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A Statistical Profile of Pharmaceutical Industry Liability, 1976-1989

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I. INTRODUCTION

The explosion in tort liability claims and awards in the mid-1980s led many observers to conclude that the nation was undergoing a liability crisis. The perception that liability costs were becoming both uncertain and excessively high, in turn, generated the impetus for a series of reform efforts, as a large number of states enacted measures to reduce liability costs. These policies consisted of a variety of damage caps, as well as reforms of doctrines such as joint and several liability.[1]

The pharmaceutical industry played a particularly prominent role in the liability reform debate. Although much of the surge in tort liability can be accounted for by asbestos cases, which made up the majority of all federal liability cases beginning in 1987,[2] the pharmaceutical industry was a prominent player in the tort liability arena as well. For example, G.D. Searle and Company suspended production of the Copper-7 contraceptive device after spending $1.5 million to defend itself against four lawsuits filed in a single year.[3] Similarly, Merrell Dow Pharmaceuticals was forced to dis-

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1 For example, three states enacted general liability reforms with damages caps in 1985, nine states did so in 1986, and sixteen states followed suit in 1987. The number of medical malpractice reforms was somewhat sparser, as four states enacted damages caps in 1985, eight states did so in 1986, and one state adopted such a cap in 1987. A breakdown of the states enacting caps and a summary of the type of reform appears in W. Kip Viscusi & Patricia Born, Medical Malpractice Insurance in the Wake of Liability Reform (1993) (Duke University Working Paper) (on file with author).

2 *See* W. KIP VISCUSI, REFORMING PRODUCTS LIABILITY 21 (1991)

3 *See* VISCUSI, *supra* note 2, at 66.

continue the production of Bendectin, the only prescription drug that the Food and Drug Administration had approved for treating morning sickness during pregnancy. This occured after Merrell Dow had incurred legal expenses almost equal to the annual sales of the product before ever having lost a case.[4] The litigation over the Dalkon Shield produced by A.H. Robins involved 195,000 claimants, leading the company to establish a trust fund of almost $3 billion (as of 1989) to pay these claimants.[5] A National Academy of Science panel concluded that the net effect of the surge in liability costs had been to discourage innovation in the pharmaceutical industry, particularly with respect to contraceptives.[6]

The purpose of this paper is to move beyond anecdotal evidence regarding the pharmaceutical industry by answering a number of questions: What is the scale of litigation involving pharmaceutical products? How has the pace of litigation been affected by the enactment of a variety of tort liability reform measures from 1985 to 1987? Finally, what is the relationship between the patterns exhibited by the pharmaceutical industry as compared to the rest of the economy? Has the pharmaceutical industry been particularly hard hit, or is the rise in enterprise liability more broadly based?

To resolve these issues, we will utilize data on federal product liability cases compiled by the Administrative Office of the United States Courts, in particular the computerized version of this data set. These data only pertain to cases in the federal courts, not to state court actions or out-of-court settlements. However, available evidence suggests that patterns in state courts are roughly similar in character so that examining the performance of federal litigation should nevertheless be instructive.[7] In addition, changes in the plaintiff success rate will have some implications for the role of out-of-court settlements.

For purposes of the study conducted, we divided companies into two groups, those that produced pharmaceutical products and other manufacturing firms. Companies that produced asbestos were excluded from the sample so that the litigation patterns

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[4] *Company Stops Making Morning Sickness Drug*, N.Y. TIMES, June 10, 1983, at A16.

[5] *See* VISCUSI, *supra* note 2, at 168-69.

[6] NATIONAL ACADEMY OF SCIENCES, DEVELOPING NEW CONTRACEPTIVES: OBSTACLES AND OPPORTUNITIES (1990).

[7] *See* GENERAL ACCOUNTING OFFICE, PRODUCT LIABILITY: EXTENSIVE 'LITIGATION EXPLOSION' IN FEDERAL COURTS QUESTIONED (1988) and GENERAL ACCOUNTING OFFICE, PRODUCT LIABILITY: VERDICTS AND CASE RESOLUTIONS IN FIVE STATES (Report HRD-89-99) (1989).

would not be overwhelmed by the surge in asbestos-related claims. The sample, which extended from 1976 to 1989, included eighteen pharmaceutical companies and 438 other manufacturing companies.[8] Liability patterns are tracked for these companies over the thirteen year period, so that this represents an extensive data base on the role of product liability lawsuits by industry. This analysis represents the first effort of its kind to distinguish federal court trends on an industry basis.[9]

The pattern of litigation that we will identify is quite striking. The statistics support the perception that there was a surge in pharmaceutical industry litigation that peaked in 1985. This litigation abated in the subsequent years, but the decline may not be a cause for complacency because of the greater role assumed by out-of-court settlements.

