

Product Liability and the Pharmaceutical Industry

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What are the implications of product liability—the legal liability of a producer or seller for harm caused by a product—for the pharmaceutical research and development (R&D) process? Observers claim that over the past 20 years, the courts have broadened the circumstances in which injured parties may collect from manufacturers, a trend particularly cited regarding the pharmaceutical industry (250). They have also suggested that the frequency of large jury awards has increased for cases proceeding to trial, raising the degree of uncertainty surrounding expected liability losses for a manufacturer or its insurer (184).

While some argue that in the pharmaceutical sector these changes successfully protect the public from unsafe drugs (522), others suggest that increased liability, losses, and uncertainty affect R&D in two other ways:

- Costs associated with bringing a new pharmaceutical to market may rise as a result of additional research that firms may conduct to ensure the safety of new drugs (239).
- Firms may decide not to pursue areas of research or product development where they fear excessive liability costs will critically lower the potential return for a particular drug (236).

This chapter focuses largely on the second hypothesis, examining how product liability rules in the United States may affect the drug projects in which manufacturers choose to invest.

PRODUCT LIABILITY AND PHARMACEUTICAL R&D

The greatest impediment to understanding the effects of product liability on the drug R&D process is the lack of evidence on trends in pharmaceutical liability cases. Data on court cases are limited because the legal system adjudicates only a small fraction of all product liability claims and because there is no



centralized database of” all product liability cases filed and decided and no centralized record of settled claims.

The liability insurance industry is a poor source of information on the drug industry’s product liability experiences because companies now largely self-insure for all but the highest liability losses. The best source of information on the costs and implications of product liability law in this industry are drug companies themselves. The Office of Technology Assessment (OTA) found no published data summarizing industry experience.¹

Despite the lack of data, it is possible to sketch a rough picture of product liability trends in the research-based pharmaceutical industry from a variety of sources that are incomplete by themselves, including trends in law and insurance markets, a few in-depth studies of product liability litigation in particular jurisdictions, and anecdotal accounts of products particularly vulnerable to liability claims:

- Over the past 15 years, product liability claims and litigation against pharmaceutical manufacturers appear to have increased as measured by numbers of cases and changes in liability insurance. The legal circumstances under which courts hold pharmaceutical manufacturers responsible for injuries to consumers also broadened in recent years.
- The increase in liability claims is not uniform across all pharmaceutical products. Contraceptives, vaccines, and drugs taken during pregnancy appear to be particularly susceptible to liability claims. The vast majority of all product liability litigation in the health care sector over the past two decades is attributable to two products—the Dalkon Shield contraceptive and Bendectin,

a drug used to treat pregnancy-related nausea.

- While data suggest the average award per liability claim has increased substantially for pharmaceuticals, a very small number of cases with very large punitive damage awards explains the bulk of these increases. However, even excluding these very large cases, there has been a general increase in awards over time.
- Assessing the impact of increased product liability on pharmaceutical firms is difficult. No data exist to measure R&D and other business costs attributable to product liability. The little systematic research done to date on whether product liability affects the rate of pharmaceutical innovation has yielded inconclusive results. Evidence drawn from the experiences of particular products or from interviews with industry executives indicates liability may inhibit or preclude R&D or marketing of reproductive-related vaccines and products.
- Although the Federal Government has not adopted product liability reforms for therapeutic pharmaceuticals, several States have, and the Federal Government has adopted no-fault compensation schemes for swine flu and childhood vaccines that could offer potential models for Federal underwriting of other product liability risks. The U.S. Congress has also considered several proposals to adopt a Federal product liability law that would supersede current State law.

PHARMACEUTICALS AND PRODUCT LIABILITY LAW²

■ Establishing Legal Liability

Liability law in this country draws more from the common law precedents of previously de-

¹ A recent **Institute** of Medicine study of contraceptive R&D, however, conducted an informal survey of companies **currently or formerly** involved in researching new **methods** of birth control. The committee surveyed the companies **about** the implications of product liability on contraceptive business, but the committee report did not provide a wide range of survey results or any information about the representativeness of the sample (207).

² This section provides only a rough outline of some of the more important concepts of relevance to product liability for pharmaceuticals. These legal concepts have been **described** more fully **elsewhere** (250,371,413).

cided cases than from statute. Rather than having a single, uniform product liability system, the United States really has 51-one for each State and one for the Federal court system. The Federal system has jurisdiction only over product liability cases in which the parties reside in different States and one requests that the case be heard in Federal court (28 U.S.C, 1332). Hence, cases heard in different jurisdictions may operate under different theories and standards for establishing a pharmaceutical manufacturer's liability (265,443).

Even with these complexities, there are some common elements in pharmaceutical liability law. In determining whether the manufacturer is indeed liable for any injuries caused by the product in question, the courts tend to establish liability for pharmaceuticals in one of two ways:

1. The courts may consider whether a design defect makes the product unreasonably dangerous—i. e., whether the risk of a drug's use outweighs its utility. Although the American Law Institute (ALI)³ recognized in its 1965 *Restatement (Second) of Torts* (Section 402A, Comment K) that pharmaceuticals have social value despite their potential to cause adverse reactions even when used as directed, some courts have applied the notion of **strict liability** to cases of injury associated with pharmaceuticals where there was no established negligence or malicious intent in the design and production of the drug⁴ (247).

According to this idea, liability lies with the party best able to prevent injury or absorb its costs—usually the manufacturer—even if that party was not responsible for causing the injury through negligence or intent (250). The courts may make this judgment independent of the U.S. Food and Drug Administration's (FDA) evaluation of the

drug's safety and efficacy, although there is a great deal of uncertainty in how one establishes design defects in pharmaceuticals (142,413,416).

