability can affect prices are considered.

**Ways in Which Substantial Liability Potential Can Affect Price**

Cost is a fundamental factor affecting price, and many of the effects of product liability on price operate through cost. However, the costs involved are subtle, and considerations other than cost must also be addressed. As emphasized in Sections 4 and 5, uncertainty and perceptions of the liability environment are fundamental to understanding decisionmaking. Section 3 pointed to factors other than cost that seem important in determining prices: the absence of vigorous price competition in many markets, the political salience of prices, and the effects of pricing on the goodwill of physicians and third-party payers. All of these factors come into play in this subsection.

**Effects Mediated Through Costs**

**The Irrelevance of Sunk Costs.** With prices of each product set to maximize profits, it follows that the costs that affect pricing of a particular unit of a particular product are the so-called economic costs of that unit: the costs incurred if that unit is made available for sale but not incurred otherwise. Costs incurred because units of a product were sold in the past cannot be avoided, are not economic costs of units yet to be sold, and hence do not directly affect profit-maximizing prices. This point is crucial for our purposes, but there seems to be some confusion about it in the product liability context. Some hypothetical examples clarify.

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14 Very little is known about the very sensitive issue of procedures used by drug and device companies to set prices. Much of the analysis here focuses on implications of assuming that prices are set to maximize expected profits with liability affecting price through expected liability costs and imputed costs of bearing liability risk.
Suppose first that a company is insured by a commercial carrier for product liability losses and that, for every additional unit of a particular product sold, they pay an additional $1 for liability coverage. This $1 would be properly viewed as part of the economic cost of future sales of the product and thus is directly relevant to pricing. Now suppose instead that a company is not insured for product liability but that decisionmakers perceive a cost of $1 per unit because there is additional liability cost potential whenever another unit is sold. This $1 per unit, although not an out-of-pocket cost, is also an economic cost of selling the product and is directly relevant to its pricing.

In contrast, suppose that a company estimates that it will make expenditures of $1 million this year to defend, settle, and pay awards for product liability for past sales of a particular product. Suppose that they expect to sell one million units of the product this year. This $1 per unit of the product is not an economic cost of future sales and is irrelevant to determining the most profitable price of future units of the product. This is because the current year’s liability expenditures result from suits for sales made in the past, cannot be affected by future sales decisions, and hence are not economic costs of future sales. Costs that are attributable to past actions—and which therefore can no longer be avoided—are often called sunk costs.

As discussed presently, what happens with suits this year as a result of past sales is relevant to predicting or estimating the liability costs associated with future sales, and this is relevant to pricing. But the distinction between sunk costs and predicted future costs is critical. For example, in popular discussions of liability and pricing, it is often suggested that if a firm is burdened with (say) a $5 million judgment, it will simply recover the money through higher prices of future sales. This makes no economic sense, because attempting to recover sunk costs in this fashion would conflict with the company’s fundamental goal of maximizing profits. In short, a company can be expected to absorb liability costs rather than passing them on to consumers when it is in its economic interest to do so.

Past Costs and Future Prices. Liability costs attributable to past sales can affect pricing indirectly if they affect some still avoidable liability costs, i.e., costs attributable to sales that have yet to be made.

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15 Although they may affect prices indirectly, as discussed below.

16 For example, it makes as much economic sense to suggest that the company will recover the sunk liability costs associated with one drug by increasing the price of some other drug. Consistent with this claim, in discussing the Bendectin withdrawal, The Wall Street Journal (1983) quotes a company spokesman as saying: “But we figured that we can’t raise the price of it any more . . . and we don’t want to raise prices on our other drugs [in response to Bendectin’s problems].” Presumably the company did not want to raise the price of other drugs because it was not in their profit interest to do so.
Proposition 7.2: Past liability expenditures related to a product can affect future pricing of that product indirectly by affecting its avoidable liability costs—for example, through effects on future litigation, insurance pricing, or perceptions of the liability cost potential of units of the product that have yet to be sold.

Past liability experience can affect litigation involving future sales and thereby the economic cost of future sales. For example, a highly publicized jury award can increase the likelihood of a suit by a patient injured by a future unit of the product, because such an award calls attention to the possibility of receiving compensation through the tort system. Such a mechanism can increase the liability cost of selling future units of the product, and therefore can increase the price of those units.

Past liability experience is used in pricing of liability insurance. As discussed above, a company that is insured for product liability can in principle avoid some insurance costs by marketing fewer units of the product. Thus, past liability costs can affect the costs of selling future units through the pricing of liability insurance. This is the second mechanism by which past liability costs can affect avoidable liability costs and, in turn, pricing.

It seems, however, that few (if any) companies are completely insured for product liability, and costs more subtle than insurance premiums are involved. As developed in Sections 4 and 5, the liability potential associated with a product encompasses expected liability costs, uncertainty about eventual liability costs, and liability risk. Most clearly, expected liability costs attributable to sales yet to be made are relevant to pricing decisions. In addition, for decisionmakers who dislike uncertainty or risk, these can affect pricing as well.

As discussed in Section 5, for products with substantial perceived liability risks, these risks are likely to be fundamental in decisionmaking. One way to see how substantial liability risks—as distinct from expected liability costs—might affect pricing is as follows. Suppose that a company imputes a cost to liability risks. The size of this imputed cost can be thought of as the maximum amount the company would be willing to pay for product liability insurance indemnifying it against liability costs in excess of expected liability costs.

Converting liability risk into cost terms allows us to use standard approaches to analyzing how cost affects price to analyze the effect of liability risk on price. For

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17 See Section 4

18 In both the context of expected utility maximization under risk aversion and the behavioral model of decisionmaking.
example, suppose that a company assesses an expected liability cost of $1 per unit of future product sold, but also perceives very substantial liability risk. It might, then, impute a cost of $10 per unit to this risk. Pricing decisions would proceed by combining a composite liability cost of $11 per unit (i.e., $1 per unit for the expected liability cost plus $10 per unit to account for liability risk) with other costs attributable to future sales.

Imputing a cost to liability risk underlies the final mechanism highlighted in Proposition 7.2. Specifically, if past liability expenditures change perceptions of the liability potential associated with units yet to be sold—expected liability costs, uncertainty, or risk—then past liability expenditures can affect pricing indirectly through this mechanism.

**Degree of Competition and the Effects of Costs.** But the pricing of many of the products of concern is not determined solely by costs.

*Proposition 7.3:* Changes in perceived liability cost cannot be inferred directly from price changes, because price does not equal cost in markets lacking strong price competition.

The sensitivity of price to cost depends on the market environment. According to standard economic theory, for markets with vigorous price competition, prices equal marginal cost. In such markets, product liability would increase prices by the same amount that it increased the unit costs perceived by firms. For the example above, if all companies had the same perceptions of the liability environment and attitudes toward liability risk, the price of the product would be $11 per unit higher because of liability. However, price competition is generally not strong in the markets of interest here. Under the imperfect competition characterizing these markets, price will exceed marginal cost, and generally will not change dollar for dollar with cost. In fact, prices might increase less than dollar for dollar or the opposite.

Consider the example of Bendectin, whose price is reported to have increased by 250 percent because of increases in liability potential. Under the inappropriate premise that the increase in price is equal to the increase in liability cost, one would infer that the liability costs—expected plus imputed for liability risk—were more than 70 percent of the product's price. But, according to a monopoly model of pricing, this could substantially underestimate or overestimate the perceived increase in per-unit liability cost driving this price increase.

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19 Imputed liability costs, being quite subjective, might differ greatly across companies. If so, in the presence of price competition, there would be a tendency for the companies imputing relatively high costs to withdraw from the market.
Price Effects Mediated Through Other Factors

Changes in the perceived liability potential of a product can affect prices through other mechanisms.

Proposition 7.4: Liability may affect product prices indirectly by causing changes in
(a) the degree of competition and (b) the political or goodwill
consequences of price changes.

The discussion in Section 3 emphasizes as factors affecting pricing the degree of
competition, political environment, and sensitivity of buyer goodwill to prices.
Section 6 discusses instances in which some producers of a product withdrew
and others remained and also that major liability costs often generate substantial
public awareness. These factors are relevant to interpreting price changes
associated with major changes in liability potential.

As the number of competitors decreases, all other things being equal, prices
would be expected to increase. If congressional and public awareness of major
liability costs associated with a product relieves companies of criticism and
pressure when its prices increase, prices would be expected to be higher than
otherwise. Finally, if physicians, third-party payers, and patients are aware of
unusual liability costs, prices can be raised at a smaller cost in goodwill. All of
these cases involve mechanisms for price increases triggered by liability, but they
are less direct than increases in price due to increases in perceived liability
potential. In all of them, the price increase is meaningfully attributed to liability.

But it is useful nonetheless to clarify the mechanism involved. Doing so can
forestall naive methods for estimating liability costs and clarify the potential
price effects of future market entry.

The case of IUDs illustrates both of these points. Observing the $46 price
increase for Alza’s IUD, some might infer that Alza’s perceived liability costs
increased by roughly this magnitude. But even if one interprets liability costs
broadly to include imputations for risk, that inference would be unwarranted,
because the price increase occurred after Alza had become a monopolist. (A year
earlier, it had roughly 10 percent of the U.S. IUD market and competed with two
major pharmaceutical companies.) If the withdrawal of the competing IUDs is
attributed to liability, the component of the price increase due to the attainment
of a monopoly position is attributable, albeit indirectly, to liability.

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This is likely to be more important for drugs than devices, because drug prices attract more
attention in political forums.
Considering the potential role of changes in the degree of competition also allows one to anticipate that entry of another competitor would tend to decrease prices, which would not be the case if price were equal to cost. Consistent with this suggestion, when GynoPharma entered the U.S. market for IUDs in 1988, its product—which could be used for four years—was priced at $140\textsuperscript{21}—less per year than Aiza’s price shortly after it became a monopolist.

The recent history of childhood vaccine pricing also illustrates these mechanisms. As evident from Figures 7.1 through 7.4, real prices rose substantially during the mid-1980s. As explained above, at least major portions of the increases in DTP prices may reasonably be ascribed to liability potential. But all of the indirect routes discussed above are plausibly involved as well.

Upon Wyeth’s withdrawal from the market in June 1984, the number of producers of DTP declined from three to two. Hence, some of the price increases in DTP might be attributable to a decrease in competition. In addition, if concerns about political backlash or buyer goodwill had been playing a role in restraining DTP prices, the liability events of the period may have weakened these forces; this, too, would tend to increase prices.\textsuperscript{22} While increases in perceived liability costs are likely to have played a role in price increases for the other childhood vaccines, decreasing political pressure or sensitivity of goodwill to price increases may have played a role here as well.

Effects on Prices of Other Products

Like our discussion up to this point, discussions of the effects of liability on price generally involve liability for a product and the price of that product. However, this view seems too narrow.

Proposition 7.5: Changes in the liability environment for some products can lead, through demand effects, to price changes for other products.

The pricing of saline-filled breast implants illustrates this possibility. The recent attention to breast implants—liability suits, media accounts, regulatory action—has centered on silicone-gel implants. Saline implants, on the other hand, are widely viewed as a safer alternative.\textsuperscript{23} There has been no indication of increases in insurance costs for saline implants or any other apparent reason to infer that


\textsuperscript{22}Politics might be especially important in the context of childhood vaccines, roughly 50 percent of which are purchased with public funds, and especially the contract prices.

\textsuperscript{23}Allegations of injury generally involve the health effects of silicone.
the perceived liability costs associated with saline implants have increased dramatically recently. 24 But by April 1992, the price of saline implants had increased by 50 percent in the wake of mounting liability costs for the silicone ones. 25 If these increases are viewed as out of line with increases in perceived liability costs 26 for the saline implants, another explanation is available: reduction in competition from silicone implants (upon withdrawal of Dow Corning Wright and Bioplasty).

Thus, in principle, when discussing the pricing effects of liability, analysis may not safely focus on products that appear to involve unusual liability costs or threats. In environments in which competition is too weak to keep prices in line with costs, liability developments concerning particular products can trigger forces affecting the prices of related products, even if these products do not involve substantial liability threats.

**Tort Reform and Pricing**

Vaccine prices provide the sole empirical basis for considering the effects of tort reform on pricing.

**Proposition 7.6:** Tort reforms with major implications for liability costs should affect pricing, but not dollar for dollar. Reforms using excise taxes on products to fund a compensation scheme—such as the National Childhood Vaccine Injury Act—should not be expected to raise product prices by amounts equal to the taxes.

Let us return to childhood vaccine pricing. Figures 7.1 through 7.4 indicate that real prices have leveled off or fallen since 1988. Consideration of NC VIA is helpful in interpreting these developments and drawing lessons about the pricing effects of tort reforms more generally.

Recall from Section 4 that, at the beginning of 1988, this program instituted excise taxes for each dose of the vaccines under consideration and also various measures designed to reduce the liability threat to their manufacturers. Marwick (1988) compares the changes in catalog prices for the childhood vaccines from 1987 to 1988 to the sizes of the excise taxes. He concludes that some manufacturers had passed on the entire tax in the form of price increases and

24 Although saline implants will—like other medical devices—be subjected to additional FDA attention in the future, and safety studies will be required. (Weber, 1992a.)
26 Skepticism that the price increases were driven by cost increases is evident from the title of Weber (1992a): “I Guess the Price of Salt Water is Going Up.”
others had not. But vaccine pricing is more complex than that, and considering these complexities is instructive.

Price increases equal to the amounts of the taxes would be expected if all other factors affecting price had remained constant and pricing were competitive.\textsuperscript{27} But all other things were not equal: NCVIA was expected—indeed, designed—to decrease company liability costs at the same time that it imposed the taxes. It is unclear how much liability relief the companies would have perceived in 1988. Moreover, pricing cannot reasonably be presumed to be competitive here, so the catalog (private sale) prices of the vaccines would—holding liability costs constant—have tended to increase by an amount different from the amount of the tax. However, the reduction in liability burden would tend to decrease price. It seems quite remarkable, then, that the price increases were approximately equal to the taxes: That would have required the price-reducing effect of decreased liability burden to offset exactly a tendency for the tax effect to exceed the level of the tax.\textsuperscript{28}

But there is a simpler and more plausible explanation. Suppose that, after NCVIA was implemented, the profit-maximizing prices in the absence of political and goodwill influences were higher than the 1987 prices plus the excise taxes. Then if politics and goodwill considerations were irrelevant to pricing, prices would have risen from 1987 to 1988 by more than the amount of the tax. It might very reasonably be supposed that increasing prices by up to the amount of the tax—just about what all manufacturers did—would not trigger political backlash\textsuperscript{29} or damage goodwill with physicians or third-party payers, but that exceeding this level would have been very costly in these regards.\textsuperscript{30} Then it is quite plausible that profit maximization would have required companies to limit their price increases to the amount of the tax.

\textsuperscript{27}Strictly, this would be the prediction in the short run only if demand were perfectly inelastic or marginal costs were constant in the relevant range of output.

\textsuperscript{28}Such a tendency is not implausible qualitatively. For example, in standard noncompetitive pricing models (e.g., monopoly), if marginal costs and price elasticities of demand are constant in the relevant range of outputs, the profit-maximizing price can be written as a multiple greater than one of marginal cost (e.g., Pindyck and Rubinfeld, 1992, p. 343). Price cannot generally be related so simply to marginal cost, but a relationship like that described holds at the margin in many noncompetitive models, including pure monopoly.

\textsuperscript{29}Political considerations might be especially salient here. Congress had just passed controversial legislation in response to the pleas of (among others) vaccine manufacturers that the liability burden was making the childhood vaccine business unprofitable. It is easy to imagine that subsequent price increases that were viewed as unreasonable might have unleashed considerable congressional ire.

\textsuperscript{30}Because politicians, physicians, and third-party payers think it quite reasonable for the tax to be "passed on."
Why have the childhood vaccine prices declined somewhat since 1988? One plausible explanation is related to perceptions of the effects of the NCVIA on the liability environment. In particular, perhaps the actual operation of the program and decreases in rates of private litigation have led the manufacturers to perceive that liability potential has indeed decreased. Alternatively, the companies may be responding—for political or goodwill reasons—to public perceptions that prices should fall as liability experiences improve.

**Price Effects of Insubstantial Liability Threats**

Since any drug can cause injury, and the same can be said for many devices, at least some liability costs may be expected for every drug and many devices. In principle, then, liability might be expected to lead to at least small increases in prices for most products. But some considerations suggest otherwise.

*Proposition 7.7: For many products, price effects of liability are likely to be nonexistent or very small.*

As discussed in Section 4, liability potential varies greatly across products. In Section 5, it was suggested that even moderate liability costs are likely to seem implausible for some products. Liability may be essentially irrelevant in pricing such drugs and devices. Products for which liability potential is not perceived to be substantial may include most products that do not fit the stereotypes of products that pose exceptional liability threats and that have not generated substantial litigation.

No empirical evidence is available on the liability effects on price for such products, but the foregoing analyses allow an educated guess. If the perceived liability costs for a product are small, these costs cannot have a substantial direct effect on price.\(^{31}\) Pricing of drugs and devices is often driven by strategic, political, and goodwill factors—subjective considerations all—and pricing often seems anything but precise. For many products, then, liability costs may not directly enter pricing decisions or may be a very minor consideration. The indirect routes through which liability can affect price also seem unimportant in these cases. Specifically, when perceived liability potential is not substantial,
liability would not be expected to cause producers to withdraw from the market or to attenuate any pressures for price restraint associated with politics or goodwill.

Social Functions of Liability-Related Price Increases

Price Premiums and Compensation Funds

Judicial opinions have noted the possibility that if liability costs are incorporated in price, purchasers of a product implicitly contribute to a fund from which they may be compensated if they are injured. From this perspective, liability-induced price increases may be an integral part of an implicit, socially useful insurance mechanism.

Proposition 7.8: Compensation funds implicitly created by liability-induced price premiums for products with substantial liability potential will often turn out to be either much larger or much smaller than actual liability costs. For products without substantial liability potential, these funds may often closely approximate actual liability costs.

First consider compensation funds on a product-specific basis. From Propositions 7.1 and 7.7, the large liability-induced price premiums predicted for products with substantial liability potential imply substantial funds, and the small or nonexistent premiums predicted for other products imply the opposite. Will these funds closely approximate eventual liability costs?

To answer that question, consider the predictability of eventual liability costs at the times that pricing decisions are made. In the cases of products marketed despite substantial liability potential, eventual liability costs are very unpredictable when pricing decisions are made, and the range of possible outcomes is very wide. Because of this, it would seem that only in rare cases

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32 For example, the opinion in Escudo v. Coca-Cola Bottling Company, 24 Cal. 2d 453, 462, 150 P.2d 436, 440-441 (1944) reads in part: "[T]he risk of injury can be insured by the manufacturer and distributed among the public as a cost of doing business..." (Fox and Traynor, 1991, pp. 8-9.) In Reyes v. Wyeth Laboratories, 498 F.2d 1264 (9th Cir. 1974), the court wrote: "Statistically predictable as are these rare cases of vaccine-induced polio, a strong argument can be advanced that the loss ought not lie where it falls (on the victim), but should be borne by the manufacturer as a foreseeable cost of doing business, and passed on to the public in the form of price increases to his customers." (OTA, 1979, p. 92.)

33 Priest (1987, p. 1525) writes: "The most fundamental of the conceptual foundations of our modern law is that the expansion of tort liability will lead to the provision of insurance along with the sale of the product or service itself, with a portion of the insurance premium passed along in the product or service price."

34 Vargas (1991b, pp. 75-81) critiques the idea of "The Producer as Insurer" in the general product liability context and more broadly than the issue addressed here.
would the additional revenues attributable to liability price premiums be close to the eventual liability costs.

For products whose liability potential is not thought substantial, price premiums are expected to be nonexistent or very small. When perceptions are accurate, eventual liability costs should also be quite small, so the implicit compensation funds should be roughly the right size. While it has been argued that some products may have much more liability potential than is commonly suggested, it is likely that most products do not have substantial liability potential. Thus, most very small implicit compensation funds are likely to be about the right size.

The fundamental problem in the case of products with substantial liability potential is familiar: Accumulated funds can be expected to approximate actual losses closely only when these losses are essentially predictable. When losses tend to average out over various unrelated risks combined in an insurance pool, predictability can be achieved. Here, however, product-specific liability costs are very unpredictable. Moreover, pooling across various company products is not sufficient to make liability costs predictable even for large, diversified companies. It is impossible to have a prospective funding mechanism that generally provides anything close to the quantity of funds that will eventually be needed to cover liability costs.

Since injury risk cannot be eliminated and since risk pooling is at best incomplete, someone must bear risk. It seems that patients and companies are left with considerable shares. Compensation for product injuries—through insurance and the tort system—is quite incomplete. Companies bear considerable liability risk for some products. Liability arrangements—and the market and regulatory rules accompanying them—affect both the amount of injury risk and who bears it.

If companies charge price premiums in excess of expected liability cost—as they would tend to, for example, if they impute costs to bearing liability risks—they may in fact be collecting substantial revenues in exchange for bearing substantial

\[35\] Indeed, the unpredictability and potentially enormous magnitudes of liability losses for drug companies may go a long way toward explaining the apparent prevalence of self-insurance for product liability. Even for commercial insurance companies—which can in principle pool risks across numerous firms in an industry and across numerous industries and countries—the averaging out of losses in pools including product liability for drug companies is not believed to be sufficient to reduce insurance rates with largely predictable risks. This risk leads them to set premiums that are higher than seem attractive to drug companies; hence, insurance contracts are not written. Among these lines, see Kunreuther (1989) for an analysis of the difficulties in setting insurance premiums for "ambiguous" risks, underwriter responses to these difficulties, and effects.

\[36\] An extreme case is one in which surprisingly large liability costs emerge, the product is withdrawn from the market, and liability costs mount for years thereafter.
risks. At the same time, the manufacturer would generally prefer that the risk did not exist and that the price were correspondingly lower.37

**Price Premiums and Purchase Decisions**

The law and economics literature adds the idea that liability-induced price increases may also help consumers make more appropriate consumption choices. For example, if consumers are ignorant of injury risks associated with a product, these risks cannot directly affect purchase decisions. If injury risks are not considered by consumers, economic efficiency is undermined. Suppose, however, that the expected injury cost associated with the product were incorporated in its price. Then, consumers would implicitly consider the safety costs and, all other things being equal, be less inclined to buy products with larger safety risks because of their higher prices. Through this mechanism, then, liability-induced price premiums may serve to deter product use in ways that contribute to economic efficiency.