II. Litigation Patterns

Figure 1 presents the trends in the total number of product liability cases filed each year in federal courts for the pharmaceutical industry and for the rest of the manufacturing sector. To put these statistics in perspective, note that the relative share of the pharmaceutical industry in the entire manufacturing sector of the economy is not great. In the last year of the sample, 1989, the manufacturing sector excluding pharmaceuticals was four times as large as the pharmaceutical industry, where the measure used is the dollar value of shipments.[10]

Notwithstanding the substantial discrepancy in the size of the pharmaceutical industry and the rest of the manufacturing sector, the number of suits filed is roughly comparable in each case. Indeed, in 1985, pharmaceutical industry cases were almost twice as numerous as those instituted against the rest of the manufacturing

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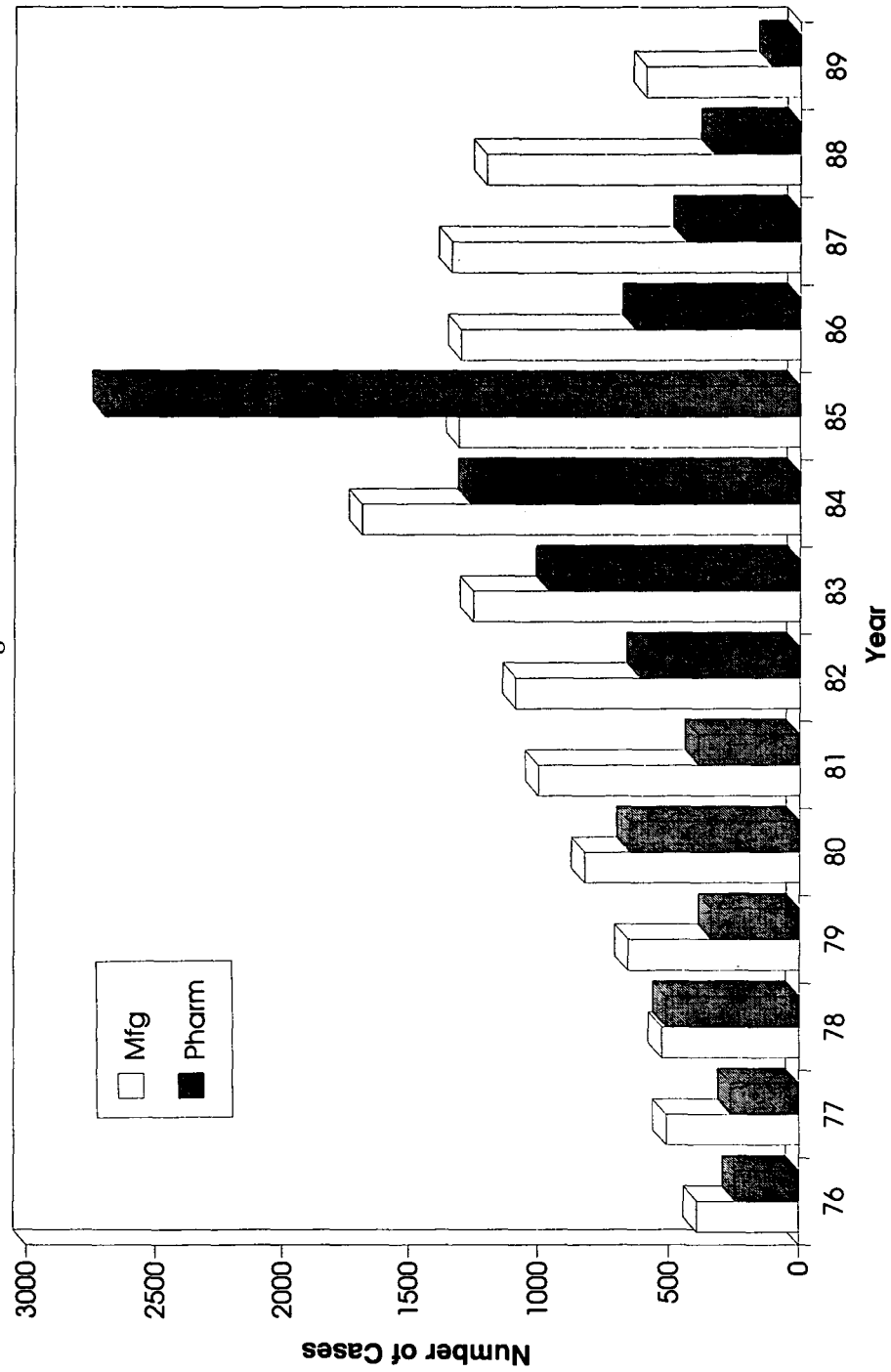
[8] This matching process was undertaken by the authors based on judgments regarding the principal industry in which the firm operated. Industry codes are not included in the original data base, but corporate names are.

The following were the pharmaceutical companies included in the sample: A.H. Robins Co., Abbott Laboratories, Allergan Inc., Alza Corporation, American Home Products, American Cyanamid, Bristol Myers Squibb, Eli Lilly & Co., Glaxo Holdings PLC, Johnson & Johnson, Marion Merrell Dow Inc., Merck & Co., Pfizer Inc., Schering-Plough, Smithkline Beecham PLC, Syntex Corp., Upjohn Co., and Warner-Lambert Co.

[9] The only possible exception is that of asbestos, which is broken out separately in the federal court data.

[10] In particular, the dollar value of shipments in the pharmaceutical industry was $46.8 billion. *See* U.S. Dep't of Commerce, 1990 U.S. Industrial Outlook 50-2 (1990). The total shipments of the manufacturing sector overall were $232.7 billion in 1989. *See* Economic Report of the President 409 (1993).