2. A more common means of claiming liability is to show a drug is "unreasonably dangerous as marketed" because the manufacturer has given inadequate warning of the drug's risks (413,416). Determination of a failure to warn focuses on information about the drug that the manufacturer targets to prescribing physicians. A warning may be inadequate because it is factually wrong or incomplete or because it is not conveyed in an effective way.

Even though the FDA must approve a drug's labeling, packaging materials, and advertising claims, courts have often found firms liable for adverse events that the FDA determined lacked a scientific basis for inclusion among the drug's warnings. Courts have also found inappropriate promotion can render warnings ineffective and the failure of a physician to consult materials describing a drug's risk (such as the *Physician's Desk Reference*) does not absolve the manufacturer of liability (413).

Once a court has determined that a manufacturer is liable for any injuries resulting from a pharmaceutical's use, the court must decide whether the product caused the specific injury in question. In cases where a class of plaintiffs (i.e., injured parties) cannot identify the specific manufacturer because of the passage of time, the courts of some States have adopted a "market share" theory to determine causality. Under this theory, plaintiffs may receive damage from all manufacturers of product in proportion to their market share (243,263).

³The ALI is a nonprofit membership association of judges, legal academicians, and lawyers. The institute's purpose is the "clarification and simplification of the law and its better adaptation to social needs."

⁴There have been relatively few cases where injured parties have established negligence in the *manufacture* of pharmaceuticals. Observers have suggested the FDA's tight regulation of Good Manufacturing Practices and quality control are the reason (416).

■ Jury Awards

Across all types of liability (product, malpractice, and personal injury), in an average year only 2 percent of all insurance claims are resolved through litigation (i.e., a court case). Of these, only 5 percent (or 0.1 percent of all liability insurance claims) result in a trial verdict. The remainder are settled by the parties (247). Despite the relative infrequency of litigation, however, changes in judicial rules, decisions, and outcomes are important barometers of the total climate in which the U.S. product liability system exists.

In cases where courts establish a manufacturer's liability, juries' awards to the injured party have increased well in excess of the rate of inflation during recent years. While these verdicts comprise both compensatory and punitive awards, the bulk of the increase is attributable to punitive actions (192). A study by the Rand Corporation using data drawn from Cook County (Chicago) and San Francisco found substantial growth in the size of jury awards for all types of product liability suits.⁵ From the 1960-64 to the 1980-84 period, the mean award for all product liability cases (not just pharmaceuticals) in San Francisco grew 1,116 percent in real terms and 312 percent in Cook County (318). In each city, the mean awards were substantially greater than the median, reflecting the small number of very large awards. The probability of actually winning a case that goes to court did not change over this period (318).

PRODUCT LIABILITY INSURANCE

Manufacturers traditionally protect themselves against the financial risk of product liability damage awards by buying insurance. Changes in pharmaceutical manufacturers' liability premiums, claims, and uninsured expenses provide a measure of the financial impact of product liability on a firm's cost of doing business and

presumably reflect the changes in risk or expected losses posed by product liability claims.

Through the 1970s, most pharmaceutical firms protected themselves against liability losses with insurance that consisted of three pieces:

- The manufacturer paid a *deductible* for the first portion of each claim.
- Once the deductible was met, the *basic insurance* policy paid claims up to specified limits.
- Most companies also held *excess insurance* to pay claims above the basic policy up to another specified limit (443).

For the manufacturer, the total costs attributable to product liability include deductibles, any other losses not covered by insurance, any legal or administrative costs borne by the firm, and insurance policy premiums.

Most of the pharmaceutical firms interviewed by OTA indicated they can no longer get any basic insurance coverage in the traditional liability insurance market. The policies available today carry higher deductibles and premiums, with lower limits on how much they will pay per claim and in aggregate than did past policies (510). Some policies have excluded specific products or types of products thought to carry a higher than average risk of product liability loss. Consequently, pharmaceutical manufacturers have increasingly self-insured to compensate for lost basic insurance coverage by setting aside reserves to cover expected losses, establishing special lines of credit to cover unanticipated liability losses, and establishing "captured" insurance companies that are wholly or primarily owned by the insured pharmaceutical firm and have no other policyholders.⁶

Some companies also transfer a portion of their liability risk to insurance companies established in consortia with other manufacturers. Two exam-

⁵This research is limited. **Variation** between Cook County and San Francisco and between San Francisco and other California communities calls into question the **representativeness** of trends observed in these particular areas for product liability claims, suits, and awards to the country as a whole.

⁶ Insurance industry observers have suggested that one reason for setting up a captured insurance company is some excess insurers require **firms** to have basic insurance in order to get an excess policy (5 10).

pies of such insurers mentioned to OTA by drug manufacturers are the American Casualty Excess, Ltd. (A. C. E.) and X.L. Insurance Company, Ltd. X.L. provides coverage below A, C. E., and A.C.E. insures against the highest losses suffered by a firm. Both insurers were established in the 1980s and are funded through premiums paid by manufacturers (243,490).⁷

PRODUCT LIABILITY CLAIMS AND R&D

Systematic attempts to determine product liability costs borne by the pharmaceutical industry, and the impact of product liability on firms' R&D decisions, innovation, and drug safety would require data from several sources, much of which is currently unavailable. Firms do not routinely report to the public on liability claims made on their products or settlements made by the firm or their insurers. Insurance companies collect data on claims made under their policies but do not report on claims associated with particular companies or products. For the minority of claims proceeding to litigation, court records exist but are not centralized across different State and local jurisdictions.