However, various considerations work against placing much confidence in the effective operation of such a mechanism in the context of drugs and devices.

*Proposition 7.9:* Liability-induced price premiums may only very crudely serve economic efficiency by deterring the use of drugs and devices.

For liability-induced price premiums to correct inefficiencies in product-use decisions, two conditions must be satisfied: (a) The price premiums reflect the expected costs of injuries due to risks the purchaser does not perceive, and (b) purchasers bear the costs of the price premiums. Neither of these conditions seems well approximated in the context of drugs and devices.

Regarding the first condition, there are two basic sources of doubt. First, as discussed above, liability-induced price premiums may not accurately reflect the company's expected liability costs. Second, liability costs may not accurately reflect injury risks of which purchasers are unaware; for example, liability costs may result from injuries not caused by the product, and injuries caused by the product may not lead to liability costs.

Regarding the second condition, in many cases the party making the purchase decision is not responsible for paying the product price. With physicians viewed as making the purchase decision, it is doubtful that the price premium would effectively deter product use, because physicians are typically unlikely to be

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37While companies adjust to higher risks, they would generally prefer them to be smaller.
cognizant of or responsive to price. If the patient is viewed as making the purchase decision, but has insurance to reimburse some or all of the price, the deterrence mechanism under consideration is attenuated or eliminated.

**Conclusion**

In sum, it appears safe to conclude that, for products perceived to have very substantial liability potential, product prices are substantially higher because of liability. In these cases, price premiums for liability may often exceed the expected costs of liability to companies. Thus, in cases of substantial liability potential, companies may expect to collect more revenues from these price premiums than they will bear in liability costs. At the same time, companies bear very large liability risks. For products perceived to have liability potential that is not substantial, it is plausible that there are no substantial price effects of liability.

It seems implausible that price premiums due to liability effectively play the socially useful roles that are sometimes ascribed to them. The ability of price premiums accurately to fund a compensation scheme for substantial liability costs is undermined by the fundamental unpredictability of eventual liability costs. The ability of price premiums to guide purchasers implicitly to incorporate safety risks that they do not appreciate is undermined by many factors, including the lack of concordance between such safety risks and the costs of injuries for which companies are held liable, and the fact that many purchase decisions are made by individuals who are not responsible for paying the price.

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38 For example, see Temin (1980, pp. 102–119).

39 OTA (1993, p. 26) reports an estimate that, in 1987, 70 to 74 percent of Americans had some insurance coverage for outpatient prescription drugs.
8. Product Liability and the Safety and Effectiveness of Existing Drugs and Devices

The social value of drugs and devices results from their effectiveness in promoting the health or well-being of product users. Injuries from product use are among the major social costs of drugs and devices and are the fundamental economic rationale for product liability. Both present and future product safety and effectiveness are major policy concerns. Future safety and effectiveness depend on innovation, which is the subject of Section 9. This section considers existing products.

The previous two sections reviewed observable outcomes resulting directly from specific company decisions. In contrast, safety and effectiveness are not observable, and they are the indirect result of many decisions by companies, the FDA, physicians, and patients. Consequently, the analysis in this section is more intricate.

This section considers several company decisions determining intermediate outcomes affecting safety and effectiveness. Drug and device designs are an intermediate outcome influenced by many decisions within the product development process. Warnings to physicians and patients affect how many and which patients are treated with a particular product, how the product is used, and how many patients are helped or injured. Decisions about product promotion also play a role in determining safety and effectiveness. Product availability is revisited as well. For example, product withdrawal averts injuries, but also eliminates effectiveness.¹

As discussed in Section 2, the central issue is the extent to which product liability contributes to or detracts from the economic performance of the drug and device industries, or equivalently how liability affects economic efficiency. Changes in economic outcomes promote efficiency only if their benefits to society exceed their costs to society. For example, suppose that a particular aspect of the liability system leads to increases in product safety. The increases in safety are social benefits, and the benefits are greater the larger the increases in safety. But

¹In addition, product pricing affects safety and effectiveness by influencing use. This link is not emphasized.
increases in safety generally can be achieved only by devoting additional economic resources to that end. The value of the resources used up in increasing safety represents a social cost of additional safety. In addition, many increases in safety are accompanied by decreases in effectiveness. In these instances, the social costs of additional safety also include the social value of the effectiveness lost as a result of the safety increase. Some increases in safety are efficient—that is, their benefits exceed their costs—and others are not.

Assessing the safety and effectiveness effects of liability and their costs and benefits requires an indirect approach: Safety and effectiveness are unobservable, and their benefits and costs are impossible to quantify with any precision. The approach here uses FDA policy as a benchmark. Three premises motivate the approach. First, the FDA has substantial influence over the relevant decisions. Second, FDA policy is influential in liability litigation. Third, FDA policies can be characterized—albeit incompletely—in terms of economic efficiency.

The analysis is structured as follows. The next subsection considers how product liability alters company incentives created by FDA policy and considers the efficiency of FDA safety standards for different classes of products. Whether a company alters its behavior in response to liability incentives depends on the profitability of doing so, and the subsequent three subsections consider such questions for three sets of decisions: design and testing, information provision through labeling and promotion, and product availability. The last subsection draws together conclusions from preceding subsections to assess the likely effects of product liability on safety and effectiveness and on economic efficiency. A fundamental conclusion is that these effects are likely to be quite different across three broad product groupings: drugs, extensively regulated devices, and other devices.

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2 For example, resources involved in additional product testing.
3 For example, safety is enhanced at the expense of effectiveness when a product is barred or withdrawn from the market, and decreasing the recommended dosage often has such an effect. Other trade-offs between safety and effectiveness are discussed below.
4 As discussed in Section 3, the FDA has authority—either directly or through its ability to restrict market access—over all decisions emphasized in this section.
5 Swazy (1991) discusses product liability and drug safety, addressing some of the issues considered below. She relies on confidential interviews and review of various literature. While quotes from her interviews seem informative, they are not treated as data here, because they are anonymous and unverifiable. Some conflicts between her conclusions and those here are indicated below. In instances of overlap, the contribution here includes development of economic rationale.
Product Liability Incentives, FDA Safety Standards, and Compliance with Regulations

Recall from Section 3 that product safety depends on the FDA safety standards—the level of safety that would result if all regulations were strictly obeyed—and the degree of compliance with FDA regulations. Our first two propositions involve this distinction.  

Proposition 8.1: Product liability considerably strengthens company incentives to comply with FDA regulations.

This proposition follows from premises that seem widely accepted. First, as reported in Section 4, regulatory compliance can be a crucial issue in product liability cases. Specifically, failure to comply with FDA regulations can be very damaging to the liability case of a defendant—and the basis for punitive damages—while evidence of compliance with FDA regulations is often very helpful to defendants. Second, potential liability costs are often large enough to enter company decisions.

This proposition may have important implications for safety, because such incentives may affect company behavior. The FDA does not have the capability to ensure compliance with all its regulations. While the prevalence of noncompliance is unknown, credible allegations of compliance failures—especially failures to report all relevant information on product approval applications, or to report postmarketing safety problems—are not uncommon. Products associated with serious or widespread injuries often generate such allegations. Thus, it appears that improvements in regulatory compliance might confer substantial safety benefits.

Proposition 8.2: Product liability creates incentives for companies to exceed FDA standards for safety.

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6Gradowski (1991) emphasizes this distinction in briefly considering the effects of liability in pharmaceuticals. The analysis here is much more detailed than Gradowski’s, but the general conclusions are consistent with his. Viscusi (1991b) argues that using product liability to support regulatory policy is desirable, but that liability often undermines regulatory policy. He sees drug regulation as perhaps the most important application of his policy recommendations following from this view. These recommendations are discussed in Section 10.

7For example, liability costs can be substantially larger than any penalties that can be imposed by the FDA. Recall from Section 6 that Dow Corning Wright’s potential civil liability involving silicone-gel breast implants has been projected by some to exceed $1 billion. In contrast, Galen (1992) reports that the company faces fines of up to (only) $1 million for regulatory violations. Recall also, however, that the market and criminal justice system can also provide strong incentives for regulatory compliance.


9Kolata (1992a) provides several examples; see below.
As reported in Section 4, FDA standards are generally interpreted by courts as minimum standards. A company can be held liable for injuries linked to its product on the basis of scientific opinions rejected by the FDA. While in some states comment k immunizes companies from findings of design defects, in other states designs approved by the FDA can be found defective. A company that provided all relevant information to the FDA can be held liable for failure to provide warnings not required by the FDA or even warnings that FDA refused to allow. These possibilities give companies incentives to pursue safety levels beyond those required by the FDA standards.\(^\text{10}\)

Do companies respond to such incentives? Various aspects of this question are addressed in the next three subsections. The extent to which various responses would promote or undermine economic efficiency depends on the efficiency of FDA safety standards. The next proposition highlights that issue.

**Proposition 8.3:** The economic implications of exceeding FDA safety standards may be very different for drugs, strictly regulated devices, and other devices.\(^\text{11}\)

As discussed in Section 3, all drugs and their labeling are reviewed in detail by the FDA before they can be marketed in the United States. This review is based on information provided by companies,\(^\text{12}\) including results of clinical trials, reviews of scientific literature, and foreign experience with the drug. Regulations also require reporting of adverse experiences. Compliance by at least some companies may be quite incomplete, but the standards themselves for marketing approval and continued marketing seem very stringent. If product liability causes companies to exceed these standards, the effectiveness costs might exceed the safety benefits.\(^\text{13}\)

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\(^\text{10}\)Recall also, however, that, very recently, some federal appeals courts have held that the 1976 Medical Device Amendments (MDA) preempt liability actions against devices that have undergone the premarket approval process. These rulings are based on MDA language forbidding states from imposing any requirement in addition to those imposed by the MDA. (National Law Journal, 1993, Bureau of National Affairs, 1993a.) If this view is widely adopted, incentives to exceed FDA safety standards for strictly regulated devices will be attenuated and perhaps eliminated.

\(^\text{11}\)In the context of regulated products generally, Viscusi (1991b) also distinguishes between the levels of standards and the extent of compliance and argues that the phenomena summarized in Propositions 8.1 and 8.2 apply quite generally. However, unlike the case here, Viscusi argues that liability incentives to exceed regulatory safety standards are generally inefficient. (See particularly Viscusi, 1991b, pp. 121, 129.)

\(^\text{12}\)Whether companies report to the FDA completely and accurately is a compliance issue emphasized below.

\(^\text{13}\)For example, as discussed in Section 3, much of the literature in economics—which focuses on restrictions on and delays in product availability—concludes that FDA safety standards implicit in the drug approval process are too stringent in the sense that incremental safety benefits fall short of incremental effectiveness costs. No comparable literature seems to exist regarding labeling or postmarketing regulation or compliance.
Section 3 also reports that since 1976, some devices have been regulated in ways quite similar to drugs. These are referred to here as strictly or extensively regulated devices. FDA safety standards for such devices may be similarly stringent as those for drugs. If so, and if product liability causes companies to exceed these standards, the effectiveness costs might exceed the safety benefits.

However, Section 3 also reports that the FDA has been substantially less thorough and stringent in regulating some medium- and high-risk medical devices. In particular, many pre-1976 devices have not been reviewed by the FDA, and many others have been introduced since then without extensive regulatory review. For such devices, a strong case might be made that FDA safety standards fall short of efficient levels.

The safety of individual products results from both FDA safety standards and the degree of compliance with FDA regulations. Often, the FDA is criticized by Congress, consumer advocates, and others because of the safety of a particular drug or device. To the extent this reflects the view that safety should be maximized—regardless of costs—it rejects the relevance of economic efficiency.

However, in principle, injuries triggering such criticism might also reflect inefficiently low levels of safety. For drugs and extensively regulated devices, it seems that safety shortfalls are most often attributable to failure to comply with FDA regulations—and especially regulations requiring reporting of safety information—rather than inefficiently low FDA safety standards. For example, Kolata (1992a) provides an extensive discussion of concerns about FDA’s protection of product safety. Five drugs are discussed, and in every instance

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14Specifically, those devices subjected to the premarket approval application process or extensive review within a hybrid 510(k) procedure.

15Controversy over device regulation has focused principally on the devices that have not been extensively reviewed and on the ineffectiveness of systems for reporting adverse events. (See Section 3.)

16Especially under the 510(k) procedure based on claims of “substantial equivalence” with pre-1976 devices. (See Section 3.)

17For example, for devices on the market because they are substantially equivalent to devices marketed before 1976, it seems reasonable to say that there is no FDA safety standard for reaching the market. It is very difficult to characterize FDA standards for remaining on the market. As reported in Section 3, prior to 1990, only 1 percent of device problems at hospitals were being reported to the FDA, and the FDA had not used its authority to require device recalls or notifications. The extent to which such outcomes reflect FDA standards rather than compliance failures is unclear.

18Especially salient examples in the liability context are the Shiley heart valve, Halcion—see Section 6—and Oradex—see Wall Street Journal (1985).

19Halcion, Versed, Seleryn, Oradex, and Vyrio. The only device discussed by Kolata (1992a) is silicone-gel breast implants; here, too, allegations center on failure of companies to provide safety-related information to the FDA. Also consistent with the view that FDA failures to protect safety are generally due to compliance problems rather than inadequate safety standards is the emphasis placed by FDA Commissioner Kessler on enforcement as the key to restoring FDA credibility. (See, for example, Buskoltz, 1991.)
the apparent regulatory shortfall involved failure of companies to report information to FDA, i.e., compliance failures. In contrast, for devices that are not extensively regulated, inefficiently low levels of safety may be primarily attributable to inefficiently low safety standards.

**Effects Mediated Through Design and Testing**

It has been argued that product liability costs can be incurred for failing to exceed FDA safety standards, and liability thereby creates incentives for companies to exceed these standards. This subsection considers two ways companies might respond within the product development process: altering the physical characteristics of products to make them safer than required for FDA approval and testing them more thoroughly.

**Does Liability Cause Design Changes Enhancing Product Safety?**

Taking the current regulatory environment as given, should one expect product designs to be safer because of product liability? The answers are different for drugs, vaccines, and devices.

*Proposition 8.4: Liability-induced changes in the chemical compositions of drugs are likely to be the exception, not the rule.*

One way to reduce the liability potential of a drug is to improve its safety through alterations in chemical composition. However, widespread responses of this sort seem implausible. Safety-enhancing efforts beyond those implied by

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20 Allegations of compliance failures also play a prominent role in the history of the Shiley heart valve, but this history also suggests inefficiently lax FDA safety standards. (See, for example, U.S. House of Representatives, 1990; Burischolz, 1991.)

21 For example, neither the Dalkon Shield nor the silicone-gel breast implants were reviewed prior to marketing. (The former was withdrawn before the FDA had authority to regulate devices.) Many of the breast implants were marketed on the basis of substantial equivalence to pre-1976 devices and FDA requested safety data only a few years ago. These are allegations, however, that some companies marketing breast implants have provided inaccurate safety information to FDA. (See Section 6, below in this section, and Kolata, 1992a.)

22 Product design is observable to the FDA, and there is little scope, for example, for a company to market a product whose design is not approved. The possibility that a design is approved on the basis of incomplete or misleading information submitted by a company—a compliance issue—is considered below.

23 The extent of product testing required by the FDA is determined on a case-by-case basis, and the possibility that a company fails to adhere to an agreed-upon testing regimen is considered in this subsection. The possibility that a company fails to report test results completely and accurately is considered below.

24 Another approach—not attempting to develop a drug—is viewed as an innovation issue. (See Section 9.)
FDA standards would generally involve company costs much larger than their value in reducing liability potential.

Developing effective drugs that meet FDA safety standards for marketing is costly and difficult. As discussed in Section 3, each year the U.S. pharmaceutical industry spends almost $10 billion on R&D, and thousands of new chemicals are synthesized. However, only 20 to 30 new drugs reach the U.S. market each year, and less than one-quarter of drugs that enter clinical testing ever reach the market. Evidence of substantial safety problems prior to marketing seriously compromises chances of FDA approval. If substantial safety problems emerge after marketing commences, the FDA can remove drugs from the market.

As highlighted in Proposition 8.2, liability implies potential rewards for safety in excess of that required for FDA approval. However, the nature of the legal benefits and the technology of drug development suggest that these additional incentives will rarely lead to changes in the chemical structures of drugs, because responding to such incentives is very unlikely to be profitable. Regarding legal issues, as discussed in Section 4, findings of design defects for drugs are quite rare. Regarding technology, attempts to improve the safety of a drug by altering its chemical composition are very likely to fail because of the trial and error nature of the process, and even a successful effort to do so is very time consuming and expensive, especially after clinical trials commence.\footnote{These costs—including the possibility that in the interim a competitor will market a similar product—are discussed in Section 3.}

As discussed in Section 3, “rational drug design” and drug design based on biotechnology may lead to substantially safer and more effective drugs. Success in developing safer drugs can be expected to decrease liability potential. But the market and regulatory incentives for developing new approaches to drug development are so powerful that it is hard to ascribe a major role to product liability in spurring these trends in technology.

Proposition 8.5: Liability tends to discourage development and marketing of live-virus vaccines. If companies respond to this incentive, the safety benefits are likely to be outweighed by a sacrifice in effectiveness.

Vaccines employing live (attenuated) viruses appear more hazardous than those using killed viruses. A live-virus vaccine can cause the disease for which immunity is sought, while a properly manufactured killed-virus vaccine cannot. Thus, the liability system may induce companies to prefer killed-virus vaccines. But live-virus vaccines are generally more effective in conferring immunity, and...
live-virus vaccines can also confer immunity on those who are not vaccinated but come in contact with those who are.\textsuperscript{26}

The trade-offs between safety and effectiveness for live versus killed polio vaccines were at the heart of a case that is a cause celebre for tort reformers. As discussed in Section 4. in \textit{Johnson v. American Cyanamid} (overturned on appeal), a design defect was ascribed to the live (Sabin, oral) polio vaccine—and punitive damages were awarded—because an allegedly safer killed (Salk) vaccine was available. One of the reasons this case caused such an uproar is that U.S. public health policy favored the Sabin vaccine despite its greater risks.

\textit{Proposition 8.6: Product liability may often have important effects on device designs. In some cases, the safety benefits are likely to outweigh their costs.}

The effects of liability on product design may be very different for drugs on the one hand and some devices on the other. This is because of differences between drugs and some devices in liability doctrine, technologies of product development, and FDA regulation. These considerations are discussed in turn.

Regarding legal doctrine, comment k appears to provide devices with less protection against findings of design defects than it does for drugs. As a result, liability provides device manufacturers with greater incentives, all other things being equal, to develop safer designs.\textsuperscript{27}

The technology of development for at least some devices seems to leave much more room than is the case for drugs for safety improvements at relatively low cost. Unlike drugs, many devices are aimed at compensating for well-understood physical problems, and the required action is more specific. This aspect of device technology suggests that the safety of some devices may be improved prior to clinical testing at costs consistent with profit maximization. Such possibilities are illustrated—relying on hindsight—by three well-known cases: the Dalkon Shield (a major safety problem was the wicking action of its multifilament tailstring),\textsuperscript{28} the Shiley heart valve (welding can be avoided by a design in which the struts are an integral part of the valve),\textsuperscript{29} and the silicone-gel

\begin{itemize}
  \item \textsuperscript{26}Mckenna (1988, pp. 950–951) elaborates on these claims and provides references to the scientific literature.
  \item \textsuperscript{27}This may change if the recent federal preemption rulings for strictly regulated devices are widely followed.
  \item \textsuperscript{28}Mastrianni et al. (1991, p. 127).
  \item \textsuperscript{29}Such a "monostrut" design has been used by Shiley recently. (Meier, 1990.)
\end{itemize}
breast implants (concerted engineering efforts might have produced covers less prone to rupture and leakage).  

Regarding differences in FDA regulation, effects on device design are especially plausible for devices that are not strictly regulated. For such devices, legal defenses against allegations of design defects may be much weaker because of the lack of extensive FDA review and approval. If so, there is a correspondingly greater legal benefit to design improvements.

If liability does induce increases in device safety beyond the levels required by FDA standards, this may or may not be efficient. Safety increases involve resource costs, and may decrease effectiveness, for example, if they delay product introduction. The degree to which different devices are regulated by the FDA appears to be an important consideration in this context. Specifically, for devices that are not strictly regulated, FDA safety standards may leave considerable room for efficient increases in safety. Such possibilities seem more limited for strictly regulated devices.

Does Liability Cause Companies to Test Products More Extensively?

Proposition 8.7: It is doubtful that product liability often leads firms to test drugs or extensively regulated devices more than required by the FDA; if liability induces extra testing of these products, this will generally involve increased compliance with FDA regulations. Liability may often induce testing of less-regulated devices beyond that required by the FDA, as well as additional compliance with FDA testing requirements.

It is doubtful that product liability often leads to more extensive testing of drugs or extensively regulated devices than required by FDA safety standards. First, cases of liability because a company "should have known" of a safety risk that would have been apparent from more extensive product testing—if any exist—are not prominent. Second, in many cases, a company has overseas marketing experience with the drug or device prior to FDA approval; extra information available from more extensive clinical testing is correspondingly less valuable. Finally, extra testing is unlikely to provide useful information about latent injuries or injuries associated with long-term use—factors often associated with mass-tort potential—without requiring prohibitively costly delays. In sum,

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30The extent of such engineering efforts is unclear. Apparently, at least one manufacturer was aware of silicone leakage and ruptures since the 1970s. (Chenow, 1992a; Smart, 1992.)
despite some incentives created by liability, it seems very unlikely that drug
companies would often find it profitable to exceed FDA requirements for clinical
and other tests.