Figure 1
Total Cases: Manufacturing and Pharmaceuticals



sector, excluding asbestos. The surge in pharmaceutical industry liability in 1985 is attributable largely to mass lawsuits against two companies. Merrell Dow Pharmaceuticals, the producer of Bendectin, accounted for 1,319 cases in 1985, and A.H. Robins, the producer of the Copper-7, accounted for 1,185 cases. The decline in the number of cases filed against Merrell Dow to 140 in 1986 and the similar drop of A.H. Robins cases filed to 302 in that year accounts for the stark decline in pharmaceutical industry cases in 1986.

Although companies incur litigation costs irrespective of whether they win the cases, the outcome is pertinent in that it affects whether there is an award to the plaintiff. If the awards are large, they provide financial incentives for others to file claims with the hope of obtaining similar renumeration. The fraction of product liability cases won by plaintiffs is illustrated in Figure 2.

If the stakes of the plaintiff and defendant are even in all cases and the situation is otherwise symmetric, some legal scholars have hypothesized that there should be a fifty-fifty split in court verdicts between plaintiffs and defendants.[11] The reasoning is that any differences that favor one party over another will be anticipated during the settlement process. The parties will consequently incorporate effects, such as pro-plaintiff leanings in a particular jurisdiction, into their settlement efforts. The cases that are litigated will consequently be a random mix of cases that emerge once this case selection process has occurred.

Evidence for the 1970s suggested that this fifty-fifty split did not hold, as defendants won a greater proportion of the cases.[12] Such a situation would arise if the stakes for the two sets of parties were not identical. In particular, if manufacturers had a larger stake in the outcome than plaintiffs, one would predict that the pattern of settlements would generate a mix of cases in the courts in which defendants won more often than did plaintiffs.[13] Such an inequality would arise, for example, if a company's loss in a case had broad ramifications for an entire pattern of litigation against the product. In such a situation, the company's expected loss (i.e., probability of losing multiplied by the size of the loss) may exceed the expected court award to that particular plaintiff. To avoid high

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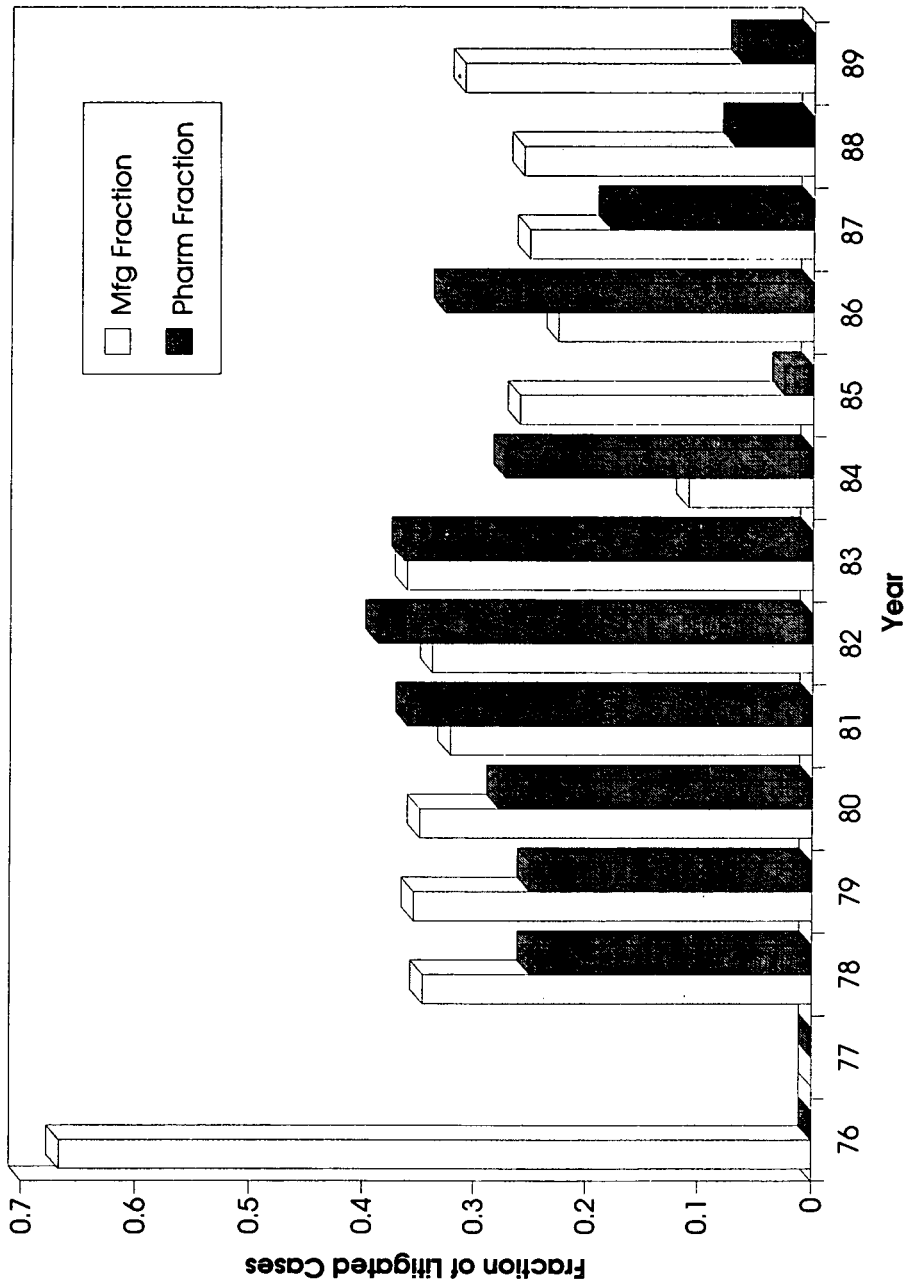
11 *See* George Priest & Benjamin Klein, *The Selection of Disputes for Litigation*, 13 J. LEGAL STUD. 1 (1984).