■ Overall Trends in Pharmaceutical Product Liability Litigation

TRENDS IN NUMBERS OF CASES

In 1988, researchers at the Rand Corporation analyzed product liability cases filed in the Federal District Courts between 1974 and 1986 to identify trends in the number of cases over time and their concentration within particular industries and products (1 15). They focused on the Federal court system because of the availability of a single computerized data system. However, these data have several limitations:

- Most product liability cases are heard in State courts, making the Rand analysis potentially unrepresentative of all litigation.
- The analysis is unrepresentative of product liability claims and settlements not resulting in litigation, which constitute the vast majority of all claims.
- The database records only the first named defendant in cases with more than one defendant.⁸
- Because this database does not mention the product involved in each suit, the Rand researchers classified defendants by the company's Standard Industrial Classification (SIC) code (which reflects the company's primary area of business activity). However, since many companies have diversified product lines, a suit against a firm with a pharmaceutical SIC code does not necessarily mean the suit itself concerns a pharmaceutical product.

The analysis found 85,694 different Federal product liability cases involving a total of 19,456 lead defendants. Pharmaceuticals and health care products represented 13.5 percent of the total cases but only 2.2 percent of the total number of defendants. Of the 11,292 suits for pharmaceutical and other health products filed, 72 percent are attributable to five firms, and 60 percent are attributable to two companies--A.H. Robins and Merrell Dow Pharmaceuticals.⁹ Figures 7-1 and 7-2 show trends in these cases over time.

The Rand researchers concluded that A.H. Robins's Dalkon Shield contraceptive intrauterine device (IUD) and Merrell Dow's Bendectin antinausea medicine for pregnant women explained the bulk of liability cases for these two

⁷The Federal Government has tried to facilitate risk pooling by erasing barriers to firms or other organizations to form "risk retention groups" (RRGs) that write product and general liability insurance policies and collect premiums or "purchasing groups" (PG) that pool risk in order to get additional coverage or cheaper premiums than if they were purchasing insurance alone (Public Laws 97-45, 98-193, and 99-563). To date, firms have not made much use of these options (489,5 10), and pharmaceutical executives interviewed by OTA did not mention RRGs as part of their insurance protection against liability.

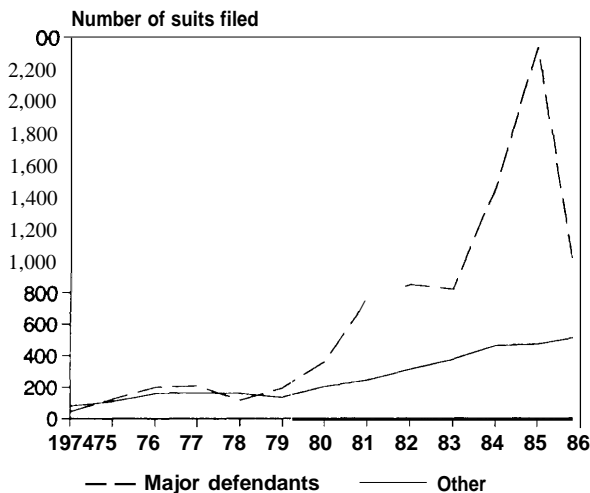
⁸ The Rand researchers conducted a separate analysis of paper records of Federal product liability cases filed in California between 1977 and 1986. They found, on average, each case had 2.2 defendants, and codefendants (i.e., other than the lead defendant mentioned in the computerized Integrated Federal Courts Database) are sued infrequently in the Federal courts.

⁹ A.H. Robins was the defendant in almost 5,700 cases, and Merrell Dow in just under 1,300.

firms. The dropoff in numbers of new cases involving these firms in 1985 and 1986 is attributable to a cutoff for new claims against the Dalkon Shield on April 30, 1986 (following A.H. Robins's bankruptcy in August 1985) and a district court ruling in favor of Merrell Dow in a February 1985 judgment involving 800 consolidated Bendectin suits. The Dalkon Shield and Bendectin cases are discussed further in the section that follows on products involving reproductive health.

Despite the overwhelming number of cases probably attributable to two products, the researchers noted a significant increase in the number attributable to other defendants during the 1980s and a contemporaneous increase in the number of defendants. The number of cases more

Figure 7-1—Filing Patterns of Federal Pharmaceutical Product Liability Cases, 1974-86

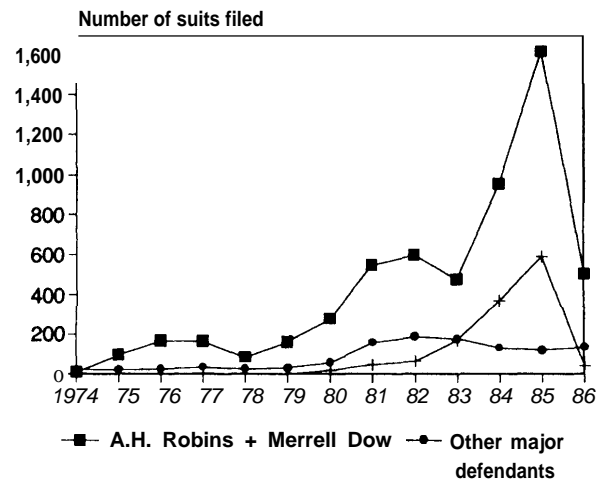


SOURCE: T. Dungworth, *Product Liability and the Business Sector: Litigation Trends in Federal Courts* (Santa Monica, CA: The Rand Corporation, 1988).

than doubled between 1981 and 1986, of a rate of increase greater than that for all Federal product liability cases during the same period.