It is much more plausible that liability often deters companies from compliance
shortfalls regarding testing of drugs and extensively regulated devices. Evidence
of failures to conduct the tests required by the FDA can be very damaging in a
liability suit and can be the basis for punitive damages.

The situation is somewhat different for devices that have not been extensively
regulated. Here—as with drugs and extensively regulated devices—liability may
give companies considerable incentive to comply with whatever testing is
required by the FDA. But the major effect on testing may involve increases
beyond levels required by the FDA. When the FDA has not required and
reviewed safety data, the company does not enjoy the legal benefit of FDA
approval of its safety studies, and it might perceive major legal benefits to testing
beyond the level required by the FDA. It is unclear whether the incentives
provided by the liability system have, in fact, led to extra testing of devices. But
this issue has become very prominent of late in the context of silicone-gel breast
implants.31

Effects Mediated Through Information Provision
to Physicians and Patients

The information companies provide to physicians and patients may have crucial
implications for safety and effectiveness.32 In fact, the apparent inability of the
market alone to bring forth complete information about drug and device safety
and effectiveness is the major rationale for both FDA regulation and product
liability.33 Specifically, suppose physicians and patients were well-informed
about the benefits and risks of drugs and devices without any impetus from the
regulatory or liability systems. Then, purchase decisions might be expected to
incorporate this information, thus providing companies with market (i.e., profit)
incentives to provide the efficient levels of safety and effectiveness.

31See, for example, Reinstein (1992). Issues that have arisen, but are far from resolved,
regarding the breast implants are the extent to which companies have conducted safety studies, the
extent to which the FDA regulations required them to do so before safety data were specifically
requested by FDA in the last few years, and the extent to which companies accurately and completely
reported safety information to the FDA.

32In her concluding section, Swazy (1991, p. 325) writes, "[i]t seems reasonable to assume that
product liability would have its greatest effect on the content and timeliness of information conveyed
to physicians, and to patients, through the types of materials that FDA defines as labeling."

33See, for example, Grabowski and Vernon (1985, pp. 6–7) and American Law Institute (1991a,
Ch. 7).
Information about product hazards can affect decisions of physicians and patients concerning whether a product will be used and also how it will be used. For example, warnings about side effects can deter a physician from prescribing a particular product, and information about contraindications is intended to help physicians avoid product use for specific patients. Such information can also be used by physicians and patients in deciding whether to discontinue product use if symptoms appear and in avoiding dangerous drug interactions.

Proposition 8.2 applies in the context of information provision: Liability creates incentives to exceed FDA safety standards for some forms of information provision. This subsection begins with three propositions. Unlike most effects of liability, the first two propositions refer to effects pertaining to most, if not all, product areas. Implications of effects on information provision for safety and effectiveness are discussed in closing this subsection.

**How Does Product Liability Affect Information Provision?**

**Proposition 8.3:** Product liability encourages companies to provide physicians with very extensive and detailed information for most, if not all, drugs and devices.

As discussed in Section 2, the package insert when the product is first marketed is generally lengthy and detailed. It typically becomes more lengthy and detailed as it is revised on the basis of accumulating experience. Much of the content is description—rather than interpretation—of what happened in clinical trials, the nature and frequency of reports of adverse reactions, and the results of scientific studies. Finally, unsystematic review of many package inserts

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34. In a broader context, Henderson and Tverski (1990, pp. 285–289) and Viscusi (1991b, p. 134) distinguish these two roles for product warning information. Similarly, in the drug context, Brushwood and Simonaitis (1986) distinguish between “risk assessment” and “risk management” (which occurs after prescribing) and emphasize the importance of patient participation.

35. The compliance issue is not emphasized in this subsection because it seems to be relatively little scope for noncompliance in this context. The FDA can observe written information provided to physicians and patients, and thus it is relatively easy to detect compliance failures. In fact, FDA actions to require changes in written promotional materials are not uncommon. However, the FDA also regulates oral representations about products, and enforcement is more difficult here; this issue is not pursued for lack of information.

36. Product inserts for most products are reprinted in the Physician’s Desk Reference (PDR), which is published annually. Warnings are also conveyed orally by sales representatives, but it is unclear the extent to which these conversations serve to clarify, interpret, or highlight the written information.

37. For example, from reports of adverse experiences, Phase IV clinical trials, and epidemiological studies.

38. This is also true of the “brief summaries” of the product inserts.
suggests that almost all of them contain language suggesting that the product
either not be used by pregnant women or that such use be considered very
carefully.

Product liability doctrine encourages provision of extensive, detailed information
to physicians. Product liability actions allege failure to warn, and
adequacy of the warning to the physician is generally a key issue. Research for
this study has uncovered no indication that warnings to physicians have been
ruled legally inadequate because they are too detailed, or extensive, or provide
descriptive information without interpretation.

Once in court, failure to warn of a risk of the plaintiff’s injury can be very costly.
This is more likely if, for example, a subject in a clinical trial suffered a similar
injury or the company had received adverse reaction reports involving similar
ones. Even if causation is doubtful, there can be a large legal benefit to including
a warning about such an injury. With products being used by thousands or even
millions of patients, the potential for ever more detailed and extensive warnings
to physicians is obvious. There is also an apparent disadvantage to companies of
more extensive warning: discouragement of product use. But it seems that
companies often find it better to be legally safe than sorry.

**Proposition 8.9:** Product liability doctrine discourages companies from providing
warning information to patients.

Patients are rarely warned directly by manufacturers. PPIs are required by the
FDA for four types of products, and some forms of direct-to-consumer
advertisements require inclusion of the brief summary of the package insert. For
most products, patients receive no warning information directly from the
manufacturer and receive whatever information they have orally from their
physician or pharmacist. Moreover, except for PPIs, the written information

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39. Henderson and Tverski (1990) present a detailed analysis in the context of product liability
generally, concluding that current doctrine leads to warnings that are too extensive and detailed from
a risk-utility (economic) point of view. They are particularly critical of the failure of courts to defer to
the FDA and other safety regulators on the adequacy of warnings. (Henderson and Tverski, 1990,
pp. 320–321.)

40. Henderson and Tverski (1990) reinforce the view that such cases may be nonexistent.

41. Physicians may be less likely to be discouraged from prescribing a product by warnings
largely motivated by liability concerns than patients might be from using such a product. Physicians
are more able to distinguish between more and less critical warnings.

42. See, for example, Brushwood and Simonsemeier (1986, p. 280, fn. 5). One is oral contraceptives,
and existence of PPIs for them was a factor weakening the learned intermediary defense for them.
(See Section 4.)

43. Morris et al. (1986) indicate that patients receive less information from their physicians than
might be imagined. For example, a survey of patients indicated that 26 percent were told of
precautions and 23 percent about side effects. Sixteen percent consulted a reference book about their
last prescription.
patients receive from manufacturers is not designed for their use: The brief summaries—which typically contain a page or more of fine print—are designed for physicians, and their interpretation requires expertise.

Provision of warnings to patients is discouraged by product liability doctrine. The manufacturer generally has no duty to warn patients directly, but if it does, the manufacturer may invite a judge or jury to find the warning inadequate and responsible for the plaintiff’s injury.44 This appears to be a powerful disincentive to providing patients with warnings.45

Proposition 8.10: For some types of products, direct-to-consumer advertisements—including advertisements accompanied by the brief summary—can be sufficiently profitable to outweigh the extra liability potential.

Promotion to patients has become much more common in recent years, and FDA regulation of such promotion can have important implications for liability.46 When the FDA requires the brief summary to be incorporated in a direct-to-consumer advertisement, the company bears additional legal risk, because this can be viewed as a warning directly to patients.47 Nonetheless, the prevalence of direct-to-consumer advertisements including the brief summary has increased dramatically in the last few years.48

Why would a company choose to promote a product in a way that is legally hazardous? Presumably because of the belief that the extra liability potential is justified by the potential payoff. Thus, it might be anticipated that products are advertised directly to patients when the company expects the benefits in terms of profits to outweigh the advertising costs and the costs due to expanded liability exposure.

44There may be no cases of liability for the inadequacy of a warning a company had no duty to supply. Of course, this may be due largely to the fact that companies rarely even provide such warnings. The difficulty of providing legally adequate warnings to patients is illustrated by MacDonald v. Ortho Pharmaceutical Corp., which involves the PIL for oral contraceptives; see the discussion of exceptions to the learned intermediary rule in Section 4.

45But there is another disincentive: such warnings may discourage patients from using the product.


47See the discussion of exceptions to the learned intermediary rule in Section 4.

48The FDA lifted a moratorium on direct-to-consumer advertising of prescription drugs in 1985. Two product-specific advertisements—i.e., ones for which the brief summaries were required—were introduced in early 1985, and only two others ran before that time (Zoller, 1989). But by early 1992, direct-to-consumer advertisements for prescription drugs including the brief summary had become much more common.
What types of products are likely to be advertised directly to consumers? Products for which the costs of expanded liability are likely to be small are those that appear to involve only infrequent or relatively minor injuries. Products for which direct-to-consumer advertising is likely to expand sales considerably beyond the level achievable with promotion only to physicians would include those for which many affected patients would not seek advice from a physician. This would be the case for conditions that do not seem to call for visiting a physician—either because the condition is tolerable or it can be treated with OTC products—or more serious conditions for which treatment has only recently become available.\footnote{Masson and Rubin (1985), for example, cite such possibilities in making their case for encouraging direct-to-consumer advertising.} Products promoted directly to patients in 1992 and 1993 include a treatment for pattern baldness (that is used topically and hence seems very safe), an antihistamine that does not cause drowsiness (and competes with OTC products), and newly introduced skin patches used to aid smoking cessation.

**What Are the Implications for Safety and Effectiveness?**

It has been concluded that product liability may have substantial influence on information provision to physicians and patients. However, the implications for safety and effectiveness—while potentially crucial—are equivocal. Whether changes in information provision that are encouraged by liability promote economic efficiency seems controversial in every instance.

*Proposition 8.11:* Product liability may have major effects on safety and effectiveness that operate through the amount and character of information provided to physicians. Whether these are on balance socially beneficial or detrimental is unclear.

In the case of warnings to physicians, liability encourages provision of very detailed, extensive, and often descriptive warnings. In the context of product liability in general, it is often noted and lamented that the liability system creates powerful incentives for warnings to proliferate. The resulting "label clutter" is widely believed to result in warnings that are effective in promoting the legal safety of the manufacturer but counterproductive in promoting the physical safety of the product user.\footnote{See, for example, Henderson and Tverski (1990), Viscusi (1991b, Section 7) and Viscusi (1991c).}
However, standard arguments that proliferation of warnings is counterproductive are less persuasive in the context of warnings to physicians. For example, in the general product context, the argument that many warnings are counterproductive because they crowd out or dilute more important warnings relies on consumer unwillingness to wade through and inability to interpret extensive and detailed warnings. But in our context of package inserts, brief summaries, and physicians, these arguments—while perhaps valid—have less force.51 Most physicians are unusually competent. In addition to their abilities to understand detailed, technical information, they have incentives created by professional responsibility and the threat of malpractice suits to read and carefully consider labeling of drugs and devices they prescribe.

Proposition 8.12: Product liability may have major effects on safety and effectiveness that operate through discouraging provision of information to patients. Whether these effects would be socially beneficial or detrimental on balance seems controversial.

The almost total lack of warning information provided to patients about prescription drugs and various medical devices stands in marked contrast to the typical situation for hazardous consumer products. As discussed presently, some patients would benefit from having more information, and others would be harmed. Whether providing more safety information to patients would improve the balance of safety and effectiveness is controversial and is likely to remain so.52

If the information that would be provided to patients is the package insert or brief summary, the typical concerns about "label clutter" and its effects would seem to apply. Provision of well-designed warning information intended for patients might be another story.53 However, the FDA program on PPIs was controversial.54 Arguments for the provision of information focused on aiding patients in recognizing side effects and contraindications. Arguments against

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51 Nonetheless, Cooper (1986, pp. 237–238) is very concerned about liability leading to warning information that is counterproductive from a medical point of view, and Swarz (1991, p. 315) also emphasizes the problems of "sensory overload" in this context. Schwartz (1992, p. 566) cites six cases—four of which involve drug manufacturers—in which courts have declined to find warnings inadequate because of concern about information overload. Viscusi is more optimistic about the ability of physicians to deal with extensive, detailed warning information—partly because of their medical training and partly because of the standardized format of drug labels—than he is about the ability of consumers to use the typical warning information accompanying consumer products. (See especially Viscusi, 1991b, p. 151.)

52 See, for example, Brushwood and Simonsmeier (1986).

53 See, for example, Kanouse et al. (1981) for a summary of the results of experiments to evaluate the effects of providing different types of information to prescription drug users.

54 For example, Brushwood and Simonsmeier (1986, p. 280, fn. 5): "The pharmaceutical manufacturers and health care professionals reacted negatively to the PPI program."
included the possibility that such information would needlessly worry patients and deter them from complying with their prescribed therapies. Available information does not permit an assessment of net effects.55

It has been argued above that product liability tends to deter companies from using direct-to-consumer advertisements, especially advertisements that require inclusion of the brief summary. The effects of direct-to-consumer advertisements on safety and effectiveness are also controversial.56 The fact that companies incur large additional costs to advertise to consumers indicates that they believe that such advertisements increase sales. But whether one believes this is socially desirable depends on various issues raised in the debate about the desirability of direct-to-patient advertisements. Because of the "information overload" problem, the provision of the brief summary to consumers in some advertisements may not promote safety very much. Concerns about information for patients being counterproductive to effectiveness (i.e., by discouraging patients from taking their medicine) are relevant here as well.

**Effects Mediated Through Product Availability**

As discussed in Section 6, product liability is likely to have played a central role in decisions to withdraw some products from the U.S. market. If a product is withdrawn when the FDA has all required information and is willing to keep the product on the market, FDA safety standards are exceeded. It was also argued that incentives created by product liability to comply with FDA regulations may prevent some products from reaching the U.S. market. Clearly, a product that is not available can neither cause injury nor promote health and well-being.

*Proposition 8.13: Whether the social benefits of liability-induced product withdrawals exceed the social costs is likely to differ from product to product.*

When the only product to treat a particular condition is withdrawn—for example, Bendectin—there is a cost in terms of foregone health benefits, since patients who would have benefited from using the product cannot turn to a substitute product.57 But because no drug or device is perfectly safe, there is always a safety benefit to a product withdrawal: avoidance of injuries that would have been caused.

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56 See, for example, Masson and Rubin (1985) and Cohen (1986).
57 Skolnick (1986) reviews information about health costs of the withdrawal of Bendectin.
When a product is withdrawn, but a close substitute remains on the market—for example, IUDs or DTP—the situation is not as clear. To the extent that usage of this type of product falls—IUDs are a clear example—there is a cost in terms of effectiveness and a benefit in terms of safety.\footnote{When product withdrawals contribute to price increases—DTP vaccine, for example—this can also be expected to reduce product usage.}

All withdrawals have some safety benefits and some effectiveness costs. The relative sizes of the effectiveness costs and safety benefits are case specific. Some product withdrawals often attributed to liability are widely viewed as socially beneficial; in some cases the opposite view is widespread; and in other cases there is substantial controversy.\footnote{There is widespread agreement that the Dalkon Shield withdrawal was socially beneficial, but it was argued that market forces were likely to have caused it to be withdrawn eventually. Wyeth’s withdrawal of pertussis vaccine—which was argued to be more meaningfully attributed to liability—is generally viewed as socially detrimental. The social desirability of the Bendectin withdrawal—which was also argued to be meaningfully attributable to liability—is more controversial than either.} Recall from Proposition 6.1, however, that it is more plausible to attribute product withdrawal decisions to liability for products with widespread support in the medical community than for products lacking such support. This suggestion tends to make the role of liability in product withdrawals look less favorable in terms of safety and effectiveness.

**Proposition 8.14:** If liability restricts availability by increasing regulatory compliance, the social benefits are likely to exceed the social costs.

Proposition 8.1 highlights the fact that liability creates powerful incentives to comply with FDA regulations. In Section 6, the possibility was considered that a product may fail to reach the market because a company responding to such incentives would choose to report safety problems to the FDA that it would otherwise not report. Similarly, incentives created by liability might lead to more conscientious reporting to the FDA of adverse postmarketing product experiences and thereby contribute to product withdrawal. Such effects of liability would be invisible to the public. But if they exist, such effects would be socially beneficial to the extent that improved information aids the FDA to balance social costs and benefits efficiently.

**Conclusions**

A definitive assessment of the effects of product liability on the safety and effectiveness of drugs and devices is not possible. But the conclusions above suggest some systematic differences among broad groups of products.
Drugs

Except for vaccines, it has been concluded that major liability effects on drug design are unlikely. For vaccines, there may be important, inefficient effects operating through design. Liability may lead to additional testing of drugs; such responses are likely to involve improved compliance with FDA regulations rather than testing beyond levels required by FDA standards. There may also be major, undesirable effects associated with information provision and the withdrawal of products (such as DTP vaccine and—more controversially—Bendectin). However, there may also be major—albeit publicly invisible—beneficial effects operating through increased compliance with FDA regulations requiring information reporting.

Strictly Regulated Devices

Because of similarly stringent FDA safety standards, many of the conclusions for strictly regulated devices are similar to those for drugs. The major exception is attributable to differences in product-development technologies between drugs and devices and the fact that comment k provides more protection against liability for design defects for drugs than it does for devices. As a result, it was concluded that liability may often lead to safety-enhancing effects on device designs. However, because FDA safety standards are stringent for these devices and such increases in safety may involve decreases in effectiveness—for example by delaying product availability—such effects might often be inefficient. Widespread preemption of liability claims by the 1976 Medical Device Amendments—which may be emerging—could reduce future incentives to exceed FDA safety standards.

Less-Regulated Devices

These products provide the strongest case for efficient overall effects of product liability on safety and effectiveness. FDA safety standards for many devices may leave substantial room for efficient increases in safety. Here it was concluded that product liability may often lead to socially desirable increases in design safety and the degree of product testing. If liability caused—or more plausibly, hastened—the withdrawal of the Dalkon Shield, this would be widely viewed

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60. It was marketed and withdrawn before the FDA had authority to regulate devices. (See Section 6.)
as a major social benefit. If silicone-gel breast implants are found to pose serious health hazards, similar comments may someday apply to them. Finally, such effects of liability may be expected in the future. It is unlikely that all medical devices with substantial potential for injury will be strictly regulated any time soon.\textsuperscript{62}

\textit{Summary}

The effects of product liability on safety and effectiveness depend on several issues that can be analyzed but not resolved. Where FDA safety standards are stringent, the potential of liability to strengthen regulatory compliance is countered by the potential to undermine other aspects of FDA policy. It is likely that liability effects on the safety and effectiveness of existing products are much more socially beneficial for less-regulated devices than for drugs or strictly regulated devices. One's views concerning the effects of product liability on safety and effectiveness might depend crucially on one's views about the value of providing various types of information to physicians and to patients. While the extent and social costs of regulatory noncompliance are unclear, there seems little doubt that some regulatory violations involve substantial risks to public safety. Deterrence of such behavior might be the most socially valuable function of product liability.

\textsuperscript{61}Some were marketed before the FDA had authority to regulate devices, and others were introduced after 1976 on the basis of substantial equivalence with pre-1976 devices. (See Section 6.)

\textsuperscript{62}Recall from Section 3 that there are roughly 1,200 types of devices, 50,000 separate products, and 2,000 manufacturers (of which 5,000 produce medium- and high-risk devices). In light of the FDA's limited resources, the numbers of companies and devices for which it has responsibility, and the rapid rate of innovation in devices, it seems likely that many possibly hazardous devices will be less strictly regulated than drugs for several years.
9. Product Liability and Innovation

Society also has a major interest in the safety and effectiveness of drugs and devices in the future. This section considers the effects of product liability on innovation—the process by which new products become commercially available. This encompasses, first, product development (R&D) and, second, market introduction.

As discussed in Section 3, new product development is essential to the long-run financial performance of companies in the industries under study, and competition to innovate is vigorous. Innovation is of social concern because of its potential to enhance future product safety and effectiveness and to reduce health care costs. Effects on innovative effort may be the most important element of the effects of liability on the economic performance of these industries.

Furthermore, the effects of product liability on pharmaceutical innovation have been a central element in discussions of the broader economic effects of liability. In his recent book on the economics of product liability, Viscusi (1991b, p. 66) writes: “Much of the concern regarding the potentially adverse effects of tort liability on innovation has stemmed from a series of case studies, most of which have involved the pharmaceutical industry.” Thus, additional evidence of liability’s effects on pharmaceutical innovation and additional perspective concerning what aspects of the industry underlie these effects could be very valuable in informing the wider policy debate.

Developing such information is challenging. Because innovation is so crucial to private performance, R&D strategies and activities are typically closely guarded secrets. As a result, very little systematic information about the innovative efforts of individual companies is publicly available. Thus, our analysis of innovation relies especially heavily on inference.

An observation fundamental to drawing such inferences is that both product development and market introduction are investment activities. These activities involve major expenditures by companies—expenditures that are incurred in the hopes of substantial future returns. Estimates of the costs of developing new pharmaceuticals were reviewed in Section 3. The costs of market introduction include both the investment necessary to achieve commercial-scale production and the promotion costs involved in launching a product. The question is how
product liability in the United States affects the willingness of companies to undertake investments in innovation.\(^1\)

Most of this section is devoted to a quantitative assessment of the degree to which liability uncertainty and risk may dampen incentives to innovate in particular product areas. First, however, we discuss evidence regarding industrywide effects and the perspectives companies are likely to adopt in incorporating liability into their investment decisions.