12 *See generally* VISCUSI, *supra* note 2, at 42-61.

13 *See* W. Kip Viscusi, *The Determinants of the Disposition of Product Liability Claims and Compensation for Bodily Injury*, 15 J. LEGAL STUD. 321 (1986).

Figure 2
Fraction of Litigated Cases with Judgment for Plaintiff:
Manufacturing and Pharmaceuticals



litigation costs and pattern-setting outcomes, the company may be willing to offer the plaintiff a larger amount to settle the case than the company expects to lose based on the court verdict alone and its chance of losing, even if the company has a very good chance of winning the case. It is noteworthy, for example, that producers of breast implants established a compensation fund in 1993 at the early stage of the litigation, whereas such measures were undertaken at a much later stage for asbestos and the Dalkon Shield. The persistent plaintiff success rate of less than fifty percent from 1978 to 1979 illustrated in Figure 2 is consistent with this view that the stakes are not symmetric.[14]

There is, however, an alternative hypothesis that the absence of a fifty-fifty split in the cases in the late 1970s and early 1980s was a short-run phenomenon, as the courts had not fully adjusted to the advent of strict liability and other changes in liability doctrine. The patterns in Figure 2 suggest, however, that the defendant success rate in excess of fifty percent was not an aberration, but in fact remained fairly steady and even increased through the latter part of that decade.

Significantly, the pharmaceutical industry's performance improved considerably after 1986. Whereas it lost over thirty percent of the cases in 1986, by 1989 it was losing fewer than ten percent. In contrast, the manufacturing sector experienced a steady rise in the fraction of cases won by plaintiffs.

One should, however, be cautious in interpreting these statistics as providing evidence in favor of shifts in liability criteria applied in the courts because these data pertain to the mix of cases litigated. Companies and plaintiffs should presumably take into account changes in liability laws that affect their prospects in court. Changes in the patterns of out-of-court settlements will alter the mix of cases litigated and the success rate pattern for cases taken to verdict. An open issue is the speed with which the parties adapted. The mid-1980s witnessed an explosion of cases and the enactment of many liability reforms. Did the explosion in litigation costs lead companies to settle more cases? Or did the high plaintiff awards in the mid-1980s raise expectations so that cases with little chance of success were filed? A final possibility is that parties were slow to react to the liability reform changes. The apparent persistence of a low plaintiff success rate suggests that the effect of the changing

[14] Other interpretations are possible as well. For example, one might claim that the case selection models simply do not hold.

litigation stakes on out-of-court settlements may be most influential.

The rise in the plaintiff success rate for manufacturing in the late 1980s is not surprising because it appears to have been aberrantly low in 1984. What is more surprising is that the plaintiff success rates for manufacturing and pharmaceuticals move in opposite directions from 1986 to 1989. One possible explanation is that the rise of mass toxic torts for pharmaceuticals that became so pronounced in 1986 had so raised the stakes for pharmaceutical firms that companies became increasingly willing to settle out of court. The only cases remaining to be litigated were those in which plaintiffs had little chance of success.