In 1988, the U.S. General Accounting Office (GAO) published a study of its own examining trends in Federal product liability filings between

Figure 7-2—Federal Pharmaceutical Product Liability Patterns for Major Defendants, 1974-86



SOURCE: T. Dungworth, *Product Liability and the Business Sector: Litigation Trends in Federal Courts* (Santa Monica, CA: The Rand Corporation, 1988).

1974 and 1985 (432). Although GAO did not examine cases involving pharmaceuticals separately, it found that a few products—including the Dalkon Shield and Bendectin--were responsible for the bulk of the growth in filings during this period (432).

TRENDS IN JURY AWARDS AND JUDGMENTS AGAINST MANUFACTURERS

OTA found no systematic attempts to examine the monetary awards resulting from pharmaceutical product liability litigation. The Rand analysis of jury awards for all product liability cases (not just those involving drug companies) in San Francisco and Cook County showed that once sued, the number of claimants and the total amount claimed tended to be large and to have increased over time (318,388). Increases in the magnitude of the largest awards and in the probability of a plaintiff winning indicated manufacturers may have faced a greater expected loss if they allowed claims to proceed to trial.¹⁰

¹⁰ Although there is no systematic analysis to date of jury awards specifically involving the pharmaceutical industry, the Rand Corporation is currently examining how product liability affects company decisionmaking and industrial economic performance (142).

■ Liability Claims Involving Reproductive Health Products

THE DALKON SHIELD AND OTHER CONTRACEPTIVES

The Dalkon Shield and Bendectin are both products intended to affect the reproductive health of women in childbearing years. A.H. Robins acquired the rights to the Dalkon Shield in 1970. Claims of the device's effectiveness as a contraceptive were based on a 1-year study of 640 women, which showed a 1.1-percent pregnancy rate during the trial period (103). At that time, Federal law did not require FDA approval of medical devices such as the Dalkon Shield.¹¹

A.H. Robins began to market the contraceptive device in the United States in January 1971 despite questions among the firm's medical staff about the validity of conclusions drawn from the single effectiveness study (288).

During the first 3 years of marketing, A.H. Robins received evidence the Dalkon Shield could and did cause uterine infections and septic abortions, but it did not change the product or its labeling. In June 1974, A.H. Robins withdrew the device from the market after the U.S. Centers for Disease Control (CDC) had reported complications among 62 percent of women who became pregnant while wearing the Dalkon Shield (288).¹²

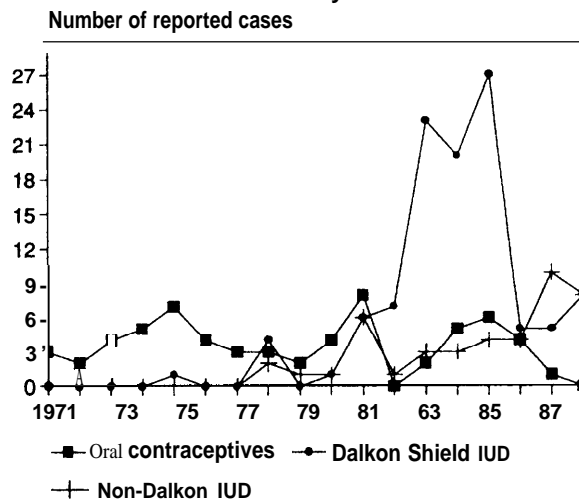
After the Dalkon Shield suits forced A.H. Robins into bankruptcy, the courts imposed an April 1986 filing deadline for new claims. By that time, about 320,000 claims had been filed against the firm for injury caused by the Dalkon Shield (206). Of the 4,400 claims resulting in litigation, A.H. Robins paid \$250 million in out-of-court settlements and another \$25 million in punitive awards imposed by 11 juries. As part of its bankruptcy plan, the courts required A.H. Robins set aside another \$2.475 billion for unsettled claims (288).

Although the Dalkon Shield is not a pharmaceutical product, some observers have suggested that claims made against it have led to successful claims made against pharmaceutical products, including oral contraceptives (9, 192). However, the data do not exist to measure whether there has been a significant increase in liability losses for contraceptives other than the Dalkon Shield. As measured in terms of decided court cases (i.e., not including those settled or otherwise resolved before completion of a trial), oral contraceptives show cyclical variation in numbers of cases over time, but the average number of cases within each cycle remained relatively constant between 1971 and 1988 (see figure 7-3).

BENDECTIN

First sold in the United States in 1956, Bendectin is a combination drug consisting of a vitamin, an antispasmodic, and a sedative. It is the only pharmaceutical ever approved in this country for the treatment of "morning sickness"

Figure 7-3—Yearly Reported Oral Contraceptive and IUD Liability Cases



SOURCE: L. Mastroianni, P.J. Donaldson, and T.T. Kane (eds.), *Developing New Contraceptives: Obstacles and Opportunities* (Washington, DC: National Academy Press, 1990).

¹¹ Congress amended the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) in 1976 to require premarketing approval of medical devices (Public Law 99-295).

¹² Withdrawal from the market did not eliminate the potential for the IUD to cause new injuries, since many women kept implanted Dalkon Shields in place after 1974.

associated with pregnancy.^{1 3} Beginning in 1969, the medical literature reported cases of congenital defects in babies born to women who had taken Bendectin during pregnancy. Because the number of deformities attributable to Bendectin was expected to be small if it *did* cause birth defects, establishing this relationship with any degree of statistical confidence was problematic.