**Effects on Innovation Across the Drug and Device Industries**

Advocates of product liability reforms assert that liability—and particularly the associated uncertainties—can "stifle" innovation. Reform opponents counter anecdotes concerning discouraged innovations with their own anecdotes about innovations that make products safer. Such discussions are hampered not only by their anecdotal nature, but also by the fact that they focus on too broad a question. Policy discussions typically address "the" effect of liability on innovation—that is, economywide or industrywide effects.\(^2\) The issue emphasized here is effects of liability on the mix of innovative efforts.\(^3\)

The drug and device industries are widely believed to face unusually large degrees of product liability exposure. However, they are among the most research-intensive and innovative of industries,\(^4\) and perhaps increasingly so. Annual data on industry-level R&D for the pharmaceutical industry indicate that the proportion of sales invested in R&D is substantially higher now than it was 20 years ago and has grown steadily since the late 1970s.\(^5\) Although some would

\(^1\)The market-introduction decision can be made country by country, but R&D decisions are influenced by market, regulatory, and liability environments in many countries.

\(^2\)Even analyses that go beyond anecdotes might encourage this view. Viscusi and Moore (1989, 1991) present statistical evidence on the effects of product liability on innovation. Viscusi (1991b, p. 70) describes the conclusions: "Except in very high levels of liability, the net effect of product liability is to foster innovation rather than to deter it. Once the level of liability in an industry becomes too great, however, the dampening effect takes hold." See also Viscusi and Moore (1993).

\(^3\)This emphasis is similar in spirit to Wiggins (1981a, 1981b, 1983), who studies the effects of FDA regulation on R&D spending and product introductions by therapeutic class.

\(^4\)For example, Business Week (1991) reports 1990 R&D expenditures as percentages of sales for companies classified into roughly 40 industry groups. The group averages for the two segments of the health care industry—drugs and research, and medical products and services—are 10.3 percent and 6.2 percent, respectively. Only three industry groups had percentages exceeding 10.3 percent (the highest is 13.3 percent), and two others had percentages exceeding 6.2 percent.

\(^5\)PMA, *Statistical Fact Book* (1991, Table 2-1). Until 1980 this proportion hovered in the range of 11 to 12 percent but has grown steadily to over 16 percent in recent years. OTA (1993) interprets this growth as a response to relatively high industry rates of return to R&D.
take this as evidence that concerns about liability's detrimental effects on innovation are groundless, such a conclusion seems too hasty.

Research-based companies realize that they cannot achieve their long-term aspirations if they do not develop new products. While product liability poses downside risks that are in principle unlimited, this potential is more apparent for some products than others. The economics of the industry impel companies to innovate, but liability concerns may steer them away from some types of innovation that appear to pose relatively large liability threats. The question pursued here, then, is not: "Does liability discourage innovation?" Instead, we focus on: "What types of innovation does liability discourage and to what degree?" 6

Reports from independent panels conclude that product liability has substantially discouraged innovation efforts in vaccines, 7 contraceptives, 8 and orphan drugs. 9 There are also claims that product liability concerns hinder development efforts in biotechnology, 10 especially for vaccines in general and an AIDS vaccine in particular. 11

More specific information is available with regard to contraceptive development. Mastroianni et al. (1990, p. 59):

Over the past three decades, at least nine large U.S. pharmaceutical companies have been involved in research and development of new contraceptives. By the mid-1980s, however, only Ortho Pharmaceutical Corp. (a subsidiary of Johnson & Johnson) continued a significant contraceptive research and development program.

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6Discouraging innovation for some types of products might or might not depress overall innovative effort. To the extent that R&D expenditures are determined as a percentage of sales (a "top down" budgeting procedure), it would not. But if R&D budgeting is "bottom up"—with projects funded on their own merits without regard to total spending—then it would. It seems R&D budgeting has important elements of both. Wiggins (1981b, p. 75) provides some evidence on this issue based on interviews at 12 major pharmaceutical companies.

7IOM (1985).

8Mastroianni et al. (1990).

9U.S. Public Health Service (1989). Orphan drugs show promise for the treatment of rare diseases, but have limited profit potential.

10For example, Weaver (1988). Burell (1987, p. 1146) reports that "69 percent of companies surveyed in all [biotechnology] market segments believe that product liability is an important factor to consider in the decision to proceed with commercial introduction."

11For example, Cohn (1992). Fenyes (1992) recounts a recent case in which a company's liability concerns resulted in an apparently costly response: "Bristol-Myers Squibb has offered to donate to the U.S. government all the data its researchers have gathered over the years on the company's AIDS vaccine ... requesting in exchange only that the government assume responsibility for any future liabilities." Keystone Center (1991) discusses difficulties in assessing the effects of liability on efforts to develop AIDS vaccines and considers some policy responses. See also OTA (1993, pp. 179, 182). However, McKenna (1988) argues that liability is not a serious impediment to the development of an AIDS vaccine.
Contraceptives are, of course, one of the product areas routinely mentioned as involving unusual liability potential. The reported dramatic decrease in the number of major pharmaceutical companies seriously pursuing contraceptive research may well be attributable partly to liability concerns, but other factors are apparent.\textsuperscript{12}

The characteristics of firms pursuing contraceptive development reinforce some of our views about decisionmaking. Mastroianni et al. (1990, p. 1) report that "non-profit organizations and small firms have become more important for contraceptive development." This is consistent with the observation in Section 6 that small firms may be less susceptible to major liability actions, because they do not have deep pockets and because their downside risks are limited in absolute terms.\textsuperscript{13} The fact that Ortho—which was and is quite specialized in contraceptives\textsuperscript{14}—is the only major company that has remained committed to contraceptive development is consistent with the view that companies are more prone to take large risks if they cannot attain their aspiration levels without doing so.

Innovation by major companies has not ceased in vaccines and contraceptives. As reported in Section 6, new vaccines have been introduced in the last few years by Merck, Lederle, and SmithKline Beecham, none of which is small. There is also evidence of widespread effort to develop vaccines, many using biotechnology.\textsuperscript{15} In February 1991, an under-the-skin contraceptive implant (Norplant), developed by the (not-for-profit) Population Council,\textsuperscript{16} was marketed by a major pharmaceutical company (Wyeth-Ayerst). In January 1993, Upjohn—another major company—launched Depo-Provera, an injectable contraceptive.\textsuperscript{17}

Finally, as discussed in Section 3, drug innovation involving biotechnology is burgeoning. Concerns about liability and biotech drug development seem to

\textsuperscript{12}For example, Mastroianni et al. (1990, p. 151) emphasize FDA regulation and market factors in addition to liability. Connell (1997) emphasizes liability, but also public misunderstandings and a decline in federal funding for contraceptive research. Hills (1990) emphasizes the politics of contraception and abortion and related public-relations concerns.

\textsuperscript{13}In addition, firms specializing in contraceptives may be less sensitive to concerns about product areas outside of contraceptives such as consumer boycotts.

\textsuperscript{14}For example, Weber (1992a) characterizes Ortho as "narrowly focused on contraceptives." See also Abeisson (1990).

\textsuperscript{15}For example, PMA (1990) reports that of over 100 "biotechnology medicines in development.

\textsuperscript{16}Hills (1990).

\textsuperscript{17}Brooks (1993).
reflect hypothetical liability problems\textsuperscript{18} and belief in the great social value of encouraging innovation in biotechnology.\textsuperscript{19} Perceived liability potential can affect behavior in the absence of actual liability costs, but there is scant evidence that liability is indeed discouraging drug innovation involving biotechnology.

Thus, direct evidence allows no clear conclusion about how product liability may be affecting innovation across the drug and device industries. The available evidence leaves room for some to assert that such effects are beneficial or trivial, while others assert that they are disastrous. Is this range of disagreement inevitable, or might it be narrowed somehow?

A View of Decisionmaking by Affected Companies

What types of innovative activities might be discouraged by potential liability and to what extent? Perspectives on decisionmaking discussed and developed above seem helpful.

Perceived liability potential varies greatly across product areas. While the eventual outcomes of R&D activities are sometimes quite surprising,\textsuperscript{20} a company typically has more or less precise views about what types of products are likely to emerge from a contemplated product development activity. If these products are perceived to involve substantial liability potential, liability may affect the decision to proceed. At the time of a product introduction decision, the liability potential of a specific product is involved, and this can be assessed more precisely.

According to the behavioral model in Section 5, if a contemplated action—R&D activity or product introduction—is perceived to involve substantial liability potential, companies seek ways to mitigate this potential. For R&D activities, this may largely involve development of contingency plans.\textsuperscript{21} For products that are ready to be introduced, this may involve development or institution of unusual procedures to guard against liability exposure,\textsuperscript{22} as well as contingency plans. Once measures to mitigate liability potential have been considered and the contemplated action revised accordingly, a company assesses the extent of

\textsuperscript{18}O'Reilly (1987) argues that the state-of-the-art defense is particularly weak for biotechnology products. However, it may be that no liability suit has yet been filed against a biotechnology drug.

\textsuperscript{19}For example, Fox and Traynor (1991).

\textsuperscript{20}For example, as discussed in Section 3, efforts aimed at developing a cancer therapy might lead to a treatment for heart disease.

\textsuperscript{21}Such as planning to keep unusually detailed records concerning regulatory compliance activities, be especially energetic in pursuing approval of extensive warnings, or withdraw the product as soon as any liability problems emerge.

\textsuperscript{22}For example, see the discussions of Acutane, Clozaril, and Cytotec in Section 6.
the remaining liability potential. In extreme instances, the remaining liability potential may be unacceptable.

**Proposition 9.1:** Companies may refuse to take actions perceived to involve a risk of financial disaster without even considering potential profitability.

A company might be unwilling even to consider R&D projects targeted at products with extremely large liability potential, no matter what their profit potential. This is more plausible when the company can meet its performance targets (i.e., achieve its aspirations) without taking such a risk.

If no company is willing to consider innovation in a product area because of perceived liability threats, then innovation in that area would be “stifled” in the strongest sense of that word. There is only one type of product for which the evidence suggests this is plausible: products for conditions specific to pregnancy (e.g., to treat morning sickness, to prevent miscarriage). Liability risk in this area is very salient to industry decisionmakers: the very costly DES and Bendectin episodes are extremely well known. Finally, none of the information reviewed for this study suggests that any company is, in fact, attempting to develop products for conditions specific to pregnancy.

**Proposition 9.2:** Companies are generally willing to consider development efforts for products perceived to involve substantial liability potential.

Unless the perceived probability of disaster is unusually high, a company will weigh perceived liability potential against the profit prospects associated with an investment in innovation. The more substantial the perceived liability potential, all other things being equal, the more attractive the profit prospects must be for a company to proceed. Thus, innovative efforts are discouraged—but not necessarily deterred—in products areas perceived to involve substantial liability potential.

This leaves us with the following question: When the perceived liability potential is insufficient to make a company simply unwilling to proceed with an investment in innovation, but substantial enough to enter the decision, to what extent might liability discourage the investment?

**Quantifying Effects on Company Incentives: Approach**

The remainder of this section develops quantitative information concerning the question just posed. It is emphasized that the analysis is not informative about the profitability of R&D in the pharmaceutical industry, or about the profitability
of R&D for individual pharmaceutical products. For an extensive analysis of the former issue, see OTA (1993).

Recall that an assessment of liability potential encompasses three aspects: expected liability costs (a best guess), the degree of uncertainty (or unpredictability) about eventual liability costs, and the liability risk (potential for large liability costs).\textsuperscript{23} Expected liability costs directly reduce expected profits and thereby tend to discourage investment. It seems almost universally agreed that all other things being equal, uncertainty tends to discourage investment, because decisionmakers would prefer less uncertainty to more uncertainty. The management literature emphasizes that risk—or the potential for large losses—is a particularly important aspect of uncertainty, especially if such losses would threaten the viability of a company.

The quantitative analysis emphasizes liability uncertainty and risk associated with particular product areas. It considers their effects on incentives to invest in innovative activities targeted at those areas. This emphasis reflects the facts that the quantitative significance of expected liability costs can be assessed more straightforwardly than the effects of uncertainty and risk, and that uncertainty and risk are often emphasized in discussions of the effects of liability on innovation.\textsuperscript{24}

The analysis considers the extent to which the additional unpredictability of liability costs—including the consequent risks—associated with some products tends to discourage companies from investing in them. The effects of liability uncertainty and risks in excess of those for typical products are simulated. Thus, when considering the "effects" of liability uncertainty and risk in this section, the alternative scenario is any institutional arrangement under which the levels of liability uncertainty and risk for a product subject to unusual liability potential are reduced to the level presently characterizing typical products.

It is unknown what procedures are actually used by drug and device companies to take account of liability in investment decisions. Undoubtedly, procedures for weighing liability potential against profit potential vary considerably across companies and even across decisions within companies. In practice, some decisions may rely on highly structured, quantitative analyses and others almost

\textsuperscript{23}See Section 4.

\textsuperscript{24}For example, see both IOM (1985) and Mastroianni et al. (1990) in the respective contexts of vaccines and contraceptives, and Lasagna (1991) concerning pharmaceuticals more broadly. In the context of product liability generally, U.S. Senate (1991, p. 9) concludes its section on product innovation with: "Thus, considerable testimony was received that the uncertainty of the system is a deterrent to the research and scientific investigation necessary to develop ideas that ultimately become innovative products."
entirely on intuition. To develop quantitative information, however, our analysis must be sufficiently structured to produce numerical answers. The model is offered as a predictive device, not as a description of the process by which liability typically enters decisions.

In the model developed here, product-development or product-introduction investments are based on quantitative assessments of their financial value. The incentive to incur the costs of such investments is the profit that might result. But the profits that will accrue in future years are unpredictable; risks must be taken to be in a position to profit; and, if an investment in innovation is successful, profits will be earned only after several years. All other things being equal, additional uncertainty, additional risk, and additional delay make an investment less attractive to a decisionmaker, i.e., reduce the incentive to invest.25

It is assumed that incentives to invest are determined by projecting a profit profile for the product and discounting to present value. The profit profile is interpreted as expected profits net of expected liability costs. Liability uncertainty and risk are incorporated as part of the discounting procedure: All other things being equal, higher discount rates are used the larger perceived liability uncertainty and risk are and the more averse decisionmakers are to these aspects of liability potential.26

Liability uncertainty and liability risk may independently discourage investment in innovation. The analysis here treats them jointly. For expository ease, for the remainder of this section we use the term liability risk to refer jointly to all decision-relevant aspects of liability potential other than expected liability costs.

The basic perspective and procedure are applicable to both drugs and devices. However, the quantitative analysis focuses on the pharmaceutical industry, because the necessary information is unavailable for devices. The analysis is based on publicly available information. The data involve fundamental aspects of the pharmaceutical industry that are reported and compiled for purposes having nothing to do with liability. The model is grounded in extensive literature on investment evaluation in the face of risk.

25 Throughout, we use the term incentive to connote an evaluation of the profit potential associated with an investment. To arrive at an investment decision, this incentive is compared to the cost of the investment.

26 Incorporating uncertainty and risk in investment evaluation by adjusting the discount rate cannot be rigorously justified or rationalized from an economic point of view. (See, for example, Sugden and Williams, 1978, pp. 61-63.) It is employed here as a predictive tool, because it is common in practice (see below) and is relatively simple.
The remainder of this subsection describes the method in some detail. This description should allow interested readers to judge the validity of the approach and the reliability of quantitative inputs, and to replicate or modify the analysis.

As discussed in Section 3, the innovation process involves numerous decisions, and to reach the market, a product must clear hurdles at various decision points. These involve diverse decisions discussed in Sections 2 and 3. Two decisions are whether to commence clinical trials for a compound that has been identified as promising and whether to launch a product in the United States (assuming that FDA approval is obtained). For concreteness, the discussion that follows focuses on these two decisions. It begins by laying out the method for projecting profit profiles, then explains how risk is taken into account, discusses choices of discount rates, and concludes with an explanation of how delay enters the model.

**Projected Profit Profiles**

The goal is to represent the expected profit levels over time that a company might project for a drug that it is considering developing or introducing. Data on the profitability of individual drugs are proprietary, but they may be approximated for present purposes as follows.

Recall that products that do reach the U.S. market typically experience a distinctive sales profile, illustrated in Figure 3.1. The profiles in Figure 3.1 are for three drugs: an unusually successful product (top decile), a moderately successful product (third decile), and a product whose performance placed it in the middle of the sales distribution (median product). The analysis uses these sales profiles because products in the top half of the sales distribution are the ones that seem most relevant to R&D decisions. Specifically, unless a product is projected to be at least average in terms of sales performance, a company is unlikely to be willing to invest in its development.28

The sales profiles were adjusted—as explained presently—to represent annual expected profit levels using methods employed by Grabowski and Vernon.

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27 Data on foreign sales for individual products are unavailable. As becomes clear below, for our purposes the lack of foreign data introduces inaccuracies only to the extent that time patterns of profits differ between foreign and U.S. markets.

28 For example, Grabowski and Vernon (1990, Figure 9) indicates that a third-decile product barely returns R&D cost averaged over products that succeed in reaching the market and that the median product returns about half that cost. As a product gets closer to market introduction, however, more of its investment costs are sunk and, therefore, irrelevant to future investment decisions. In the few instances in which products in the lower half of the sales distribution seem relevant, the discussion takes this into account. (See, for example, the discussion of Proposition 9.6.)
(1990). Profits during the marketing years are the sales revenues net of various costs incurred during those years. Manufacturing and administrative costs are assumed in the simulations to equal 60 percent of sales in all years, which is in the range typically considered plausible. In addition, reflecting IMS audit data and following Grabowski and Vernon, especially large promotional expenditures in the first three years of marketing were built in to represent the costs of product launches. In particular, it is assumed that additional promotional expenditures are 100 percent, 50 percent, and 25 percent of sales in the first, second, and third years during which a product is marketed, respectively.

Figure 9.1 illustrates the resulting profit profiles, and Table 9.1 presents them numerically. The losses evident in the first two years of marketing reflect the

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29 They focused on the profitability of pharmaceutical R&D projects, so accurate depiction of the absolute levels of profits was critical in their study. As becomes clear below, the results of the simulations here are insensitive to the absolute levels of profits. The key issue for our purposes is accurately depicting the shape of the profit profile over time for products that might be developed and marketed. The fact that the simulations employ data from products first marketed from 1962 to 1977—i.e., those studied by Joglekar and Paterson (1986)—is of concern only to the extent that time patterns of sales will be different in the future.

30 Note that these profit profiles ignore costs incurred before a product is marketed. These earlier costs are investment costs and enter the analysis later.

Table 9.1
Annual Profit Levels Used in the Simulations
(Millions of 1987 dollars)

<table>
<thead>
<tr>
<th>Year from Market Intro</th>
<th>Product Median</th>
<th>Third Decile</th>
<th>Top Decile</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>-0.67</td>
<td>-3.89</td>
<td>-5.99</td>
</tr>
<tr>
<td>2</td>
<td>-0.15</td>
<td>-0.74</td>
<td>-3.83</td>
</tr>
<tr>
<td>3</td>
<td>0.28</td>
<td>1.23</td>
<td>5.91</td>
</tr>
<tr>
<td>4</td>
<td>0.89</td>
<td>3.64</td>
<td>16.21</td>
</tr>
<tr>
<td>5</td>
<td>1.04</td>
<td>4.00</td>
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<tr>
<td>6</td>
<td>1.18</td>
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<tr>
<td>21</td>
<td>0.63</td>
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<td>0.39</td>
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<td>0.00</td>
<td>10.06</td>
</tr>
</tbody>
</table>

large promotional costs associated with product introductions. Otherwise, the shape and duration of these profiles are identical to the sales profiles in Figure 3.1. These expected profit levels are interpreted as incorporating expected liability costs associated with the product.

Expected liability costs can influence incentives to innovate, because such costs reduce expected profits. These costs are not emphasized in the simulations, which focus on the effects of liability risk. This is because the effects of expected liability costs on incentives to innovate can be assessed in a relatively straightforward manner. Suppose, for example, that in each year expected liability costs are judged to be 5 percent of projected profits; then, this aspect of liability potential reduces incentives to innovate by 5 percent.\(^{32}\) The effects of

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\(^{32}\) More generally, if expected liability costs are a fixed percentage of expected profits, the adjustment to the present value calculation enters linearly. A more elaborate treatment of expected
liability risk on these incentives are less intuitive and less straightforward to assess quantitatively.

**Accounting for Risk**

As discussed in Section 4, there are numerous, major uncertainties affecting investment decisions in pharmaceuticals. But—at least for some products—liability risk is unique in that the worst-case scenario is much worse than losing an entire product-specific investment. The quantitative analysis here produces estimates of the extent to which unusual liability risks associated with a product—liability risks in excess of average liability risks for all drugs—reduce incentives for innovative efforts aimed at it and thereby tend to affect the mix of innovative efforts.

In the simulations, risk is taken into account in the manner that appears to be most common in quantitative investment evaluation: applying a higher discount rate (r) for more risky investment projects and considering the sensitivity of the investment incentive to choice of discount rate.\(^3\)\(^3\) Increasing the discount rate to reflect additional risk leads to a smaller calculated present value and thereby quantitatively incorporates in the investment evaluation the degree of risk and the distaste for risk.\(^3\)\(^4\)

The component of a discount rate that represents the cost of delay, ignoring risk, is often called the pure or riskless discount rate. The component that accounts for riskiness is called the risk premium. For riskier investments, a higher risk premium is used.

To decide whether to proceed with clinical trials, the company would adjust the present values of profits projected for the marketing years to reflect the probability that the product will reach the market, and this figure would be

liability costs, while possible, seems not to add insights commensurate with the attendant complications. Various scenarios about the timing of expected liability costs are plausible, but none seems of particular interest. Readers wishing to pursue this issue could use the data in Table 9.1 to do so.

\(^3\)\(^3\) Using a higher discount rate to take account of additional uncertainty or risk is standard fare in business curricula. (For example, Weston and Brigham, 1982, Chs. 13-14.) Gitman and Forrester (1977) and Gitman and Mercurio (1982) surveyed business decisionmakers and found that this is the most common quantitative procedure for incorporating risk in investment evaluation and that sensitivity analysis is also widely employed.