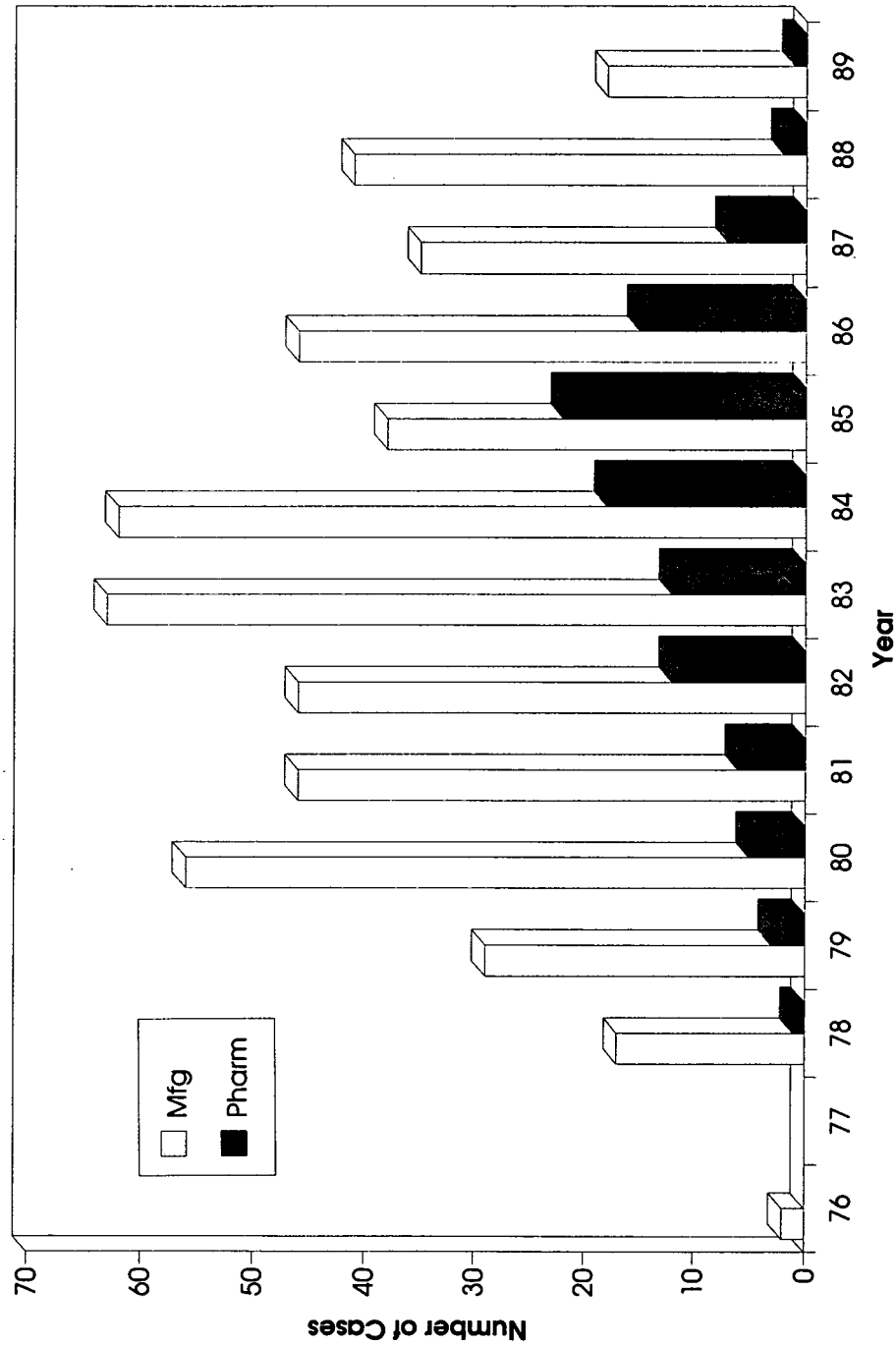
The shift in plaintiff success rates is reflected in the number of cases leading to an award (Figure 3), where these statistics reflect the compound influence of the number of cases resolved and the plaintiff success rate. These patterns are somewhat different than those in Figure 2. Whereas plaintiff success rates were relatively steady through 1984 and declined thereafter, the number of cases leading to plaintiff awards displays an inverted V-shaped pattern. Both pharmaceuticals and manufacturing display the same general pattern, but the starkness of the increase through 1985 and the decline thereafter is greater for pharmaceuticals. Plaintiff awards against other manufacturing industries do not change substantially between 1980 and 1988, with the exception of the peak award years, 1983 and 1984.

An intriguing feature is that the peak in the number of cases leading to awards occurred in 1985 for the pharmaceutical industry, but in that year the fraction of cases won by plaintiffs had plummeted to its lowest level in the period from 1978 to 1989. The volume of cases and the plaintiff success rate moved in opposite directions during that time.

III. Liability Awards

The economic impact of liability suits depends not only on the number of cases and the fraction of cases won by the plaintiff but also on the magnitude of the award. Figure 4 presents information on the mean level of an award, given that an award was made, and Figure 5 presents evidence with respect to the median award. These statistics do not adjust for subsequent reversals of cases or reductions of award levels after appeal. Consequently, they will tend to overstate the total level of awards ultimately paid. The mean award level reflects the average award that is made, but this

Figure 3
Number of Litigated Cases Resulting in Awards:
Manufacturing and Pharmaceuticals