Although the FDA concluded in 1980 **that there was not** enough evidence to ban Bendectin from the marketplace, it required the drug's manufacturer, Merrell Dow, to change its package insert to indicate while the drug had been carefully studied, it was impossible to prove it **was without** risk if taken as indicated (45 F.R. 80740).

As mentioned earlier, litigation proliferated despite the FDA's willingness to allow the drug's use. In the early 1980s, the courts consolidated 1,100 claims into a single, class-action suit **that Merrell Dow** offered to settle for \$120 million. The plaintiffs rejected the offer, and the manufacturer successfully defended itself in a jury trial. Of the 17 Bendectin **cases that** had gone to trial by July 1987, Merrell Dow had prevailed in 12 (192). According to one source, **total costs to Merrell Dow** of defending itself against Bendectin's liability suits exceeded the \$13 million in annual revenues the company received from sales of the drug, prompting the firm in 1985 to remove it voluntarily from the marketplace (61).

DES

First discovered in 1937, the synthetic form of estrogen called diethylstilbestrol (DES) was marketed as a generic product by over 300 manufacturers worldwide, especially during the 1950s, as a means of preventing miscarriages. However, research completed in 1971 showed a statistically **significant** association between DES use and

clear-cell adenocarcinoma, a cancer of the glands, among daughters of women who had used the drug. This finding resulted in a large number of product liability suits against the drug's manufacturers.¹⁴ Because of the large number of manufacturers involved and the long period between use of the drug and development of the cancer, the courts were unable **to determine** directly which manufacturer had caused each injury. The case of DES led the California Supreme Court to be the first to adopt the "market share" theory in attributing causality among drug manufacturers (142,192,263).

■ Liability Claims Involving Vaccines

Vaccines are another type of health care product frequently cited **as** prone to liability claims (9,239). Although they are usually not considered to be therapeutic pharmaceuticals—the type of health care product on which this report largely focuses—they are appropriately discussed in this chapter for several reasons:

- Because most vaccine manufacturers also produce pharmaceuticals, the behavior of firms responding to vaccine liability claims may be similar to their likely behavior in the face of pharmaceutical liability claims.
- The distinctions between vaccines and pharmaceuticals in terms of their underlying science and their R&D processes can be murky, particularly as more therapeutic pharmaceuticals rely on biotechnological techniques to replicate substances naturally found in living organisms as many vaccines traditionally have done.
- The Federal Government has attempted to absorb some of the product liability faced by vaccine manufacturers, potentially offering

¹³In 1972, as part of a review of drugs approved by the FDA before the imposition of the requirement that drugs show effectiveness to be marketed in the United States, the National Research Council and the National Academy of Sciences concluded there was no clinical evidence the antispasmodic contributed to the drug's therapeutic effect, and the manufacturer dropped this agent from the drug. This finding was unrelated to the claims that resulted in product liability litigation involving **Bendectin** (239).

¹⁴DES is not identified as a **major product** in the Rand analyses of Federal court cases described **earlier** in this chapter. This could reflect the fact that few DES cases were filed in Federal court (263). Alternatively, the number of DES cases in the Federal courts maybe obscured because of a large number of DES **manufacturers**; the Rand analysis only identifies each case according to its "lead" defendant rather than by the product name or all codefendants (142).



Photo credit BRISTOL MYERS SQUIBB COMPANY

Although vaccines can be an effective and cost-saving means of preventing diseases, manufacturers of these drugs have been the subject of many liability cases.

Lessons and insights for policy makers considering greater Federal involvement in pharmaceutical liability.

All vaccines introduce some component of an organism that causes disease into the body in order to stimulate the immunized person's own system to produce antibodies against that disease.¹⁵ For reasons not completely understood, some individuals exhibit reactions after receiving immunizations ranging from soreness in the arm to paralysis or brain damage (444). Determining the actual risk of serious harm for a given patient is difficult for two reasons: 1) they are rare; and 2) it is difficult to determine whether such harm would have occurred even if the patient had not received the vaccine (206).

The vaccine that has evoked the greatest liability concern to date is the pertussis compo-

nent of the diphtheria-tetanus-pertussis (DTP) vaccine. The risk of encephalitic brain damage was estimated in a 1981 *British Medical Journal* article as 3.2 per million injections (9), although more recent U.S. epidemiological research has suggested the risk is actually much lower (165). Risks of serious complications from other vaccines appear to be even lower than that of DTP (9,444). Furthermore, vaccines are not mentioned as frequent subjects of lawsuits (115,432).

Why, then, are vaccines frequently cited as products bearing a heavy liability burden? The answer may lie in the nature of vaccine products and their differences from therapeutic pharmaceuticals, rather than in the risks or the absolute liability burden associated with vaccines. Vaccines are an effective and cost-saving means of preventing disease. Not only do the States require children to be immunized against the most serious childhood diseases, but the Federal Government supports vaccination activities for children and adults through a variety of grants and Medicare and Medicaid reimbursement (443,449). At the same time, however, some observers suggest vaccines have relatively low profit margins (239).