\(^3\)\(^4\) Such behavior is common and may be at odds with the prescriptions of modern finance theory, according to which diversifiable risk should be irrelevant to decisionmakers at publicly held companies. Specifically, much liability risk may be undiversifiable (see Section 7), but managers also may care about and react to diversifiable risk even if their stockholders do not.
compared with the present values of expected costs of clinical trials.\textsuperscript{35} The costs of clinical trials were discussed in Section 3. In the case of the product introduction decision, all of the development costs have been incurred, and the costs of product launch are built into the profit profiles, because they occur during marketing years. Thus, the investment rule for product introductions is: Invest if and only if the discounted profit profile is greater than zero.

\textit{Choosing Baseline Discount Rates}

What discount rates are appropriate for our purposes? This involves both choice of a baseline rate for each decision and the amount that the discount rate should be increased to represent unusual liability risk. These issues are taken up in turn.

Conceptually, an appropriate discount rate for a project is the annual cost to the company of raising the capital required to finance it. Since all profit figures are expressed here in real (i.e., constant-dollar or inflation-adjusted) terms, the appropriate discount rate is a real annual cost of capital (i.e., net of financing cost due to expected inflation). DiMasi et al. (1991) and Grabowski and Vernon (1990) argue for a real annual cost of capital of 0.09 for pharmaceutical companies.\textsuperscript{36}

Conceptually, this 0.09 figure incorporates the following: (a) the pure or riskless cost of capital, plus (b) the average over all investment projects of pharmaceutical companies of the risk premiums associated with those projects. Liability risk is likely to be a relatively small component of project risk for most projects.

Some investment projects are much riskier than others. Investments in clinical trials will typically involve more risk than investments in product introductions. Choices of baseline discount rates for the two decisions should reflect this difference.

Choosing baseline discount rates requires judgment and leaves much room for disagreement. In response, the analyses are performed and results are reported for a wide range of baseline discount rates to allow consideration of the sensitivity of the conclusions to the choice of baseline discount rate.

\textsuperscript{35} The adjustment to reflect the probability of not reaching the market, which is not reflected in the tables, would have no effect on the proportionate effects on present values on which the conclusions here are based. In particular, the numerical results in Tables 9.3 to 9.5 would be identical if projected profit levels for every year were scaled up or down by the same proportion.

\textsuperscript{36} As they report, pharmaceutical companies are financed almost entirely with equity, and the 0.09 figure is their estimate of the cost of equity capital in the industry. The estimate is based on a capital asset pricing model and stock return data for years between the mid-1970s and the mid-1980s for "a representative sample of pharmaceutical firms." (Grabowski and Vernon, 1990, p. 807.) OTA (1993), which was published as the present study was being finalized, concludes that this 0.09 figure may be too low by roughly 0.01.
Determination of the plausible range of baseline discount rates for investments in product launches and clinical trials is based on the following considerations. First, the average real discount rate for the industry, 0.09, reflects averaging over all investments of pharmaceutical companies. On average, investments in product development are considerably more risky than investments in the production and marketing of existing products. Thus, the average discount rate for non-R&D investments is below 0.09, and the average for all R&D investments is above 0.09.  

Riskless investment involves a real cost of capital of about 3 percent per year, corresponding to a discount rate of 0.03. Since even non-R&D investment involves risks, the average discount rate for non-R&D investment may be presumed to be at least 0.05. Examination of publicly available income statements of various major pharmaceutical companies suggests that expenditures on production and marketing account for roughly two and one-half times expenditures on R&D. Thus, if the average discount rate for all non-R&D investments were 0.05, an average discount rate for R&D investments of 0.19 would be implied by the average discount rate of 0.09.

But product introductions are among the more risky non-R&D investments. Thus, the appropriate baseline discount rate for product launches should be above 0.05—in the discussion of the results for this decision, \( r = 0.07 \) is used. To be on the safe side, however, calculations are performed and reported for baseline discount rates as low as 0.05. Clinical trials are among the least risky R&D investments, and most R&D expenditures involve preclinical activities. Thus, the appropriate baseline discount rate for investments in clinical trials should be considerably below 0.19—in the discussion of these results, \( r = 0.12 \) is used. To be on the safe side, however, calculations are performed and reported for discount rates as high as 0.20.

**Choosing Liability Risk Premiums for the Discount Rate**

Even though it is very commonly employed, the procedure of increasing discount rates to reflect additional risk cannot be justified in a rigorous manner. Companies seem to consider in a rather ad hoc fashion the sensitivity of

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37 See OTA (1983, pp. 279-280) for a related discussion.
38 For example, over the past three decades, the average annual real yield on 10-year Treasury securities is a little under 3 percent.
39 D'Amato et al. (1991, p. 124) report a figure of 66.1 percent for the proportion of all R&D expenditures incurred in preclinical activities.
calculated present values to increasing the discount rate. There is a special case, however, in which the mathematical procedure of incorporating a risk premium in discounting can be rigorously justified. Considering this case provides an explicit—albeit indirect—means of gauging how much a discount rate might be increased to reflect unusual liability risks in particular circumstances.

In the special case, the only uncertainty associated with an investment project is the possibility in each year that the project will fail—i.e., starting in that year and for all subsequent years, the return from the project will be exactly zero. Suppose, in addition, that the project fails in any year with a constant probability equal to $p$. Use of a risk premium of $p$ is mathematically defensible for incorporating the uncertainty about the survival of the project.

Thus, we may approach the question of the sizes of the discount rate premiums relevant to liability risks as follows. Consider the extent of unusual liability risk perceived to characterize a decision of interest and how discouraging a decisionmaker would find it. Then consider the annual probability of failure of the project that the decisionmaker would consider equally discouraging. This probability may then be taken to be the appropriate risk premium associated with the liability risk under consideration. For example, if a company would be just willing to accept a 2 percent chance of product failure (in the sense defined above) every year to avoid the unusual risks associated with product liability, it would be appropriate to increase its discount rate by 0.02 to adjust the present value calculation to take account of this risk.

For our purposes, a discount rate premium of 0.02 appears conservative for some products. Recall that, for some products, the liability risk at issue includes the possibility of a mass tort and that the worst-case scenario is much worse than losing all of the potential profits from the product—much worse than "failure" of the product. While a mass tort would generally be considered unlikely, for some products a decisionmaker would rather face an additional annual probability of project failure of at least a few percentage points than accept the unusual liability.

40For example, one might consider how high the discount rate must be before the present value of expected profits falls below the present value of investment costs. (This is the "internal rate of return" of a project.) Decisionmakers then consider whether this critical discount rate seems to be greater or smaller than the appropriate discount rate.

41Discussion of this case and the basis for interpreting risk premiums is based on Sugden and Williams (1978, pp. 60-61).

42No other explicit basis is apparent. However, readers experienced in investment evaluation and familiar with adjustments made for other risks may find that familiarity useful to consider this central issue.
risks associated with the products. On this basis, the simulations consider a range of risk premiums associated with liability from 0.01 to 0.04. Even larger risk premiums seem plausible for some products, but confining ourselves to the range suffices to provide the lessons available from using even higher ones.

**Accounting for Delay**

In the case of the product introduction decision, it is assumed that if the company decides to proceed with product launch, the profit profiles depicted in Figure 9.1 would commence beginning the following year. Thus, the marketing period relevant to the product introduction decision is taken to be from the present to a time horizon of 24 years.

The delay in the case of the clinical-trial decision is considerably longer. According to DiMasi et al. (1991, p. 123), among drugs eventually achieving FDA approval, the average elapsed time from the beginning of clinical testing to the time of FDA approval is about eight years. Thus, in the simulation of incentives to begin clinical testing, it is assumed that, if the company proceeds and if the product does succeed in reaching the market, the annual profits depicted in Figure 9.1 would commence in the ninth year after the clinical-trial decision is to be made. In the case of the clinical-trial decision, then, the relevant marketing period commences about a decade after the decision and is roughly two decades long. This extra delay and longer time horizon are important considerations in the investment decision concerning the commencement of clinical trials.

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43 Additional perspective can be developed by thinking in terms of insurance. People often pay a fixed number of dollars to induce an insurance company to assume their risks. Here, a company is imagined to accept a higher probability of project failure to eliminate its unusual liability risk.

44 Recalling the characterization of liability potential proposed in Section 5, a product of average liability risk—and thus calling for no premium in the discount rate—might involve perceptions of a very small probability of moderate liability costs and a likelihood of disaster so small that it is not even considered. A premium of 0.01 might correspond to a case where moderate costs seem somewhat plausible, and disastrous liability costs are almost inconceivable but salient enough for the possibility to be noticed by decisionmakers. A premium of 0.04 might be appropriate if moderate costs are more than plausible and disastrous costs seem plausible, but still quite unlikely.

45 For example, products for conditions specific to pregnancy. If a company refuses even to consider such a product, it is implicitly acting as if the appropriate discount rate is infinite. No matter how high the expected profits and how low the investment costs, the company could not be induced to invest in such a product because the risk of disaster is simply unacceptable.

46 That is, the company would expect losses next year and the following year and would start earning positive profits beginning three years from the time that the introduction decision is to be made.

47 More precisely, 98.9 months.

48 In fact, as discussed in Section 3, the part of this time interval during which the approval application is pending at the FDA—estimated as 30.3 months in the DiMasi et al. (1991, p. 123) study—has been widely criticized as an important disincentive to innovation and has received considerable attention in the policy arena.
Effects on Company Incentives: Results

Table 9.2 reports present values of the three profit profiles in Table 9.1 corresponding to the time horizons relevant to each of the two decisions. Present values are calculated for each of the six corresponding time profiles for profits using annual discount rates from 0.05 to 0.20. For example, using the industry average discount rate of 0.09 leads to a present value of 9.95 million 1987 dollars for the expected profit profile associated with the median product if that profit stream were to begin one year in the future—the time horizon relevant to the product introduction decision. If that stream were to begin eight years later—the time horizon corresponding to the clinical trials decision—the present value (still using 0.09) falls to just under $5 million. The difference here is attributable entirely to the eight-year difference in delay involved. The effect of liability risk on the incentives to proceed with such investments depends on the baseline discount rate and the increment in the rate appropriate to the degree of liability risk perceived for the product under consideration. The information in Tables 9.3 and 9.4 is derived from Table 9.2 and expresses the sensitivity of the calculated present values in proportionate terms. Table 9.5 compares decreases in R&D incentives from liability risks with those from delay in FDA approval. One proposition is drawn from each table.

Table 9.2

Present Values of Profit Profiles for the Product Introduction and Clinical-Trial Decisions
(Millions of 1987 dollars)

<table>
<thead>
<tr>
<th>Discount Rate</th>
<th>Product Introduction Decision</th>
<th>Clinical Trials Decision</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Median</td>
<td>Third Decile</td>
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<tr>
<td>0.05</td>
<td>15.52</td>
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<td>0.06</td>
<td>13.84</td>
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<td>0.07</td>
<td>12.37</td>
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<tr>
<td>0.08</td>
<td>11.08</td>
<td>25.36</td>
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<tr>
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<td>9.95</td>
<td>23.02</td>
</tr>
<tr>
<td>0.10</td>
<td>8.96</td>
<td>20.92</td>
</tr>
<tr>
<td>0.11</td>
<td>8.08</td>
<td>19.04</td>
</tr>
<tr>
<td>0.12</td>
<td>7.30</td>
<td>17.35</td>
</tr>
<tr>
<td>0.13</td>
<td>6.61</td>
<td>15.83</td>
</tr>
<tr>
<td>0.14</td>
<td>6.00</td>
<td>14.45</td>
</tr>
<tr>
<td>0.15</td>
<td>5.45</td>
<td>13.20</td>
</tr>
<tr>
<td>0.16</td>
<td>4.96</td>
<td>12.08</td>
</tr>
<tr>
<td>0.17</td>
<td>4.52</td>
<td>11.05</td>
</tr>
<tr>
<td>0.18</td>
<td>4.13</td>
<td>10.11</td>
</tr>
<tr>
<td>0.19</td>
<td>3.77</td>
<td>9.26</td>
</tr>
<tr>
<td>0.20</td>
<td>3.46</td>
<td>8.48</td>
</tr>
</tbody>
</table>
Proposition 9.3: The incentive to introduce a product that has already been developed is sensitive to unusual liability risks. For example, liability risks as discouraging as a 1 percent annual probability of product failure reduce this incentive by about 10 percent. Unusual liability risks as discouraging as a 4 percent annual probability of product failure reduce the incentive for product introduction by about one-third.

Table 9.3 presents results for the product introduction decision. The data in the table report the proportionate decrease in the calculated present value for the indicated profit profile, baseline discount rate, and increment in the discount rate. For example, consider increasing the discount rate by 0.03 starting from a baseline discount rate of 0.06 for the third decile product. As indicated in the table, this increase in the discount rate decreases the calculated present value by 25.6 percent of its value for the baseline rate. As discussed above, a baseline discount rate of 0.07 is plausible for the product-introduction decision. For that base rate, unusual liability risk suggesting risks premiums of 0.01, 0.02, 0.03, and 0.04, respectively, imply decreases in incentives for product introduction of about 10 percent, 18 percent, 26 percent, and 33 percent for the three profit profiles. The higher the baseline discount rate, the less sensitive the present value calculation is to an increment of any particular size. But examination of the table indicates that the results are not very sensitive to choice of baseline discount rate.

Proposition 9.4: The incentive to invest in clinical trials is even more sensitive to liability risks than the incentives to introduce a product that has already been developed. For example, unusual liability risks as discouraging as a 1 percent annual probability of product failure reduces the incentive to invest in clinical trials by about 15 percent. Unusual liability risks as discouraging as a 4 percent probability of product failure reduce this incentive by about one-half.

Table 9.4 is set up the same way as Table 9.3. The results here pertain to how incentives to invest in clinical trials depend on the degree of liability risk. Because of the longer delay between this decision and the time that profits might

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49 This figure can be derived from Table 9.2 as follows: \((30.93 - 23.07)/30.93 = 0.256\) (after rounding).

50 The results are rather insensitive across the three profit profiles, because their shapes over time are quite similar. This illustrates the claim that the results—when expressed in terms of proportionate sensitivity—are insensitive to proportionate rescaling of the profit profiles. There would be no difference at all for the different profit profiles if they were, in fact, exactly proportional to each other.

51 For example, consider the median product and an increment of 0.02 in the discount rate. A baseline annual discount rate of 0.05 involves a 20 percent decrease in the calculated present value, while a baseline rate of 0.18 yields a 16 percent decrease.
Table 9.3

Sensitivity of Present Values for Introduction Decision to Discount Rate Changes

<table>
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<tr>
<th>Baseline Discount Rate</th>
<th>Product: Median</th>
<th>Third</th>
<th>Top</th>
<th>Product: Median</th>
<th>Third</th>
<th>Top</th>
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<th>Third</th>
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<td></td>
<td></td>
<td>Discount Rate up 0.02</td>
<td></td>
<td></td>
<td>Discount Rate up 0.03</td>
<td></td>
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<td>Discount Rate up 0.04</td>
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</tr>
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### Table 9.4

Sensitivity of Present Values for Clinical-Trial Decision to Discount Rate Changes

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<th>Baseline Discount Rate</th>
<th>Product: Discount Rate up 0.01</th>
<th>Product: Discount Rate up 0.02</th>
<th>Product: Discount Rate up 0.03</th>
<th>Product: Discount Rate up 0.04</th>
</tr>
</thead>
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<td>0.149</td>
<td>0.143</td>
<td>0.133</td>
<td>0.273</td>
</tr>
</tbody>
</table>
be earned, the relevant present values for a given baseline discount rate are even more sensitive to a given increment in the discount rate than the present values relevant to the product-introduction decision.\textsuperscript{52}

As discussed above, however, the appropriate baseline discount rate for the R&D decision is higher than that for the product-introduction decision. This difference tends to attenuate the degree to which incentives to proceed with clinical trials are more sensitive to a particular increment in the discount rate. For example, consider a plausible baseline discount rate of 0.12 for the clinical-trial decision. From that baseline rate, increases of 0.01, 0.02, 0.03, and 0.04 reduce the incentive to invest in clinical trials by about 15 percent, 28 percent, 39 percent, and 48 percent, respectively, for each of the profit profiles.\textsuperscript{53} Thus, incentives for investments in clinical trials appear to be substantially more sensitive to the introduction of a risk premium of a given size.

As illustrated in Tables 9.3 and 9.4, risk premiums in the range of 0.01 to 0.04 can have substantial effects on the incentive to invest in innovative activities. Additional perspective on the sizes of these disincentives is provided in Table 9.5. This table reports estimates of disincentives for pharmaceutical R&D associated with an issue that has received considerable attention in policy discussions and recent policy reforms: delays in FDA approvals of NDAs.\textsuperscript{54}

Recall that, in recent years, the average interval from filing the NDA to FDA approval was roughly 31 months for drugs that eventually received approval. An increase of one year in this figure would represent a very considerable deterioration of the situation and would be widely viewed as leading to a troublesome disincentive to new drug development.

The figures in Table 9.5 compare the disincentive effects of an additional year of FDA approval time to the disincentive effects of a risk premium of 0.01 for the various baseline discount rates.\textsuperscript{55} These figures indicate that, for all baseline discount rates below 0.17, the disincentive effect of a risk premium of 0.01 is greater than the disincentive associated with an extra year of delay. For the

\textsuperscript{52}For example, for the baseline discount rate of 0.07 discussed under Proposition 9.3, increments of 0.01, 0.02, 0.03, and 0.04 in the discount rate imply decreases in incentives for investments in clinical trials of about 16 percent, 30 percent, 46 percent, and 59 percent (as compared with 10 percent, 18 percent, 26 percent, and 33 percent for investment in product introduction).

\textsuperscript{53}As with the product-introduction decision, the results are quite insensitive to rather large changes in the choice of the baseline discount rate. Even for a baseline discount rate of 0.16—which seems implausibly high—the calculated disincentives to invest in clinical trials are only about one percentage point smaller.

\textsuperscript{54}See Section 3.

\textsuperscript{55}An additional year of FDA delay is simulated by increasing from eight years to nine the assumed lag between the beginning of clinical trials and the time of market introduction.
Table 9.5
Comparison of Uncertainty and Regulatory Lag Effects on Incentives to Begin Clinical Trials

<table>
<thead>
<tr>
<th>Baseline Discount Rate</th>
<th>Proportionate Decreases in Present Value</th>
<th>Extra Year of Delay</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Product: Median</td>
<td>Third</td>
</tr>
<tr>
<td>0.05</td>
<td>0.173</td>
<td>0.163</td>
</tr>
<tr>
<td>0.06</td>
<td>0.171</td>
<td>0.161</td>
</tr>
<tr>
<td>0.07</td>
<td>0.168</td>
<td>0.159</td>
</tr>
<tr>
<td>0.08</td>
<td>0.167</td>
<td>0.157</td>
</tr>
<tr>
<td>0.09</td>
<td>0.162</td>
<td>0.155</td>
</tr>
<tr>
<td>0.10</td>
<td>0.160</td>
<td>0.154</td>
</tr>
<tr>
<td>0.11</td>
<td>0.160</td>
<td>0.151</td>
</tr>
<tr>
<td>0.12</td>
<td>0.156</td>
<td>0.151</td>
</tr>
<tr>
<td>0.13</td>
<td>0.157</td>
<td>0.148</td>
</tr>
<tr>
<td>0.14</td>
<td>0.152</td>
<td>0.148</td>
</tr>
<tr>
<td>0.15</td>
<td>0.152</td>
<td>0.148</td>
</tr>
<tr>
<td>0.16</td>
<td>0.146</td>
<td>0.144</td>
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<tr>
<td>0.17</td>
<td>0.147</td>
<td>0.146</td>
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<tr>
<td>0.18</td>
<td>0.145</td>
<td>0.145</td>
</tr>
<tr>
<td>0.19</td>
<td>0.149</td>
<td>0.143</td>
</tr>
</tbody>
</table>

The baseline rate of 0.12, the disincentive effect associated with the risk premium of 0.01, is almost 50 percent greater than that associated with the additional delay. The implication is as follows:

*Proposition 9.5:* Unusual liability risk for a product as discouraging as a 1 percent annual probability of product failure may reduce the incentive to invest in clinical trials by more than would an additional year of expected delay in the FDA approval process.

**Effects on Innovation Decisions**

Thus, incentives to develop or introduce products may be substantially attenuated by unusual liability risks associated with them. But incentives, per se, are not the concern—it is the behavior that results. Whether product liability risk deters a specific investment depends on the cost of the investment under consideration; the level of the present value of expected profits, ignoring unusual liability risks; and how much the adjustment for unusual liability risk reduces this incentive. Our analysis to this point has focused on the last of these. Considering the first two allows us to address the investment decisions.
Proposition 9.6: Product liability risk may not often deter market introduction of a product that has already been developed.

The costs of product launch are built into the profit profiles. According to our investment model, to deter product introduction, the adjustment in the discount rate to reflect liability risk would have to cause a discounted profit profile to become negative. Inspection of Table 9.3 indicates that none of the discount rates considered is sufficiently high for this to happen. In fact, for the three profit profiles considered to this point, the discount rates would have to be implausibly high to imply a negative discounted value.56

This does not imply, however, even within our discounted projected profits model, that liability potential cannot deter introduction of products with such sales potential. For example, at the time of the decision, expected liability costs might be large enough to deter market introduction of a product expected to be an above-average (median) performer.

Moreover, unusual liability risk might deter introduction of products with less sales potential than a median performer. Recall that, in the simulations, we focus on sales profiles at least as encouraging as the median profile, because companies would not be expected to invest in the development of products with less-encouraging projected sales. Suppose, however, that a company—expecting a large market—does develop a product, but by the time it is developed, market prospects have diminished (e.g., because in the interim a competitor has succeeded in developing a similar product). Here, the firm may have to decide whether to introduce a product with quite limited market prospects. As illustrated above, the discount rate for which a calculated present value becomes negative appears to be lower for products with less projected market potential; thus, unusual liability risk may deter introduction of such a product.

The remaining propositions pertain to differences across products in the effects of liability risk on R&D investment.

Proposition 9.7: Liability risks that are far from extreme can deter R&D investments in products with limited profit prospects.