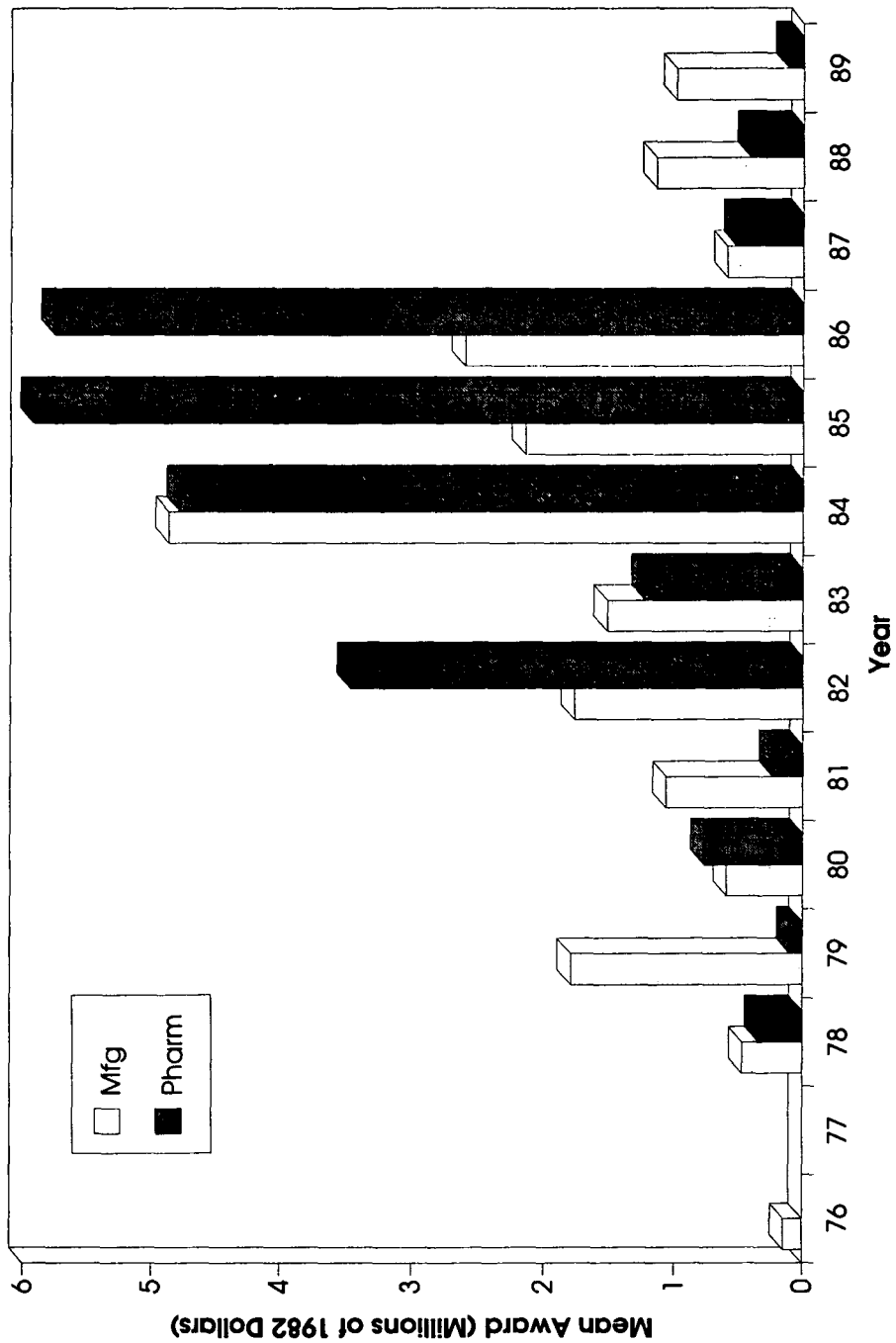


Figure 4
Mean Award/Award was Made:
Manufacturing and Pharmaceuticals

statistic may be influenced by extreme outliers, whereas the median award level is less susceptible to such impacts.

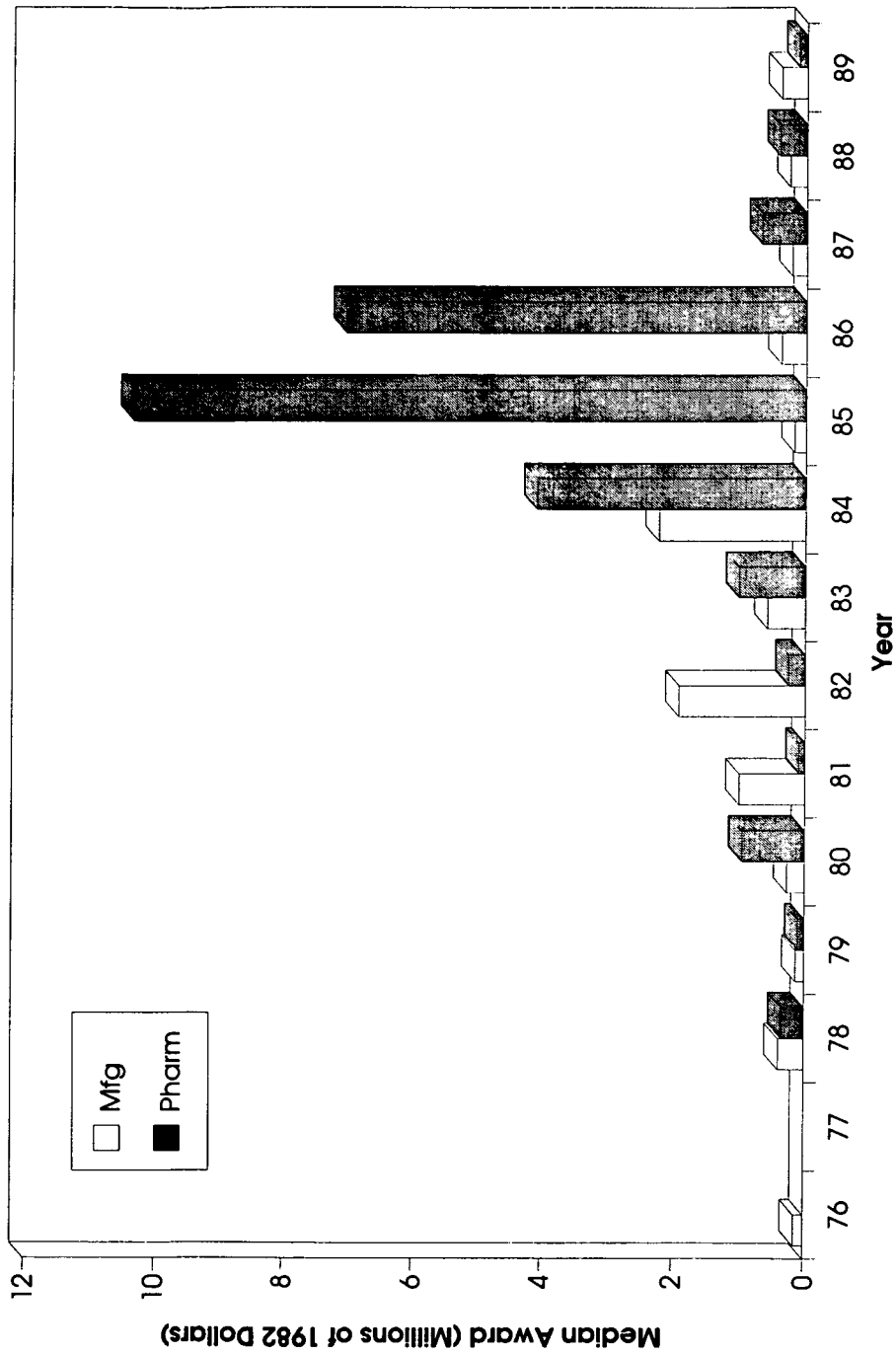
In each case, the patterns that are exhibited are quite striking. In 1985 and 1986, the average pharmaceutical award greatly exceeded that of manufacturing, and in 1984 the awards were roughly comparable. During the peak years of the liability cost explosion, it was pharmaceutical firms, rather than the rest of manufacturing, that accounted for the major awards. In the low award years, from 1987 to 1989, the pattern was reversed as the average manufacturing award exceeded that for pharmaceuticals.