The legal burden for vaccine manufacturers also rests on somewhat different grounds than it does for drug manufacturers. While courts have found in most drug and contraceptive cases that companies have fulfilled their duty to warn of adverse reactions by adequately informing physicians of risks,¹⁶ some courts have ruled that because there is no personalized relationship between physician and patient in mass immunization programs manufacturers must provide warn-

¹⁵ There are four main strategies vaccines can adopt in producing immunity:

- 1) "Killed" or "inactivated" vaccines contain dead cells of the bacteria or virus that causes the disease to be prevented. Examples include the Salk polio vaccine and the pertussis vaccine.
- 2) "Live attenuated" vaccines contain living versions of a disease-causing virus that have been weakened in the laboratory. The Sabin polio vaccine and the vaccines against mumps, measles, and rubella are live attenuated.
- 3) "Toxoid" vaccines, such as those that prevent diphtheria and tetanus, contain weakened versions of poisonous toxins produced by the disease-causing bacteria (206).
- 4) Newer, "acellular" vaccines, which contain only pieces of the disease-causing bacteria, have been developed in the search for a safer means of immunizing against pertussis (239).

¹⁶ This is sometimes referred to as the "learned intermediary" rule.

ings directly to patients.¹⁷ Finally, many vaccines, especially the DPT immunizations, have relatively common, nonserious, but disquieting adverse reactions such as fever, inconsolable crying, localized soreness, rashes, and malaise (444). Such side effects may create the perception among health care consumers that the risk of serious injury is greater than it really is; patients may be more likely to claim that health problems occurring subsequent to vaccination occurred because of the vaccination.

■ Evidence Concerning Product Liability and Innovation

Given the discernible patterns of product liability claims and costs described above, what is known about their effects on the pharmaceutical R&D process? There are at least two hypotheses one could attempt to test:

- Product liability could increase R&D costs and lengthen the R&D process as firms perform “defensive studies” to help protect themselves from subsequent negligence claims and as they absorb the costs of liability for a drug administered during the clinical R&D phase.
- Product liability burdens could lead firms not to fund R&D in certain areas or ultimately not market certain products.

OTA found no studies or other evidence that allow one to test the first of these hypotheses. In addition, it was not cited by pharmaceutical industry officials in any of OTA’s interviews at eight drug firms. Hence, OTA is unable to shed any additional light on this possible corporate response to product liability. However, there is evidence (albeit largely anecdotal) that bears on the second hypothesis.

PRODUCT LIABILITY AND FIRMS’ WILLINGNESS TO CONDUCT R&D

OTA found only one attempt to bring together industrywide data to determine if product liability inhibits pharmaceutical innovation. In a 1991 study, Viscusi and Moore compiled data for pharmaceuticals and several other manufacturing industries for the first half of the 1980s on both product liability insurance experience and innovation (501). They concluded that during the period examined pharmaceuticals were both relatively innovative and subject to a volatile liability burden—that do not lend support to the hypothesis that product liability inhibits innovation. However, their study does not control for other factors that might have affected innovation.¹⁸ In addition, their examination of industrywide data may obscure differences in access to various types of pharmaceuticals.

Much of the remaining evidence on product liability and pharmaceutical innovation is anecdotal.

¹⁷ The precedent-setting case was *Davis v. Wyeth Laboratories*, 399 F.2d 121 (9th Cir. 1968), which dealt with a polio vaccine administered in a mass immunization clinic. *Reyes v. Wyeth Laboratory*, 498 F.2d 1264 (5th Cir. 1974), reinforced this decision by ruling the manufacturer was liable because of inadequate warning even though it had manufactured the vaccine properly with printed warnings and there was good evidence the plaintiffs’ polio was caused by a virus not found in the vaccine. In this latter case, the court indicated firms should bear the cost of a potential vaccine-induced injury as a predictable business expense, passing the cost on to consumers in the price of the vaccine rather than placing the loss on the injured party (443). However, in another Federal case decided this year, *Mazur v. Merck*, the court actually ruled a manufacturer was *not* liable for an injury that occurred in a 1982 mass immunization program because a Federal agency, the U.S. Centers for Disease Control, had agreed to convey warnings to the patient (404).

¹⁸ They point out several other limitations of the data they present:

- 1) The statistics on innovation are measured at the beginning of the period examined (1980), and almost no firm changed its responses in the subsequent annual surveys conducted. Hence, there is no measured variation in innovation over time in this database or any way to determine if innovation would have been different with less or more product liability burden.
- 2) The statistics on product liability are likely not to be an accurate reflection of product liability activity in the pharmaceutical industry because the authors depend on insurance data and much of the transition to self-insurance for drug manufacturers occurred before 1980.
- 3) The largest number of liability cases (as suggested in the Rand and GAO data) and the greatest amount of attention to product liability occurred during 1985 and 1986—after the collection of the data that Viscusi and Moore examine.

dotal and tends to fall into one of two lines of argument. One line of argument cites the discontinuation of products associated with high liability costs as evidence of how product liability directly limits the availability of products to consumers and as an indirect indication that liability could inhibit R&D for similar types of products. Among the products cited are the Dalkon Shield, Bendectin,¹⁹ thalidomide as a sedative for nonpregnant women (239), and vaccines against DPT, Japanese encephalitis (254), and swine flu (293).

The second line of argument directly attributes certain changes in firms' R&D portfolios to product liability. The examples to support this argument are somewhat more general than those given above, perhaps because of the confidential nature of most firms' R&D portfolios.²⁰ Among the examples encountered by OTA:

- *Contraceptive R&D*—The number of large, U.S. research-based pharmaceutical firms engaged in contraceptive R&D has dropped in recent years from nine to two.²¹ Product liability is the most-often cited reason for the decision to end such research programs (89).²²
- *Pharmaceuticals Taken During Pregnancy*—Members of the legal staff at several pharmaceutical firms interviewed by OTA for this report indicated they would raise concerns about any potential product to be given to pregnant women. The lawyers tied their concerns specifically to the Bendectin expe-

rience. Other analysts have made similar findings (348).