For example, consider a liability risk premium of 0.01 in the discount rate. This corresponds to a product for which a company would accept an additional annual probability of product failure of 0.01 to eliminate the liability risk above

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56 Specifically, to make the present values of the profit profiles negative for the introduction decision, the discount rates would have to be roughly 0.5, 0.65, and 0.8 for the median, third-decile, and top-decile products, respectively.
the average level for the industry. This is seemingly not an extreme amount of liability risk. Discount rate premiums of 0.01 reduce the calculated incentives to begin clinical trials by about 15 percent. For products with projected profits barely sufficient to warrant investment in clinical trials, ignoring unusual liability risks, even this small a risk premium could be sufficient to deter a company from proceeding.

Recall from Section 6 that there are few apparent examples of developed products that have been deterred from market introduction because of product liability. Proposition 9.6 is consistent with this observation. But more important, Propositions 9.6 and 9.7 in combination indicate that the apparent rarity of deterrence of product introductions should not be taken as evidence that deterrence of product development is rare.

Proposition 9.8: Even very substantial liability risks may be insufficient to deter investments in developing products that are viewed as potential blockbusters.

The present value of expected profits, ignoring liability risk, represents the perceived or projected market potential of a product. A potential blockbuster has enormous profit potential. The top performers in the industry have achieved $1 billion a year in worldwide sales, and the annual profits associated with such a product may be on the order of one-half of this figure. For a product believed to have this kind of profit potential, even a large proportionate reduction in the investment incentive is unlikely to deter a company from proceeding.57

But there are two more or less plausible scenarios under which a blockbuster might, in fact, be lost because of liability. The first is the situation discussed in the beginning of this section: a product that is perceived as so risky in terms of liability that a company would refuse even to consider development efforts targeted there. It has been argued that products for pregnant women are the

57 A feel for the magnitudes can be developed as follows. Suppose that the profit profile for a blockbuster had the same shape as the top-decile profile in Table 9.1, but the blockbuster’s projected profits were to peak at $500 million (in year 7). Rescaling the entire top-decile profit profile proportionately (i.e., by a factor of 38.5) and using Table 9.2, the present value of expected profits—assuming that the product will succeed in reaching the market—revenue to the clinical-total phase (for r = 0.22) would be over $880 million. Multiplying this by 0.23 to represent the fraction of drugs that enter clinical trials that succeed in reaching the U.S. market, we arrive at an expected present value of expected profits of about $200 million—before adjusting for liability risk. Liability risk associated with a discount rate premium of 0.04 will reduce this figure by about 50 percent, but it would still be more than five times the present value of the cost of clinical trials suggested by the DiMasi et al. (1991) study (which would be somewhat less than the total out-of-pocket cost of the three phases of clinical trials of roughly $20 million). These calculations suggest, then, that the discount rate premium would have to be well above 0.04, or the cost of the anticipated clinical trials well above the average figures reported by DiMasi et al. (1991), for liability risk to deter a company from proceeding with clinical trials for a product that was expected to be a blockbuster.
leading, and perhaps sole, plausible example here. In addition, a blockbuster might be lost because a company was deterred from a line of research that did not appear to offer a potential blockbuster. This is plausible because development efforts that are aimed at one therapeutic area can lead to a product useful in another area.

Proposition 9.9: Innovative efforts are more likely to be deterred for products perceived to involve more substantial product liability risks, holding profit prospects and investment costs constant. These include the stereotypical products—vaccines, contraceptives, and products for pregnant women—but may also include products that pose substantial safety risks, products for healthy patients, treatments for relatively minor conditions, the first treatment for a condition, products for chronic conditions, and products with unusually large numbers of users.

This list of product attributes that may be perceived to engender considerable liability risks is based of the analysis in Section 4.58 All other things being equal, these characteristics would tend to discourage development efforts. However, many of these characteristics would also tend to be associated with substantial profit prospects, for example, large numbers of users, being first in the market, and treatments for chronic ailments. Again, if the profit projections are very encouraging, companies are less likely to be deterred from attempting to develop or market a product.

Conclusion

The most important of liability’s effects on innovation may be on the composition of innovative effort across product areas. The economics of the industries impels research-based companies to invest heavily in innovative efforts, but product liability is likely to discourage innovative efforts in products areas that are perceived to involve substantial liability potential.

58The most extensive discussions (of which the author is aware) of product liability effects on innovation in the industries under study are Lasagna (1991) and OTA (1993, Ch. 7), both of which focus on pharmaceuticals. The former review emphasizes treatments for pregnant women, vaccines, and orphan drugs. But he writes: “Although this chapter does not specifically address the issues of birth control or medical devices, it is generally agreed that product liability is a serious disincentive to research and development in these areas as well.” (Lasagna, 1991, p. 335.) His summary conclusion is that “the magnitude and uncertainties involved in product liability litigation serve to discourage certain kinds of pharmaceutical research, development, and marketing.” (Lasagna, 1991, p. 355.) OTA (1992, p. 179) emphasizes contraceptives, drugs taken during pregnancy, and (especially AIDS) vaccines. It concludes that “anecdotal evidence suggests liability concerns may significantly inhibit the overall level of industrial R&D effort in these areas.” (OTA, 1993, p. 182.) The analysis offered in the present section adds to these views by providing a quantitative assessment and by suggesting (relying on the analysis in Section 8) other types of innovation that may be affected.
The quantitative significance of expected liability costs for such products is relatively easy to gauge. For example, if expected liability costs are estimated at some fixed percentage of annual profits, incentives to invest in the product are depressed by that percentage.

While effects operating through expected liability costs can be important, the effects of liability uncertainty and risks may be even more substantial. These cannot be gauged as simply. The simulations presented here focus on this issue using a standard—and necessarily highly structured—model of investment evaluation. The results suggest that incentives to innovate can be very sensitive to liability uncertainty and risk.

Whether any particular decrease in incentives deters a specific innovative activity depends on the perceived profit potential of that activity. The discussion has emphasized that even very substantial degrees of liability risk are likely not to deter investments in products perceived as potential blockbusters. In contrast, much smaller degrees of liability risk may deter an investment that is attractive otherwise.

What can we say about the key medical and economic questions? If product liability deters innovative effort, would this tend to affect especially important medical innovations or ones of relatively minor importance? How well do effects on innovation correspond to the social benefits and costs of efforts to develop various kinds of products?

Definitive answers are impossible, but the analysis provides several clues. To the extent that especially valuable medical innovations can be expected to be rewarded with very large profits, product liability is unlikely to deter such innovations. Products with less market potential are more vulnerable to a given degree of liability potential. A drug that does not appear to be a potential blockbuster, or is merely marginal in terms of projected profitability, may nonetheless be worth developing from a social point of view. For example, vaccines are widely believed to be among the most socially valuable medical products, but are also widely believed not to be very profitable. An orphan drug is at the opposite end of the spectrum from a blockbuster—the rarity of the condition for which it is useful implies that the market is very small. The possibility that liability discourages efforts to develop such drugs is reasonably viewed as only one of many major impediments to their availability.

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50 See, for example, IOM (1985) and Lasagna (1991, pp. 341–342).
Part III

Implications for Policy

The final section develops lessons concerning how changes in liability policy might improve the economic performance of the pharmaceutical and medical device industries. These lessons stem from a combination of the conclusions about company responses to liability and theoretical economic perspectives on how liability might in principle promote efficient company decisions. The analysis leads to two types of lessons for liability policy in the pharmaceutical and medical device industries: (a) general guidance concerning appropriate goals for and pitfalls of economically focused policy reforms, and (b) implications concerning specific issues that receive substantial attention in the liability-policy debate. None of the policy reforms discussed is new. But the analysis here leads to an emphasis on only some of the issues that receive major attention and provides new perspectives concerning them. The analysis also leads to the conclusion that many issues that receive considerable attention are either not central to the concerns of this inquiry or cannot be usefully analyzed because a sufficient factual basis for doing so is lacking.
10. Economic Analysis of Liability Policy Reform

The motivation for this analysis is policy guidance. The issue is how product liability reforms would affect the economic performance—i.e., the economic efficiency—of the pharmaceutical and medical device industries. Pursuing the goal of economic efficiency means attempting to use resources in ways that are most valuable to society. It is helpful to think in terms of balancing social benefits and social costs.

A change in economic outcomes promotes economic efficiency only if the social benefits resulting from the change exceed the social costs. As emphasized in Section 8, particular economic effects of liability generally involve both social benefits and social costs. For example, if the safety of a particular product is enhanced in response to liability, there are social benefits of injury reduction. However, increases in safety generally require additional resources—e.g., for extra product development effort—and often require decreases in product effectiveness—e.g., because product availability is delayed.

Economic efficiency is not the only policy concern.¹ We focus on it to clarify the economic stakes in liability policy so that they may be taken into account in policy formulation.

The section contains six major subsections. The first reviews the major conclusions of Part II; this provides the basis for considering policy reform. The second and third provide an analytic framework for assessing the efficiency effects of product liability in the pharmaceutical and medical device industries. First, we consider how product liability would ideally promote economic efficiency, then we contrast that with how the current system works. The fourth subsection employs this framework to suggest economic perspectives to guide consideration of policy proposals. The fifth discusses economic implications of various classes of policy measures. The final section concludes the report.

The policy implications here cannot be presumed to apply to other industries: Our conclusions stem from aspects of the market, technological, regulatory, and legal environments of the pharmaceutical and medical device industries that do

¹Others may include compensation, justice, and adherence to legal precedent.
not characterize U.S. industry at large. Besides the degree to which they are regulated and the technologies of product development, drugs and devices seem unusual with respect to the presence of a physician between the manufacturer and the consumer, the typical degree of price competition, the private-sector importance of R&D competition, the social stakes in innovation, the difficulty of determining injury causation, and the potential for latent injuries. In addition, some aspects of the legal environment seem quite peculiar to these industries, such as comment k and the learned intermediary rule. Different conclusions drawn here follow from different combinations of such special aspects of the drug and device industries.

Economic Effects of the Prevailing Liability Environment: Summary

We have considered how product liability affects four broad sets of economic outcomes in the pharmaceutical and medical device industries: product availability, pricing, product safety and effectiveness, and innovation. Most effects are very uneven across products, and economic outcomes are best analyzed in terms of individual products or types of products. Some important questions have been answered, and others remain unanswered. These are reviewed below in turn.

What Can We Say About Economic Effects?

The available evidence supports the following conclusions:

Product Availability

- Some product withdrawals are attributable to liability, including some products with substantial support in the medical community. Other product withdrawals widely attributed to liability would probably have occurred anyway because of market and regulatory forces. These include some products whose safety costs appear to outweigh their effectiveness benefits. But liability probably hastened these withdrawals and thereby provided economic gains to society.

- It is likely that all liability-induced withdrawals of socially important products are known, with one possible class of exceptions: It is possible that companies have quietly withdrawn products causing latent injuries that have yet to become widely apparent.

- Some products whose safety costs appear to outweigh their effectiveness benefits have been marketed despite the existence of liability.
• Small, specialized companies may be more willing to develop and market products with substantial liability potential. This can avert or eliminate availability crises. But withdrawal of large companies may also reduce the scope for injury compensation and may attenuate the ability of liability to increase product safety when it is efficient to do so.

Pricing

• Liability appears to have reduced seller competition in some markets.
• Some major price increases are attributable to liability. For many products, however, price effects of liability are likely to be nonexistent or small.
• Liability-induced price increases will generally not effectively perform two socially useful roles often ascribed to them: providing adequate financing for compensation funds for injured product users and allowing more efficient purchase decisions by providing signals to consumers about safety.

Safety and Effectiveness

• Liability-induced changes in the chemical structures of drugs are likely to be the exception, not the rule.
• Liability may substantially reduce vaccine effectiveness and undermine economic efficiency by discouraging development and availability of live-virus vaccines.
• Liability may induce safer designs for many devices, and many such increases in safety may involve larger social benefits than costs.
• For almost all prescription drugs and devices, product liability generates powerful incentives for companies to inundate physicians with warnings about possible safety hazards and to provide no warning information designed for patients.
• Liability fortifies incentives to comply with FDA safety standards. To the extent that the rate of compliance is increased, economic efficiency is likely to be enhanced. For example, liability may deter companies from ignoring safety problems or concealing them from the FDA and thereby prevent marketing of inefficiently dangerous products or lead to more efficient labeling.
• Liability also creates incentives for manufacturers to exceed FDA safety standards. For drugs and extensively regulated devices, responses to these incentives are likely to undermine efficiency. However, for devices that have not been extensively reviewed by the FDA, many responses to these
incentives—such as improved designs or more extensive product testing—are likely to promote efficiency.

Innovation

- Some products may be viewed as so legally hazardous that companies would not even consider developing or marketing them. The most plausible example is products for conditions specific to pregnancy, some of which could represent efficient investments.

- Expected liability costs can substantially decrease incentives to innovate in particular product areas, but liability uncertainty and risk may be even more important. Whether dampening of incentives deters investments in particular innovation efforts depends on the sizes and profitability of the markets for products that might emerge. Liability is unlikely to deter efforts to develop products with apparent blockbuster potential. But liability can deter development efforts for socially valuable products that appear to offer more limited profit potential, and even a blockbuster can be lost if research is deterred only in areas that appear to offer only limited profit prospects.

Unresolved Issues

Many issues concerning economic effects of the prevailing liability system in drugs and devices are unresolved:

- The breadth of effects across product areas is unclear, largely because they depend on perceptions of decisionmakers and because many activities are proprietary. Pronounced effects are apparent in the areas of vaccines, contraceptives, and products for conditions specific to pregnancy. Since the potential for very large liability costs is not confined to these, there may be major effects in other product areas. This is particularly plausible for unobservable decisions, such as those involved in regulatory compliance and R&D activity.

- Liability may be important in deterring companies from ignoring or concealing safety problems to gain approval for U.S. marketing or to forestall withdrawal of approval, but no direct evidence of such effects is apparent.

- Although there is good reason to believe that product liability has selective, but pronounced, effects on incentives to innovate, very little direct evidence is available on how companies respond to these incentives in making decisions on investments in innovation.
• The analysis indicates the likely effects of liability on product design, but there is no direct evidence about such effects.

• The extent to which product labeling reflects liability incentives rather than other forces is unclear. Product safety and effectiveness—and efficiency—may be seriously undermined by two outcomes strongly encouraged by liability doctrine: the detailed nature of information provided to physicians and the lack of information for patients. However, the medical appropriateness of the different kinds of information for physicians and patients is controversial.

• While important effects on pricing in product areas that are not perceived to involve substantial liability potential seem implausible, no direct evidence concerning this issue is available.

There is potential to learn more about each of these issues, but the difficulties are very formidable in each case. Policymakers are likely to remain very uncertain about most if not all of these matters for a long time because most involve proprietary decisions or unobservable outcomes.

Theories of Efficient Liability Systems

The previous subsection suggests that the liability system has major socially advantageous effects, as well as major socially detrimental effects. This motivates consideration of reforms that might enhance the former and attenuate the latter.

To see how this might be accomplished, first consider how a product liability system would achieve economic efficiency under ideal conditions. Comparing the operation of the current liability system for drugs and devices to its operation under ideal conditions—as is done in the next subsection—provides an understanding of why the current liability system fails to produce economic efficiency and provides a basis for considering the types of reforms that would enhance efficiency.

The basic economic motivation for product liability is that injuries involve social costs that must be considered in determining efficient approaches to product

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2The discussion here applies prescriptive (or "normative") economic theories of product liability to the drug and device industries, relying on the empirical perspectives developed in previous sections. The literature includes many extensions of the basic theories outlined in the subsection, and many researchers have contributed to this literature. A particularly useful synthesis of the theoretical literature—on which the present analysis relies heavily—is Cooker and Ulen (1988, Chapters 8 and 9). Cooker (1991) provides a very useful account with almost no mathematics.
safety. However, companies cannot be expected to take account of social costs that they do not bear. Doing so would conflict with profit maximization. A liability system can alter company incentives and thereby induce efficient decisions.

A liability system is called efficient here if it induces decisions leading to outcomes that are economically efficient, i.e., decisions for which differences between social benefits and social costs are maximized. There are two approaches to designing an efficient liability system, strict liability and negligence; these alter company incentives using distinct strategies. We present an overview of each strategy, and then elaborate.

Under an efficient strict liability approach, a company pays damages equal to the social costs of injuries caused by its products. This is often called internalizing injury costs. A company is held liable for injuries caused by its products regardless of the reasonableness of its behavior, and it is irrelevant whether the injury was attributable to shortcomings in manufacturing, design, or warning. Strict liability leads to efficient decisions, because a company that bears the full social cost of injuries caused by its products takes these costs into account in formulating decisions to maximize profits. In sum, internalizing injury costs corrects the incentive problem that exists when injury costs are borne by others and induces efficient company decisions affecting safety.

There is another way to induce efficient company decisions. Under an efficient negligence approach, companies are held liable only for injuries caused by their failure to meet efficient standards of safety-promoting behavior. Standards of care (or precaution) are needed for all behavior bearing on product safety—in manufacturing, designing, testing, labeling, etc. If the damages paid because of failure to meet these standards—i.e., the penalties paid for negligence—are sufficiently large, it is more profitable for a company to meet the standards than to be negligent. Moreover, since there is no liability unless a company is negligent, liability provides no incentive to exceed the negligence standards in

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3The definitions of the terms strict liability and negligence here conform with those of economists and many, but not all, legal scholars. See the elaboration in footnote 5.

4What behavior is efficient in a particular context is case specific. However, a single general principle guides the determination: The efficient level of care in manufacturing, designing, testing, warning, or any other activity affecting product safety is the level at which the social costs of any additional care—attributable to using resources or making the product less effective—exceed the social benefits of the resulting additional safety. Our discussion emphasizes design and warning issues. In the design context, it generally takes extra engineering effort to make a design safer; it may be more costly to manufacture a safer design, but sometimes a safer product is less effective. The resource costs of adding warnings may often be very minor, as discussed in Section 8. Major issues in cost-benefit balancing for warnings are that additional warnings can (a) dilute the safety benefits of more important warnings (e.g., by obscuring their importance or deterring physicians from reading the warnings) and (b) deter product use, thereby reducing product effectiveness.
this idealized environment. In sum, efficient behavior results if standards of care
defining negligence are set at efficient levels—i.e., at the levels for which the
social benefit of any small increment of safety is just equal its social cost—and the
damages resulting from negligence are large enough to make negligence
unprofitable.5

Analyzing the operation of efficient liability systems helps to highlight some
implicit assumptions in the previous discussion and provides a structure for
analyzing what can go wrong. Figure 10.1 depicts such an analysis for efficient
strict liability (left-side path) and efficient negligence (right-side path) systems.

As indicated in the figure, a key issue is whether physicians and patients can take
actions to increase safety. If they cannot—a situation called unilateral precaution
in the literature—an efficient strict liability system is theoretically possible, and
the left side of Figure 10.1 is relevant.6 However—as indicated by the Yes or No
arrow in the figure—efficiency can be achieved with a negligence system with or
without unilateral precaution.7 The next subsection considers whether unilateral
precaution is a reasonable approximation in the industries under study.

5With this background, the differences among legal scholars in the meanings of the terms strict
liability and negligence can be addressed in detail. Phrases like “strict liability for design defect” or
“strict liability for failure to warn” are not uncommon in legal writing. But they make no sense
according to the definitions used by economists and many legal scholars: “Design defect” implicitly
involves some standard for appropriate design, and “failure to warn” involves company behavior
directly, but such issues are irrelevant to strict liability as defined here. Consistent with the view here
is the following passage from a recent article by two influential legal authorities:

[Products liability law has been in a thicket because courts have sought to transplant
the concept of strict liability from manufacturing defects to defective design—i.e.,
design defects and failures to warn... we now know that strict liability has almost
no meaning in defining defectiveness in generally dangerous products cases. It
provides no standard for measuring liability. (Henderson and Townsend, 1991,
pp. 1333-1334; footnotes omitted.)

6If physicians or patients can increase safety, an efficient strict liability system is not possible,
and the left side of the figure is irrelevant. Strict liability cannot achieve efficiency without unilateral
precaution: If patients are completely compensated for product injuries—as they must be to give
companies efficient incentives under strict liability—then physicians and patients have no incentives
to increase safety even though they are in a position to do so.

7In an efficient negligence system, negligence—i.e., any precautions that are below their efficient
levels—is deterred (as it must be for efficiency). With negligence deterred, injuries cannot be
attributable to negligence; patients are not compensated for injuries; and physicians and patients can
have appropriate incentives to take precautions. They will have such incentives if the medical
malpractice system is an efficient negligence system. In standard models, there is a single consumer,
and the potential for efficient negligence with bilateral precaution follows from the fact that the
consumer bears all injury costs under an efficient negligence (product liability) system. In our
context, however, we have a third party—the physician—who (depending on physician liability
rules) may or may not bear the costs of injury. The author is unaware of analyses of this issue.
However, application of the principles developed in the literature and described here makes it clear
that, if both product liability and medical malpractice are efficient negligence systems, then
companies and physicians will take efficient care; patients will bear all costs of injuries; and efficiency
will be achieved. However, if physicians are held strictly liable for injuries, for example, patients will
not have incentives to take care and efficiency will be undermined even if product liability gives
companies efficient incentives.
Some of the assumptions implicit in the previous discussion are highlighted in Figure 10.1. These involve company perception of the liability environment and the basis for company decisions. Specifically, in the basic theories, the company understands perfectly, for example, the probabilities of various liability outcomes of each possible action and makes the decisions that maximize expected profits. Other implicit assumptions involve factors that are simply ignored in the basic theories and thus are ignored in Figure 10.1: that liability provides the only company incentives for product safety and that the operation of the liability system does not directly absorb resources. All of these issues are considered in the next subsection.

**Determinants of Efficiency of the Actual Liability System**

What lessons can be drawn from comparing what has been concluded about the economics of how liability actually operates in drugs and devices with these basic theories of efficient liability systems in ideal environments? This subsection begins to address this question.
Figure 10.2 highlights various discrepancies between the theories depicted in Figure 10.1 and the actual situation. This subsection contains five subsubsections, each corresponding to one of the five boxes with rounded corners in Figure 10.2. An overview of this figure is presented first, followed by discussion of each component.