The extreme fluctuation in the patterns of pharmaceutical industry awards during those years is due to the clustering of key mass tort outcomes. For example, in 1984 A.H. Robins lost fourteen cases with average awards of $4.1 million. The 1986 awards were greatly affected by eleven cases lost by Merrell Dow with average verdicts of $7.1 million. Similar clustering of cases accounted for the manufacturing award rise in 1984, as Ford lost eight cases with average awards of $11.0 million, General Motors lost nine cases with average awards of $10.5 million, and Chrysler lost four cases with average awards of $9.6 million.

The contrast between pharmaceuticals and manufacturing is even more dramatic for the median award levels illustrated in Figure 5. Usually, one would expect medians of such distributions to be more compressed than means, which may be more influenced by big award outliers. In this instance, the opposite is the case as the median awards reveal an even starker explosion of award levels over 1984 to 1986. The median pharmaceutical industry award was $4.1 million in 1984, $10.4 million in 1985, and $7.1 million in 1986. These awards dwarf the median award levels for manufacturing, particularly in 1985 and 1986. Indeed, the three extreme median award outliers over the 1976 to 1989 period are the pharmaceutical industry awards in the critical mid-1980s liability crisis years.

Largely because of the greater size of the manufacturing sector (excluding pharmaceuticals) relative to the pharmaceutical industry, total liability awards in federal courts are greater for manufacturing than for pharmaceuticals, except in 1985, as is shown in Figure 6. The years 1982 to 1986 mark the principal time period in which awards were at an extremely high level. Manufacturing liability awards surged to over $300 million in 1984, and in 1985 the pharmaceutical industry award level broke the $100 million level and exceeded that for the rest of the manufacturing sec-

Figure 5
Median Award/Award was Made:
Manufacturing and Pharmaceuticals



tor. In 1987 and thereafter, awards plummeted, particularly for pharmaceutical companies.

IV. Liability Awards in the Context of Firm Operations

The relative magnitude of liability awards for the pharmaceutical industry as compared with manufacturing more generally is best exemplified by the value of federal product liability awards relative to sales, which is illustrated in Figure 7. With the exception of 1979 and 1989, two years in which liability awards were very low, pharmaceutical industry liability awards outdistanced those in manufacturing relative to sales. Perhaps most importantly, during the peak years of liability awards, from 1982 to 1986, the differences were enormous. In 1982, pharmaceutical industry liability awards relative to sales were three times as great as in manufacturing; by 1986 this differential had risen to a factor of ten. Even in 1987, when liability awards had abated, awards relative to sales were five times as great in pharmaceuticals.

Although it is clear from these results that pharmaceuticals have been differentially hard hit by liability awards, the magnitude of the awards may not seem to be great. Awards as a percentage of sales reached a peak of .05 percent in 1986 for pharmaceuticals. Awards as a share of profits are, of course, much greater. These statistics, however, understate the full impact of liability costs. The awards discussed only capture verdicts in federal courts, not awards resulting from state court actions. Moreover, because ninety-five percent of all liability claims that are not dropped are settled out of court rather than taken to a court verdict,[15] even if we had data on award levels for all courts—both state and federal—that data would capture only a minority of all payouts for liability. Addtionally, none of these award statistics reflects the role of litigation costs and changes in product design in response to the liability system. Thus, the award levels and the various statistics that have been calculated can best be viewed as an index of the relative trend in federal liability costs rather than as a measure of the absolute cost impact.