- *Vaccines Against Human Immunodeficiency Virus (HIV)*—Legal staff at a firm engaged in R&D to develop a vaccine against HIV told OTA that liability was a significant consideration each time the company decided to continue this research. Furthermore, the firm's insurer was reluctant to provide any coverage for a potential product. Legal staff at two other companies indicated their liability insurers²³ asked the firms to inform them if they decided to engage in HIV vaccine R&D. In a recent case, Abbott Laboratories withdrew its participation in a planned NIH clinical trial that would have tested vaccine to ensure pregnant HIV positive women from passing the virus to their unborn children. Abbott cited fear of liability in its decision not to provide NIH with the vaccine, called HIV hyperimmune globulin (HIVIG) (81). Other groups have also cited potential liability problems surrounding the search for a product to prevent HIV infection (9,231).

Some observers suggest the impact of liability can be inferred from the complexity and extent of safety testing necessary to receive FDA marketing approval. According to this line of argument, these regulatory requirements are largely driven by public concerns that products not cause injury, the basis for liability (243).

¹⁹ The liability experience of this drug and its withdrawal from the market has actually led one author to suggest that no company will ever again seek to market a drug to treat nausea associated with pregnancy (239).

²⁰ In OTA's interviews at eight research-based pharmaceutical firms, company officials offered specific examples of R&D projects abandoned or forgone because of liability concerns, but all firms asked that they not be identified by name with these decisions.

²¹ Ortho Pharmaceuticals, a subsidiary of Johnson & Johnson, has had an ongoing contraceptive R&D program. Eight companies that have discontinued such R&D are: Syntex, Searle, Parke-Davis, Merck, Upjohn, Mead Johnson, Wyeth-Ayerst, and Eli Lilly (207). Wyeth-Ayerst, a subsidiary of American Home products, has renewed its contraceptive R&D program in recent years, focusing on new forms of oral contraceptives (8,25 1). In addition, a relatively new, small firm, Gynco-Pharma, currently markets a copper IUD. Non-U.S. firms as well as universities and nonprofit foundations also carry on R&D on new forms of birth control (207).

²² However, product liability is not the only reason cited. Others include limitations on patents that make potential products possibly unprofitable and perceived public pressure not to engage in contraceptive R&D (89).

²³ In each case, the firms had only excess product liability insurance and self-insured against lesser claims.

GOVERNMENT POLICY AND PRODUCT LIABILITY

To what extent has government intervened in recent years to alter product liability rules or to affect the outcomes of liability claims? This section reviews recent policy initiatives of potential relevance to pharmaceutical liability,

■ Tort Reform

As States have developed different case law, some have also enacted statutes designed to alter liability law, usually in response to the perceived ill effects of court decisions. Although some attempts at changing liability law have been found in most States, a Federal review of statutes adopted by State legislatures during 1986 alone revealed the actual provisions adopted vary greatly. The most common reform (enacted by 16 States) altered the doctrine of ‘joint and several liability’ which allows multiple defendants named in a lawsuit all to be held responsible. Observers have suggested under this doctrine the wealthiest defendant often pays all or most of the damages whatever the defendant actual degree of responsibility for causing the injury (265). Other provisions adopted by States include limitations on noneconomic and punitive damages, limitations on attorney’s contingency fees, allowance for periodic payment of damage awards instead of requiring a lump sum, and modification of the ‘collateral source rule,’ which prohibits courts from considering other sources of compensation (such as personal health insurance benefits) a plaintiff may receive (490).

Over the past decade, Congress has considered several Federal product liability statutes that would supersede any relevant State statute or case

law. The 101st Congress considered, but did not adopt, “The Product Liability Reform Act” (S. 101-1400).²⁴ Of particular importance to the pharmaceutical industry, the bill would bar punitive damages for drugs or medical devices receiving approval from the FDA unless the manufacturer had withheld or misrepresented relevant information from the agency. Among other provisions of the bill were limitations on punitive damages, limits on the amount of time in which a plaintiff can bring a claim, a limitation of joint and several liability²⁵ to compensatory (nonpunitive) damages only, and incentives for parties to settle the case prior to trial (442).²⁶

One recent study suggests case law as well may be moving away from the expansion of liability and damages. In a quantitative analysis of recent State court decisions in product liability cases, Henderson and Eisenberg suggest that since the early to mid-1980s, courtroom decisions have subtly begun to favor manufacturers by placing limitations on injured parties’ ability to receive damages. They show this change predates many of the statutory reforms described above. While such tendencies are becoming evident, the authors point out it still may be too early to assess their ultimate impact (182).

■ Federal Compensation for Injuries Associated With Health Care Products

To date, the Federal Government has not established any alternative or additional remedy for injuries associated with therapeutic pharmaceuticals.²⁷ However, on two separate occasions, Congress has adopted compensation schemes for vaccine-related injuries.

²⁴ Senate Bill 1400 (101st Congress) was very similar to several earlier product liability reform bills: S. 666 (100th Congress) and S. 2790 (99th Congress).

²⁵ “Joint and several liability” refers to the liability of each defendant for all damages even if more than one defendant is found liable.

²⁶ Introduced by Senator Robert W. Kasten in July 1989, the bill reached was reported out of committee (Senate Report 101-356), but not debated on the floor before the end of the session. Senator Kasten reintroduced this legislation in the 102d Congress (S. 640).

²⁷ As mentioned earlier in this chapter, Congress has considered adopting national tort law standards, including proposals to protect manufacturers from punitive damage awards for products approved by the FDA unless the manufacturer has acted fraudulently.