First consider the left side of Figure 10.2. This side pertains to incentives, perceptions, and decisionmaking, and thus corresponds to issues highlighted in Figure 10.1. As emphasized in Figure 10.2, social injury costs are translated into the incentives created by the actual liability system. These incentives differ in many ways from the incentives created by an efficient liability system (under either regime); several examples are discussed in the first subsubsection. Moreover, liability costs resulting from company decisions are unpredictable. As a result, incentives may not be well understood by decisionmakers. Conceptually, company information and perception determine perceived liability cost potential, which drives decisions. Sources of discrepancy between actual and perceived liability

![Diagram](image)

**Figure 10.2—Determinants of Efficiency of Actual Liability System**
cost potential and their implications are reviewed in the second subsubsection. Finally, perceived liability cost potential enters the economic decision making of companies, which can deviate in important ways from the process of expected profit maximization posited in the basic theories and Figure 10.1 because of attitudes toward uncertainty and risk. This is discussed in the third subsubsection.

The right side of Figure 10.2 emphasizes two issues that the basic theories ignore. First, in making its economic decisions, a company has other incentives for safety—incentives created by markets and regulators. Implications are discussed in the fourth subsubsection. Second, the efficiency of a liability regime depends not only on the actual economic outcomes of the industries—product availability, safety, effectiveness, innovation, etc.—but also on the direct costs of the liability system. These direct (or transaction) costs, which are borne by private parties (plaintiffs and defendants) and the public, are the subject of the final subsubsection.

**Incentives Created by the Actual Liability System**

In practice, the liability system provides incentives conducive to efficient safety-related company decisions if it approximates incentives provided by either an efficient strict liability system or an efficient negligence system. For either benchmark, incentives can be conducive to efficient decisions only if the company is held liable in the appropriate situations and if the level of liability cost borne by the company is appropriate.

An efficient negligence system requires that the levels of care defining legal negligence be economically efficient and that direct and indirect liability costs resulting from negligence be sufficient to induce the company to adopt the efficient levels of care. An efficient strict liability system requires that liability be imposed for all injuries caused by product use. As discussed in Section 3, current doctrine is not based on strict liability except in the case of manufacturing defects. In practice, design defects and failures to warn are fundamentally negligence issues. Moreover, comment k often protects drug manufacturers—and to a lesser extent, device manufacturers—from findings of design defects.

Judged against the benchmark of either efficient liability regime, the actual liability system provides inefficient incentives because of numerous factors. Various distortions are discussed in the remainder of this subsubsection. Some

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8There seems to be no basis for assessing how frequently the actual liability system satisfies the latter requirement, and this issue is not pursued.
factors favor plaintiffs and others favor defendants. It is unknown—and perhaps unknowable—which side is favored on balance.

**Distortions Relevant to Both the Strict Liability and Negligence Benchmarks.**

Distortions exist under both approaches because of difficulties in attributing injuries to product use. In an efficient strict liability system, liability is incurred in all instances in which injury is caused by product use. In an efficient negligence system, liability is incurred if in addition the injury would not have occurred if the company had taken economically efficient precautions. Thus, the ability of the liability system correctly to link injury and product use is relevant to either benchmark. However, in many cases, even leading experts cannot determine injury causation for drug and device users. Often, judges and juries appear to have even more difficulty making such judgments.

Other distortions stem from the fact that liability cannot be imposed unless an injured product user brings a claim. Under both strict liability and negligence regimes, a meritorious claim may not be filed if the injured person does not associate the injury with use of the product, does not recognize that compensation may be available through a liability action, or cannot find an attorney willing to pursue the claim. On the other hand, claims lacking legal merit can also be filed. For example, injured product users and their attorneys may be mistaken about injury causation.

Efficient incentives can also be undermined, because the possibility of company bankruptcy limits liability. If the level of potential damages required to induce efficient decisions exceeds a company’s assets, the company cannot have sufficient incentives to promote safety and may for that reason fail to take the efficient amount of care. For example, a small company may have assets of only a few millions dollars, while its products may have the potential to cause social injury costs much, much larger.

Finally, additional distortions arise because a company’s actual liability costs are not limited to damages paid, and liability costs other than damages affect incentives. Defense costs can be large enough to have substantial effects on company incentives. In addition, liability can impose substantial indirect costs on companies—e.g., through reputation and lost sales.

Thus, there are major difficulties in imposing liability in the right cases and imposing the right amounts of liability costs on companies. The net effect of these distortions may be to provide companies with either too little or too much incentive to pursue product safety. The former possibility is often raised as an economic rationale for punitive damages: If companies have less incentive to pursue safety than is conducive to efficient decisions, that incentive can be
strengthened by allowing punitive damages. But punitive damages can also distort economic incentives, for example, if they are imposed when liability is inappropriate.

Distortions Specific to Strict Liability. One major impediment to pursuing efficiency with a strict product liability regime is the existence of opportunities for physicians and patients to take actions promoting safety. If injured patients are compensated, this reduces the incentives of physicians and patients to take care and can lead them to take less precaution than efficiency requires.

Moreover, providing efficient incentives under a strict liability regime requires a fine tuning of liability costs to internalize accurately the social costs of injuries caused by product use. The actual liability system may often do this job very poorly. For example, the difficulty of setting appropriate levels of damages in individual cases—and especially the dollar equivalent of noneconomic losses (such as pain and suffering)—is widely appreciated. Less widely appreciated, but perhaps even more problematic, is that accurate cost internalization requires taking account of indirect liability costs and injuries that do not result in claims and that the importance of each may differ greatly from situation to situation.

Negligence: Are the Standards Efficient? Specifying efficient negligence standards for design and warnings is very difficult. Experts find it challenging to determine even approximately the point at which the costs of extra safety outweigh the benefits. Because judges and juries determine negligence standards in individual cases, and they often frame their inquiries in terms other than those of economic efficiency, we might expect actual liability standards to approximate efficient standards rather poorly.

However, judges and juries often—but not always—refer to FDA policy in determining liability. This allows analysis of how negligence standards are likely to deviate from efficient ones. As reported in Section 4, failure to comply with FDA regulations is usually interpreted as negligence, but compliance is a minimum requirement for avoiding liability. Hence, negligence standards are

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9 See, for example, Cooter and Ulen (1988, pp. 291–295).

10 Regarding wrongful death cases, Viscusi (1991b, Ch. 5) discusses “deterrence values of life,” which provide companies with the appropriate incentives for reducing product risks from a strict liability perspective. Estimates are based on the extra wages individuals require to accept additional occupational risks and substitute possibilities of injury, pain, and suffering, as well as death. Viscusi argues that deterrence values of life are roughly ten times typical awards in wrongful death cases.

11 Recall from Section 4, however, that very recently courts have ruled that the 1976 Medical Device Amendments may preempt liability actions against devices that have gone through the premarket approval process.
taken to be typically at least as stringent as FDA safety standards.\footnote{Recall from Section 3 and 8 that we have defined FDA safety standards as the level of safety that would prevail if all FDA regulations were obeyed.} Does this promote efficient decisions?

As detailed in Section 8, for drugs and extensively regulated devices,\footnote{Specifically, those devices that have undergone the premarket approval process or that have been subjected to extensive review within a (hybrid) 510(k) process. (See Sections 3 and 8.)} FDA safety standards are quite stringent, arguably more so than is conducive to efficiency. For such products, then, actual negligence standards appear to be too stringent for efficiency, by at least the extent that they exceed FDA safety standards.

The situation is different for devices that have not been extensively reviewed by the FDA.\footnote{Specifically, medical devices marketed through 510(k) procedures (on the basis of "substantial equivalence" to devices marketed before 1976) without extensive FDA review. (See Sections 3 and 8.)} Here de facto FDA safety standards—i.e., "substantial equivalence" to pre-1976 devices—may fall short of economically efficient levels. But judges and juries may often use FDA safety standards as negligence standards even for such devices, thus failing to provide incentives for economically efficient increases in safety.

Some key issues arise only in the context of warnings. For example, except for vaccines and oral contraceptives, legal doctrine—specifically the learned intermediary rule—discourages companies from developing and providing warning information for patients. Moreover, incentives created by the liability system encourage companies to err on the side of inclusion rather than exclusion in determining the content of warnings to physicians. Is such company behavior conducive to efficiency? The relevant issues—discussed in Section 8—are controversial, but there is little basis for confidence that the status quo liability standards for warning adequacy approximate efficiency.

A final concern involves the causal connection between warnings and injury. For a negligence system to provide efficient incentives, liability must be imposed only if the warning was negligent and the injury would not have occurred if an efficient warning had been given. As reported in Section 4, doctrine generally provides a presumption in favor of the plaintiff in this regard. To the extent that this presumption imposes liability for injuries that are not attributable to failure to warn efficiently, the efficiency of incentives is undermined.
Information, Perception, and Perceived Liability Cost Potential

Even if the actual liability system were to create incentives approximating those in an efficient liability regime, efficient decisions might not result. As depicted in Figure 10.2, discrepancies can arise between actual and perceived liability cost potentials, which depend on a company's perception of a fundamentally uncertain liability environment.

As discussed in Section 5, those perceptions depend on the information available to company decisionmakers and on human psychology. As to the latter, liability costs of any particular magnitude or in any range are perceived to be more likely the easier it is to imagine or to recall similar events. Thus, information received about past liability events—such as judgments and awards—and the frequency and force with which decisionmakers are exposed to it can have major effects on perceptions influencing decisions. Liability events at other companies are often publicized by news media, trade publications, litigation reporters, and policy advocates. Such sources often emphasize liability outcomes that seem surprising, extreme, or inappropriate. In addition, liability events at one's own company seem more likely to be recounted repeatedly or in vivid terms if they have such qualities. Under such circumstances, systematic misperceptions about incentives created by the liability system may play a major role in decisionmaking.

For example, as discussed in Section 6, the liability histories of contraceptives, vaccines, and products for conditions specific to pregnancy strengthen the view that perceptions are fueled by liability against products that seem socially valuable, availability crises, punitive damages in arguably inappropriate cases, and decisions reflecting controversial science. The view that emerged from the analysis is that liability threats associated with such products may generally be perceived to be more extensive than they, in fact, are.

On the other hand, there is considerable reason to suspect that the liability potential for many other products is underestimated. One reason relates to information: Discussions of product liability in drugs and devices—especially by those advocating reduced liability burdens on business—tend to focus on the stereotypical products. Instances of potential liability cannot be recalled, and substantial liability costs are harder to imagine for products that have not triggered such costs than for those that have.

Hence, liability cost potential is likely to be overestimated for some products and underestimated for others. Such misperceptions could exist even if the actual incentives created by the liability system were conducive to efficient decisions.
Economic Decisionmaking, Uncertainty, and Risk

In the operation of the efficient liability systems depicted in Figure 10.1, decisions are made to maximize expected profits. Even if the incentives created by the liability system were conducive to efficient decisions, and these incentives were perceived accurately, liability would not induce efficient decisions as long as liability costs are unpredictable and decisionmakers do not maximize expected profits.

The view of decisionmaking developed here is that decisions are guided by pursuit of profits, with liability entering as one factor affecting profits. Companies consider expected liability costs—as posited in the idealized systems—but also the risk of major losses arising from uncertainty attached to eventual liability costs. Decisions can deviate substantially from those maximizing expected profits when the degrees of uncertainty and risk are especially high. For example, liability risk is in principle unlimited, and a perception that financial disaster will occur with a probability that is more than trivial can have dramatic effects on decisions. In short, the unpredictability of the eventual liability costs that can result from decisions and a potential for financial disaster can deter companies from taking socially worthwhile actions.

Other Incentives for Safety

The fundamental economic purpose of a liability system is to guide companies to efficient decisions affecting product safety. In the basic theories of efficient liability systems depicted in Figure 10.1, the only company incentive to promote safety is avoidance of liability costs. As indicated in Figure 10.2, however, the actual liability system operates in combination with both market and regulatory incentives encouraging product safety. Liability incentives that would promote efficiency if they were the only incentives for safety can have very different effects when they operate in combination with other safety incentives.

For example, consumers are less willing to buy (or are willing to pay less for) products they believe pose greater safety hazards. Thus, the market provides incentives for companies to promote product safety to the extent that consumers understand product hazards. The fundamental economic rationale for liability is that buyers underestimate these hazards. The actual liability system imposes penalties for injuries in addition to the market penalties that operate through the behavior of physicians and patients, and liability incentives that are appropriate in the absence of market incentives for safety can be excessive in their presence.
But our society has chosen not to rely solely on market forces and liability to encourage safety. Federal regulation of drugs and many devices is perhaps the most comprehensive consumer product safety regulation in the United States. FDA regulation, associated incentives for safety, and interactions with liability have been discussed extensively above. (See especially Sections 3, 4, and 8.)

**Direct Costs of the Liability System**

In the idealized liability systems depicted in Figure 10.1, liability induces efficient decisions without directly absorbing economic resources. But operation of the liability system requires substantial, direct inputs of human and other economic resources, e.g., the time and effort of plaintiffs, defendants, attorneys, judges, jurors, and witnesses and the use of courtrooms and offices. Using such resources involves social costs whether they are borne by private litigants or the public at large. Figure 10.2 emphasizes the relevance of such costs for evaluating the efficiency of liability. For example, if a reform of the liability system decreased direct costs while preserving or enhancing industry performance, this reform would be efficient.

**Economic Perspectives on Policy Reform**

The analysis suggests several perspectives helpful in thinking about the policy task.

**Reforms Should Aim to Strengthen Deterrence of Some Activities and to Weaken Deterrence of Other Activities**

The focus of the policy debate has been on whether the liability burden on business is too heavy. One side points to behavior that appears unreasonably dangerous and concludes that the burden is inadequate to protect safety. The other side points to liability imposed in inappropriate circumstances and evidence of consequent economic costs and concludes that the burden is excessive. The view here is that both conclusions are right and wrong. Apparently, liability fails to deter some behavior that is too dangerous for efficiency and at the same time deters behavior that promotes efficiency. Attempts to improve economic performance through liability reform, then, face the task of strengthening deterrence of inefficient behavior while weakening deterrence of efficient behavior.
It is impossible to say which type of inefficiency is more prevalent or important, but that is not the crucial question for our purposes. The crucial questions are: What are the sources of inefficiency and what might be done about them?15

**Liability Policy Should Target Safety, Effectiveness, and the Mix of Innovation**

Liability reform seems appropriate only when three criteria are satisfied: (a) The economic outcomes of concern are driven by decisions sensitive to liability policy; (b) current incentives and decision processes do not appropriately reflect the social benefits or costs of company actions; and (c) no policy instruments are better suited than liability for correcting these distortions.

These criteria lead us to focus on product safety and effectiveness (subsuming product availability) and the mix of innovative efforts. As discussed in previous sections, company decisions affecting safety, effectiveness, and the mix of innovative efforts that seem sensitive to liability include the following: product withdrawals, disclosure of safety problems to the FDA, design of vaccines and devices, provision of information to physicians and patients, and various innovation decisions. Regarding the second criterion, the analyses in Sections 8 and 9 and the discussion in the previous subsection of this section provide numerous reasons to be concerned about the efficiency of decisions regarding safety, effectiveness, and the mix of innovation under the current liability system. Finally, while regulation can affect these three outcomes, regulation is currently an imperfect policy instrument.

The proposed policy targets ignore two outcomes: the overall level of innovative effort and product pricing. Although we have not analyzed whether the former is sensitive to liability policy, overall innovative effort seems much less sensitive to liability than to patent policy or price regulation, which can have profound, across-the-board effects on incentives to invest in innovation. Pricing is not emphasized in what follows, because the major price effects of liability seem to be limited to a small number of product areas, and policy reforms that appear promising for the targets emphasized here are likely to ameliorate these.

15 The view that the focus of the policy debate on the size of the burden is misplaced is not novel. See, for example, Viscusi (1991b, p. 14) and American Law Institute (1991b, pp. 8-9). Viscusi also argues that the question of efficient incentives is much more intricate than might be inferred from the policy debate.
Efficiency Rationales for Liability are Different for Drugs and Extensively Regulated Devices Than for Other Devices

The fundamental economic purpose of product liability is to induce companies to increase product safety. As increases in safety are costly, efficiency arguments for liability must rest on the premise that product safety would fall short of its efficient level in the absence of liability. Since society has chosen to rely on regulation to increase the safety of drugs and devices, an economic case for liability must be based on the view that FDA regulation (even with the help of market forces) fails to achieve at least the efficient level of safety.

Recalling our conceptual view of the FDA as setting standards and attempting to enforce them, there are two ways that regulation could result in too little safety for efficiency:

- FDA safety standards that are too low for efficiency
- Lack of compliance with FDA standards.

As discussed in Section 8, FDA safety standards for drugs and extensively regulated devices do not seem too low for efficiency, but there is substantial evidence of incomplete compliance with FDA regulations. Hence, for extensively regulated products, the primary economic rationale for liability is taken to be strengthening compliance with FDA safety standards.

In contrast, for many devices that have yet to be extensively regulated by the FDA, it was concluded in Section 8 that de facto FDA safety standards may be less stringent than required for efficiency. In these cases, liability policy might sensibly attempt to improve economic efficiency by setting more stringent standards than the FDA does and by encouraging compliance.

Liability Policy Can Affect Incentives, Predictability, and Information, but Not the Psychology or Attitudes of Decisionmakers

As reflected in Figure 10.2, liability affects economic decisions in three ways: through the incentives it creates or influences; through information and perception, which are relevant only because liability outcomes are unpredictable; and through decisionmakers' attitudes toward profits, uncertainty, and risk. Liability policy could, in principle, influence any of these factors, and the first is clearly susceptible to influence. As for the second and third, neither the psychology of perception nor the attitudes that drive decisionmaking seem
susceptible to policy influence, but the degree of predictability of liability costs, and the information available to decisionmakers about the liability environment, are.

In searching for promising reforms, attention here focuses on
- Creating incentives conducive to efficient decisions
- Helping companies to understand the liability environment.

Earlier in this section, several factors pertaining to the former objective were reviewed. The latter might be furthered both by increasing the predictability of liability outcomes and by providing companies with more complete and balanced information about the system's operation.

**Substantial Deterrence of Inefficient Behavior Implies Some Deterrence of Efficient Behavior**

The goal is to deter inefficient behavior while not deterring efficient behavior. The analysis suggests that many relevant decisions may be sensitive to liability only if companies perceive substantial liability potential. Thus, deterring company decisions that are too dangerous for efficiency seems to require a potential for major liability costs. But because such costs cannot be completely and credibly limited to inefficient behavior, it is impossible to have strong deterrence of undesirable behavior without the potential for substantial deterrence of desirable behavior. Any liability reform—and indeed maintenance of the status quo—confronts this fundamental conflict.

**Liability Policy Might Best Vary over Products**

The effects of liability cannot be fine-tuned to strike a perfect balance between safety and effectiveness in both the present and future. Policies strengthening plaintiffs’ chances in court tend to push the balance toward safety, and policies strengthening defendants’ chances tend to push the balance toward effectiveness. Whether reform is best targeted at increasing safety or increasing effectiveness is a difficult but unavoidable question.

The answer to this question need not be the same for all products. Considerations here include the stringency of FDA regulation and the effectiveness stakes. With regard to regulation, liability appears to have considerably more scope for efficiently enhancing safety for those devices that are not extensively regulated. Plaintiffs’ chances in court might rationally be more favored, then, for such devices than for drugs and extensively regulated devices. The potential effectiveness costs
of inefficient deterrence are relatively large for products of indisputably large social value, such as treatments for life-threatening conditions. Liability rules involving less potential for inefficient deterrence might be more appropriate for such products than for products with more limited social value.\footnote{For example, the NCVIA, discussed in Section 4, might be interpreted in this way. In addition, a 1986 California statute (repealed in 1988) was intended to reduce the liability threat to potential manufacturers of an AIDS vaccine. (See Traynor and Cunningham, 1988, pp. 962-963.)}

**Implications for Some Major Policy Issues**

Many reforms of the liability system have been proposed and discussed in various forums, either in the context of product liability generally or more narrowly for drugs or devices. Several reasons that the liability system fails to induce efficiency have been considered, and it was concluded that complete remedies are impossible. The analysis here provides a systematic and detailed empirical basis for focusing on particular types of reforms and considering their likely implications for economic efficiency in the drug and device industries.

Two recent analyses proposing reforms of product liability are of particular interest for our purposes. First, American Law Institute (1991a, 1991b),\footnote{These volumes were authored by a group commissioned by the American Law Institute (ALI) but the ALI membership has not endorsed them.} contains extensive analysis of liability for various types of personal injury, including product injury. In particular, ALI (1991b) considers the pros and cons of many reform measures and offers specific proposals, emphasizing compensation goals over economic efficiency.\footnote{"We favor the basic principle that the primary (although not the exclusive) role for tort damages is to compensate injured victims for the actual financial losses they suffer as a result of personal injury." (ALI, 1991b, p. 10.) Among many other issues, ALI (1991b) considers administrative compensation funds, a subject that is not pursued below: "[W]e also believe that administrative fault is a model worth serious exploration in the case of pharmaceutical injuries..." (ALI, 1991b, p. 29.)} Second, Viscusi (1991b) considers product liability broadly and focuses on improving economic efficiency.\footnote{See, for example, Viscusi (1991b, p. 12).} In the discussion below, several arguments or recommendations advanced in these two analyses are considered that relate closely to the issue under discussion.\footnote{Various parts of ALI (1991a, 1991b) are based on Viscusi's work—see the lead footnotes in various chapters of ALI (1991a, 1991b). In cases where the ALI discussion is clearly based on Viscusi (1991b), the latter—which generally provides a more detailed discussion—is emphasized below. In some instances, Viscusi (1991b) and ALI (1991b) address the same issue, but the analyses and recommendations are very different, and both views are described below.} Other, more narrowly focused, proposals for reform are also considered.
The discussion is organized using a series of questions. Each question raises a class of policy actions that the policy debate or the analysis here suggests could have important implications for economic performance. In each case, efficiency implications of pursuing reforms within that class are considered.