²⁸ In January 1976, several soldiers at Fort Dix (New Jersey) became sick with influenza found by the CDC to be caused by the swine flu virus responsible for the worldwide influenza epidemic in 1918-19 that killed 20 million (293).

THE SWINE FLU IMMUNIZATION PROGRAM

In August 1976, in the face of an epidemic of swine flu expected during the winter of 1976-77,²⁸ Congress established a national immunization program (Public Law 94-380). As part of this legislation, the Federal Government agreed to accept liability for vaccine-related injuries. Because insurers had excluded the vaccine from product liability policies, manufacturers were unwilling to supply it without Federal intervention. Under this law, people who believed themselves to have been injured could not sue, but were permitted to make claims against the United States within 2 years of the vaccination according to the theories of liability in practice in the State where the injury took place (169).

The U.S. Department of Health, Education, and Welfare (DHEW) (now the U.S. Department of Health and Human Services (DHHS)) halted the immunization program in December 1976 after several vaccinated individuals contracted Guillain-Barré syndrome, a condition that leads to paralysis.²⁹ About 40 million people had received the vaccine. In June 1978, DHEW announced that because the vaccine label and consent form did not warn recipients about the possibility of Guillain-Barré, those claiming injury did not need to prove fault (i.e., negligence by the government) in order to receive compensation. Out of the 4,179

claims and 1,604 lawsuits filed against the government under the swine flu program, the government paid a total of \$90.1 million in 709 settled claims, 391 settled suits, and 105 judgments in favor of the claimants (169).³⁰

THE NATIONAL CHILDHOOD VACCINE INJURY ACT OF 1986

In response to concern over the ability of the dwindling number of vaccine manufacturers to provide adequate supplies of vaccine for childhood immunization during the 1980s, Congress adopted a no-fault alternative to product liability litigation for people seeking compensation for injuries related to childhood vaccines administered up to 8 years prior to the enactment of the legislation (Public Law 99-660, Title III). Under the act, Congress determines which vaccines are included, and the Secretary of DHHS determines what types of injuries are eligible for compensation through regulation.³¹

Although claimants may still choose to pursue compensation, this statute essentially constitutes Federal tort reform for eligible childhood vaccine-related injuries. By establishing a no-fault compensation scheme as the first form of redress for injuries and limiting liability for manufacturers who have met FDA requirements, Congress has, in essence, nullified case law that had previously allowed liability findings based on theories of

²⁹In addition, the epidemic of swine flu never occurred.

³⁰According to Hagan, at the time these data were gathered in January 1989, 2 claims and 17 lawsuits were still to be resolved (169).

³¹Currently, the program includes vaccines for measles, mumps, polio, rubella, and diphtheria/pertussis/tetanus (DPT). The law prohibits anyone from seeking awards of more than \$1,000 or for an unspecified amount through civil litigation without first filing a petition for compensation with the U.S. Claims Court and the Secretary of DHHS.

Compensation can include nonlegal expenses incurred as a result of the injury, lost earnings, and death up to \$250,000. The program allows compensation for attorneys' fees regardless of the outcome of the petition.

The compensation mechanism is "nonexclusive" in that claimants may choose to pursue remedies through the courts rather than accepting an award through the no-fault process. However, if a claimant sues, the law tries to protect manufacturers from claims of design defect if they have complied with all relevant FDA regulations in establishing a drug's safety and efficacy.

Compensation for vaccines administered before October 1, 1988 comes from appropriated funds which have averaged \$80 million per year since Congress first funded the program in fiscal year 1989 (Public Law 100-436). A tax added to the cost of each vaccine funds a National Vaccine Injury Compensation Trust Fund, which pays damages awarded for vaccines administered after October 1, 1988. The tax rate is set according to evidence about the frequency and expected damages associated with each type of vaccine (169).

As of June 18, 1991, the U.S. Health Resources Services Administration, which is charged with implementing the compensation program within DHHS, had received 4,095 petitions for pre-October 1988 injuries and 127 for injuries on or after October 1, 1988. Of the 306 petitions acted on as of June 18, 1991, 66 were withdrawn or dismissed before being adjudicated, 188 were deemed compensable, and the remaining were ruled not compensable. The government has paid a total of \$122.4 million in awards that individually ranged from \$48,510 to \$2.9 million. The average award for pre-1988 cases is \$1.2 million (465).

strict liability and a failure to warn. The experience of this program could offer insights into the potential effects of adopting a similar no-fault compensation system for acquired immunodeficiency syndrome (AIDS) vaccines, as suggested by the Keystone AIDS Vaccine Liability Project (231), or into the implications of other product liability reform proposals like those mentioned earlier in this chapter.

CONCLUSIONS

Despite a lack of systematic data, it is possible to piece together the major implications of product liability on pharmaceutical R&D. Although health care products appear to be a part, if not a significant part, of the increase in product liability litigation over the last 20 years, the vast majority of health-care-related cases have involved only certain types of products, contracep-

tives, and other pharmaceuticals that affect reproductive health, and vaccines. Although some firms continue to pursue R&D in these areas, anecdotal evidence suggests liability concerns may significantly inhibit the overall level of industrial R&D effort in these areas. Both industry and government have implemented novel forms of underwriting health-care product liability risks, although no systematic evidence exists to evaluate the extent to which these programs enhance firms' willingness to conduct R&D for vaccines and reproductive health products. As suggested by recent experience, fear of product liability may be a particularly significant barrier to industry's willingness to develop, test, and market potential **vaccines against HIV and may** become a major **policy** concern for the Federal Government.