**Does Strict Liability or Negligence Seem More Economically Promising?**

Attempts to achieve economic efficiency in design or warnings through either type of liability regime confront major difficulties.\(^{21}\) Difficulties specific to a strict liability approach include the inaccuracy with which injury costs are internalized and the tendency for a strict liability regime to undermine incentives for physicians and patients to promote safety. With regard to the accuracy of cost internalization, our understanding of many factors is so rudimentary that it is unclear how to design a workable system that would address problems discussed above relating to claiming behavior, bankruptcy potential, liability costs other than damages, and the monetary equivalents of injuries. In sum, a well-functioning strict liability system is not a plausible policy goal.

Approximating efficiency using only a negligence system is also problematic. A negligence system would be efficient only if negligence standards are set at efficient levels; standards are applied accurately; decisionmakers can confidently predict what standards will be applied to their decisions; and the penalties for negligence are sufficiently large to deter negligence. None of the first three conditions characterizes the prevailing liability environment, and none can be achieved easily through reforms. If these difficulties could be surmounted, making sure that penalties are sufficiently large to deter negligence would seem less problematic than accurately internalizing injury costs.

Thus, there are major difficulties in pursuing efficiency relying on either approach to liability alone. However, other incentives for safety have yet to be considered.

As discussed presently, for drugs and extensively regulated devices, a negligence approach relying on FDA safety standards seems promising. This is because, for these products, liability can be used to supplement incentives determined by FDA standards that may reasonably approximate efficiency.

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\(^{21}\) As discussed in Section 4, manufacturing defects are rare for drugs, but more common for devices. There seems to be widespread agreement in the context of product liability generally that strict liability for manufacturing defects is appropriate. (See, for example, ALI, 1991b, p. 13; Val cus, 1991b, p. 85; and Henderson and Twerski, 1992.)
However, such an approach is not promising for less-regulated devices because of the lack of even approximately efficient de facto FDA safety standards. For these products, liability has a much larger role to play in promoting efficient safety. However, we have concluded that relying on product liability alone—guided by either strict liability or negligence principles—faces major difficulties. How to pursue efficiency for less-regulated devices through liability is a conundrum.\textsuperscript{22}

\textbf{Would a Regulatory Compliance Defense Promote Economic Efficiency?}

The analysis here supports the view that a liability system including a regulatory compliance defense would promote economic efficiency for drugs and extensively regulated devices. This does not apply to less-regulated devices.

Specifically, consider a liability system in which compliance with FDA regulations shields companies from any liability—i.e., provides a regulatory compliance defense\textsuperscript{23}—and also holds them liable for injuries caused by lack of compliance.\textsuperscript{24} This is a negligence system with FDA safety standards used as the legal standards for negligence.\textsuperscript{25} According to the analysis above, such a system could be expected to lead to efficient company decisions only if four conditions are met:

\begin{itemize}
  \item FDA safety standards are efficient.
  \item Liability costs due to noncompliance are sufficient to induce compliance.
\end{itemize}

\textsuperscript{22}\textsuperscript{See ALI (1991b, Ch. 2) for an analysis and recommendations concerning tort approaches to design and warning defects when explicit regulatory standards are not available to serve as negligence standards.}

\textsuperscript{23}\textsuperscript{ALI (1991b, p. 91) reports that several states have legislated such a defense specifically in the context of FDA drug regulation. The recent federal appeals courts rulings that the 1976 Medical Device Amendments can preempt liability claims against some devices—see Section 4—may signal that regulatory compliance will shield manufacturers of some devices more often than in the past.}

\textsuperscript{24}Consistent with discussions above, compliance includes providing all required information in an accurate and timely fashion.

\textsuperscript{25}ALI (1991b, pp. 55–57) summarizes their proposal for a regulatory compliance defense shielding a defendant from liability for negligence. The proposal does not, however, clearly indicate that failure to comply should be taken as negligence, perhaps on the view that this is true of the status quo. (See, for example, ALI, 1991b, p. 84.) ALI (1991b, pp. 101–105) also discusses ways that such a regulatory compliance defense might be sensibly limited, including providing it as a defense against punitive damages, but not liability, and restricting the defense to particular products. In the latter regard: "Pharmaceuticals present a special combination of circumstances justifying such a defense." (ALI, 1991b, p. 103.) Finally, S. 640, a federal product liability bill considered by the U.S. Senate in 1992, specified a regulatory compliance defense against punitive damages for drug and device manufacturers that would seem not to apply to less-regulated, prescription devices. (See U.S. Senate [1991].) On the apparent lack of applicability of the defense to prescription devices that have not been extensively reviewed by the FDA, see especially U.S. Senate [1991, p. 36].)
• Company decisionmakers understand the standards.
• Decisionmakers are confident that the doctrine will be applied accurately.

In combination, the first and second conditions mean that incentives provided by the liability system are conducive to efficient decisions. The third guards against distortions due to misperception of incentives, and the fourth reduces uncertainty and risk and thus the distortions due to decisionmaker aversion to these factors.

A liability system approximating these conditions reasonably well would appear preferable to the current system. It would provide companies with substantial incentives for compliance with FDA regulations and provide plaintiffs and their attorneys with substantial incentives for discovering instances of noncompliance that cause injuries.

According to our discussion in the previous subsection, designing liability to focus on strengthening compliance with FDA regulations is appropriate for drugs and extensively regulated devices. To the extent that FDA safety standards for these products deviate from efficient standards, a reform establishing FDA safety standards as negligence standards would tend to fall short of achieving efficiency. But such a reform might reasonably be expected to contribute to efficiency by increasing deterrence of socially detrimental noncompliance and attenuating incentives to exceed FDA safety standards.

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26 Problems might be substantially weakened, however, by protective orders that maintain the confidentiality of evidence of noncompliance discovered by plaintiffs. (See Section 4.)

27 Grabowski (1991) considers pharmaceuticals only and makes a case for what he calls a "regulatory standards defense" largely consistent with the view developed here. For example: "Tort liability would then reinforce regulatory incentives for risk reduction but avoid the extra costs and disincentives for drug innovation now present." (Grabowski, 1991, p. 365) Viscusi (1991b)—who considers product liability broadly—argues for regulatory compliance defense against findings of design defects when designs are regulated or effective warnings are given. It is clear that FDA regulation of drug marketing and warnings would qualify for this defense under Viscusi's proposal. (Regarding design defects, see especially Viscusi, 1991b, p. 129; regarding warnings, see especially Viscusi, 1991b, pp. 149–151, 154.) But interpreted in the context of drugs and strictly regulated devices, Viscusi's support for a regulatory compliance defense clearly emphasizes avoiding inefficiencies from exceeding regulatory standards. For example: "[T]he typical regulatory mandate push the agencies to go beyond the efficient level of precautions in setting the risk level." (Viscusi, 1991b, p. 115); and "FDA [pharmaceutical approval] regulations receive full compliance..." (Viscusi, 1991b, p. 121.) (See also ALL, 1991a, pp. 246, 248.) Finally, focusing on pharmaceuticals, a somewhat different approach has been advocated: "Specifically, the courts should center their analysis on the administrative law concern of whether or not the FDA has supplied the requisite information and has arrived at a reasoned determination." (Harvard Law Review, 1990, p. 785.)
Could Reforms of How Science Is Used in Court Be Economically Advantageous?

Errors in attributing injury causation undermine the efficiency of incentives under either strict liability or negligence regimes. Failures to attribute injuries actually caused by product use to product use tend to lead to too little safety, and incorrect attributions of injury to product use tend to lead to too much. Our analysis suggests that errors of the second kind are perceived by company decisionmakers—perhaps incorrectly—as distressingly common and may have major effects on economic outcomes, especially for products where there is a substantial background rate of unexplained injury or where sympathy for injured product users is expected to be especially high.

The liability system would promote efficiency more effectively if reforms could strengthen the beliefs of decisionmakers that injuries caused by their products will be recognized as such and at the same time allay concerns that their companies will be held liable for injuries not caused by their products. Improving the scientific basis for legal determination of liability is a policy initiative that could strengthen efficient deterrence while attenuating inefficient deterrence.

Various measures have been proposed and discussed that aim to improve the scientific basis for assignment of liability. Many of these are reviewed and analyzed by Brennan (1989), who proposes additional reforms. Our analysis suggests that the efficiency stakes are very high in the context of drugs and devices. Determination of injury causation is especially difficult, and the potentials for mass torts and major economic effects of liability are apparent. The efficiency benefits of reforms might more than repay the very substantial efforts that would be required to implement them.

What Might Be Done to Improve the Efficiency of Warnings?

Physicians and patients affect the safety and effectiveness of drugs and medical devices through their purchase and use decisions. How well their behavior promotes product safety and effectiveness depends in large part on what product

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28 ALI (1991b, Ch. 11) relies heavily on Brennan (1988, 1989). The recommendations respond to various problems in dealing with difficult scientific issues in an adversarial environment. ALI (1991b, Ch. 11) recommends more extensive use of court-appointed experts under current federal procedure, use of science panels to weigh scientific evidence and deliver their opinions to courts to be used as evidence, and the creation of a federal science board. Elliott (1989) approaches the issue of regulating scientific evidence from the perspective of how procedures affect the incentives and, hence, the behavior of litigants.
information they receive from companies. In fact, inducing companies to provide the information that would be most helpful to physicians and patients may be the critical economic role for the liability system: If physicians and patients are able to incorporate actual product hazards in their purchase and use decisions, companies have market-based incentives to choose efficient product designs.

As discussed in Section 8, warning doctrine may have important effects on what information companies provide to physicians and patients. The kinds of changes in information that would promote efficiency are controversial, but there is good reason to suspect that efficiency might be improved by reforming warnings doctrine.

Warning doctrine discourages failure to warn—as contrasted with inefficient warning—and the learned intermediary rule generally exempts companies from a duty to warn patients. Consistent with these incentives, companies supply extensive, detailed, and descriptive information to physicians and almost no information to patients. As discussed in Section 8, the desirability of the status quo in information provision is controversial.

The FDA allows companies to behave this way. This may reflect a judgment on its part that the status quo is economically appropriate. But another explanation is plausible. Even if providing more information to patients or providing more limited, succinct, or interpretive information to physicians would be much more efficient, the FDA may allow companies to behave the way they do to avoid a direct conflict between FDA regulations and sanctions imposed by the liability system. For example, suppose that the FDA decided that warnings to physicians are too detailed and ordered deletion of many warnings currently included in package inserts and brief summaries. Then, instances in which companies are held liable for failure to provide warnings that the FDA would not allow might become common.

The latter explanation points directly to a regulatory compliance defense for warnings for drugs and extensively regulated devices. Such a defense would remove an impediment to FDA reconsideration of warning policy, but would not lead to changes in warnings unless the FDA were to lead the way.

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29Recall, however, from Section 8, that some courts have acknowledged the information overload issue in declining to find warnings defective.  
30See Cooper (1986), Walsh and Klein (1986), and the discussion of punitive damages in Section 4.  
31Visconti (1991b, pp. 149–154) discusses regulatory compliance defenses against findings of warning defects: his discussion indicates that FDA regulation of pharmaceuticals would be one of very few instances in which he would presently recommend such a defense.
How Could the Efficiency Effects of Punitive Damages Be Improved?

From the standpoint of strict liability theory, punitive damages may be useful in adjusting for factors that prevent some of the social costs of injuries from being internalized. From the standpoint of negligence theory, punitive damages may make penalties high enough to induce companies to behave efficiently. Thus, in principle, punitive damages can be an integral part of a well-functioning liability system.\textsuperscript{32}

However, our analysis has also pointed to uncertainty and risk as major factors in determining the efficiency effects of liability. Punitive damages may be among the most important considerations in this regard. Several factors combine to support the view that punitive damages can have major effects on company decisions. As discussed above, these include the potentially unlimited size of punitive damage awards, the likelihood of distorted perceptions concerning their actual frequency and magnitude, and the perception that their incidence and size are very unpredictable.

Some economic effects of punitive damages are undoubtedly socially beneficial, and others are undoubtedly socially detrimental. The policy challenge is to limit, accurately and credibly, the incentive effects of punitive damages to behavior that is best deterred. This is much easier suggested than accomplished.

One essential aspect of such an endeavor would be to increase predictability by clarifying the standards for punitive damages and applying them consistently. What this means is explicitly specifying behavior for which punitive damages should and should not be awarded.\textsuperscript{33} Of course, complete predictability of punitive damages is an ideal that cannot be achieved.\textsuperscript{34} However, without substantial movement in this direction, it can be expected that punitive damage

\textsuperscript{32}Viscusi (1991b, pp. 93-94), focusing on efficient internalization, argues that using deterrence values to set compensatory damages would "make it possible to eliminate the need for punitive damages." But his analysis ignores a standard economic rationale for punitive damages in the context of strict liability: Damages are not assessed in all instances of injury caused by product use.

\textsuperscript{33}In contrast, in policy debates "clarifying" standards is often intended and understood to mean "narrowing" the scope for punitive damages. Critics of the status quo of punitive damages often use the pejorative term "arbitrary" to describe the status quo. (See, for example, Kuhlik and Kingham, 1990; Pharmaceutical Manufacturers Association and American Medical Association, 1990.)

\textsuperscript{34}Even if the behavior warranting punitive damages were specified much more explicitly than under prominent, current reform proposals. For example, ALI (1991b, p. 264) recommends a standard of "clear and convincing evidence of reckless disregard for the safety of others in the decisions made by management officials or other senior personnel." The federal product liability bill discussed above - S. 640 - specifies a standard of "clear and convincing evidence that the harm suffered was the result of . . . conscious, flagrant indifference to the safety . . ." (U.S. Senate, 1991, p. 33.)
potential will deter desirable behavior along with undesirable behavior. The more unpredictable punitive damages remain, the greater this danger is.

The other essential aspect of efficient use of punitive damages is specifying the standard. In the strict liability context, presuming that liability costs are not, in fact, already larger than social injury costs, the goal would be for punitive damages to correct for the joint effect of numerous factors contributing to underdeterrence of inefficient behavior. But our lack of understanding of these factors suggests that such an endeavor would be doomed to fail.

The situation is more hopeful in a negligence context. If the incidence of punitive damages could be predictably restricted to inefficient behavior, the amount of damages need only satisfy the condition that this level is sufficient to deter such behavior. Making punitive damages large is not conceptually difficult.

However, because the incidence of punitive damages cannot be credibly limited to inefficient behavior, larger potential for punitive damages implies more deterrence of efficient behavior. As discussed in the previous subsection, since deterrence cannot be precisely targeted, how bold one should be in pursuing safety through liability should vary across products. For example, the potential safety benefits of liability may be greater for devices that are not extensively regulated by the FDA. Also, the potential effectiveness costs of inefficient deterrence are higher for products that are especially socially valuable. Accordingly, punitive damages might be prescribed in cases involving products for life-threatening conditions only for more extreme behavior than in cases involving other products.

In sum, the difficulties of efficiently targeting incentive effects of punitive damages can be taken into account but are not nearly overcome by liability policy reform. It may be that, no matter how the standards and allowable damages are specified, unacceptable amounts of egregious behavior will exist; efficient behavior will be deterred to unacceptable degrees; or both. If so, help might be sought from other deterrence mechanisms.

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35. American Law Institute (1991), Ch. 9 offers recommendations concerning determination of the sizes of punitive awards in situations involving small numbers of injuries and in mass tort contexts.

36. Some might consider criminal approaches. Criminal sanctions can have powerful incentive effects and may be easier than civil sanctions to limit to undoubtedly inefficient behavior. If criminal deterrence of extremely dangerous behavior could be strengthened without deterring efficient behavior, the efficiency costs of limiting punitive damages would be lessened. Moreover, criminal sanctions may be less susceptible to attenuation by bankruptcy possibilities. But, like civil liability, criminal liability is a two-edged sword: if it is not credibly limited to socially undesirable behavior, socially desirable behavior will be deterred.
What Efficiency Issues Are Peculiar to Mass Torts?

Mass torts are especially salient in the drug and device industries. They have occurred for both drugs and devices, and the risk of injury inherent in such products suggests that they can occur in the future. Issues that arise in the general context of liability and economic efficiency are greatly magnified in importance when mass torts are considered. In addition, some issues seem important for economic efficiency only in the context of mass torts.

A by-now-familiar problem is that the potential for mass torts is difficult to limit to behavior that is best deterred. The potential for latent injury combined with widespread product use implies that drugs and devices can cause mass injury. The potential for mass injury suggests that efficiency may require a potential for extremely large liability costs. But, in principle, mass torts can arise for products that do not cause mass injuries (e.g., Bendectin, in the opinion of many) or whose efficiency is undoubted despite numerous injuries (e.g., childhood vaccines). Because mass torts raise the possibility of financial disaster even for large companies, the potential for mass torts can have particularly important economic effects. The stakes in restricting liability to inefficient behavior are magnified in the context of mass torts.

Consequently, the aim is to focus mass tort potential predictably and credibly on behavior that is best deterred: behavior that risks serious, widespread injuries without correspondingly large effectiveness benefits. Other parts of this section consider specific aspects of—and difficulties involved in implementing—that general prescription.

The potential for mass torts does highlight two aspects of the liability system that may not be important in other contexts. These are the possibility of company bankruptcy and the direct costs of the liability system. Bankruptcy potential can undermine incentives to take efficient care but also deter efficient behavior.

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37In contrast, Viscusi (1991b) argues that the ability of the tort system to provide efficient incentives in the context of long-term, latent injury and legal standards that change over time is so doubtful that "the solution to mass toxic torts ... is to eliminate the involvement of the products liability system." (Viscusi, 1991b, pp. 173-174. See also especially Viscusi, 1991b, p. 138.) Viscusi prefers to rely on the regulatory system to protect against such injury risks. (See Viscusi, 1991b, Ch. 8.) The view here differs from Viscusi's despite the sources of doubt he raises: The scope for company noncompliance with regulations suggests that enormous inefficiencies might result from simply removing the massive financial incentives of companies to be concerned about long-term, latent injuries: it seems sensible to require regulatory compliance as a condition for avoiding mass torts.

38Bankruptcy itself, however, need not involve—as is often suggested—enormous direct costs or displacement of employees. Business bankruptcy often involves corporate financial reorganization rather than liquidation. In the context of mass torts, bankruptcy may generally involve transfer of ownership of (much of) the company's assets to tort claimants rather than cessation of company business activity. Consistent with this view, the maker of the Dalkon Shield (A. H. Robins) was not
The potential for very high direct liability costs (i.e., transaction costs) implies a large social incentive to find ways to reduce them. Various means—especially several approaches to aggregating cases—are used to reduce the direct costs of mass torts, due partly to necessity rooted in the limited capacity of the court system.

How Much Might Efficiency Be Enhanced by Improvements in Information About the Liability System?

There are two fundamental approaches to decreasing the uncertainty faced by company decisionmakers and the inefficiencies that result from them:

- Increasing the predictability of liability outcomes
- Improving decisionmakers’ information about the liability system.

Policy reforms aimed at the former have been discussed. The latter approach is considered here. It is concluded that, while providing additional information has some scope for improving the efficiency of decisions, this scope is somewhat limited, and information provision is not a promising substitute for increasing the predictability of liability outcomes.

Much information about litigation is in the public domain. Much has been learned about litigation outcomes, such as the numbers of case filings, proportion of plaintiff victories, frequency of punitive damages, levels of compensatory and punitive awards, and frequency with which awards are overturned or adjusted after trial. But the picture is still incomplete, and progress requires very laborious data-collection efforts. A major effort to create a central database of state court outcomes, for example, might be worth the considerable cost.

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32 For example, Viscusi (1991b, p. 169) discusses information suggesting direct resource (transaction) costs of liability activities in the Dalkon Shield case of almost $800 million, even ignoring direct costs borne publicly.

33 ALI (1991b, Ch. 13) argues that a major concern in mass tort litigation is the waste involved in “redundant relitigation of common issues” (ALI, 1991b, p. 395). (See especially ALI, 1991b, pp. 397–399.)

34 Peterson and Selvin (1988) present a conceptual overview of approaches to and issues in aggregating mass tort claims and apply it to two cases.

35 ALI (1991b, Ch. 13) details various recommendations including more extensive reliance on mandatory consolidation for consideration of common issues of law or fact in mass tort situations. In addition, for cases involving long latency periods for injuries (for example, the Dalkon Shield and DES), they recommend that latent risks be viewed as injuries and that insurance funds be used to compensate future losses as they are incurred.

36 For example, Daniels and Martin (1990), Galanter (1983), GAO (1988, 1989), Rustad (1991), and studies by the Institute for Civil Justice.
However, most liability claims are resolved without trials, and much information
about these claims is proprietary. Moreover, even if data on such outcomes were
available, they would be uninformative about several issues of central concern;
for example, what portion of a settlement is attributable to fear of punitive
damages or to plaintiff difficulties in discovering relevant information?

Finally, some important issues concerning case outcomes are essentially
subjective in nature. Of substantial significance in the present analysis are issues
like the frequency with which cases are resolved in conflict with widespread
scientific views, punitive damages are triggered by socially appropriate behavior,
or punitive damages are not triggered by egregious behavior. The inherent
subjectivity of such questions weighs heavily against any hope of attenuating
misperceptions about them by provision of information.

In Conclusion

Many consider national economic performance a crucial concern in formulating
product liability policy. Various ways have been identified in which the
prevailing liability environment in the pharmaceutical and medical device
industries undermines their contributions to current and future standards of
living in the United States. It is not possible, however, to achieve even nearly
efficient outcomes through product liability reform, because knowledge is
lacking about many elements of the problem. Moreover, it may not be desirable
to focus reform efforts entirely on economic goals; other considerations—such as
compensation—are also considered crucial by many. The analysis here is offered
as a guide to those attempting to identify reforms that would improve efficiency
in the pharmaceutical and medical device industries and those considering
reforms for other reasons.
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