It has often been hypothesized that liability awards may depress research and development (R&D) because they discourage innovation in new products with unproven designs.[16] These risks

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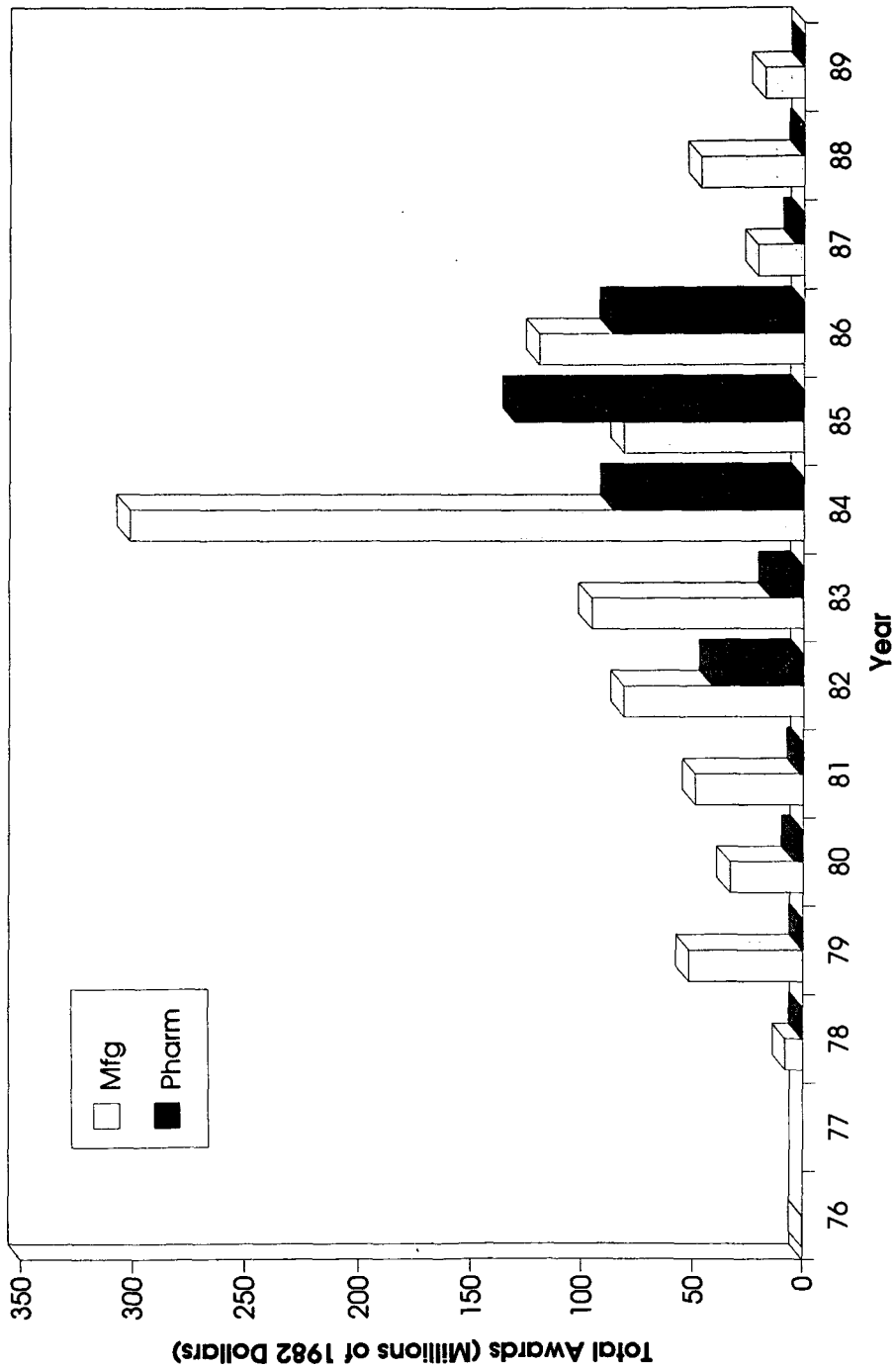
15 *See* Viscusi, *supra* note 2, at 48.

16 A statistical analysis of these linkages appears in W. Kip Viscusi & Michael J. Moore, *Product Liability, Research and Development, and Innovation*, 101 J. Pol. Econ. 161 (1993); W. Kip Viscusi & Michael J. Moore, *An Industrial Profile of the Link between*

Figure 6
Total Awards from Litigated Cases:
Manufacturing and Pharmaceuticals



have been particularly highlighted in the case of many pharmaceutical products, such as those relating to contraception and pregnancy. The countervailing incentive effect is that greater liability awards may stimulate innovation in safety-related product features in an effort to decrease subsequent liability awards.

Although the trends in R&D expenditures relative to sales as illustrated in Figure 8 are not conclusive with respect to these different hypotheses, they do nevertheless present some intriguing patterns.[17] Perhaps most striking is the different level of the value of R&D expenditures relative to sales. Throughout the time period examined, the pharmaceutical industry has consistently undertaken roughly three times as much R&D relative to sales as the rest of the manufacturing industry. The very high liability costs of the pharmaceutical industry are coupled with extremely high R&D levels, a combination that has led many observers to link the uncertainties associated with product innovation to high liability costs. The causality is, however, two directional. Although liability awards may be greatest for innovative firms, liability also affects innovation by encouraging safety innovation and discouraging risky product innovations.

The overall trend in R&D relative to sales for pharmaceuticals has remained relatively steady, except for a brief dip in 1986, whereas there has been more of a plateau for manufacturing R&D since 1986. Unfortunately, it is not possible to distinguish the character of the R&D expenditures. To what extent are these expenditures defensive expenditures intended to mute the liability burden, as opposed to expenditures that are on the frontier of developing new and innovative products? The available data do not enable us to distinguish between these two hypotheses.

V. CONCLUSION

Examination of the liability statistics for the federal courts is instructive for several reasons. First, these data confirm what many

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Product Liability and Innovation, in THE LIABILITY MAZE: THE IMPACT OF LIABILITY LAW ON SAFETY AND INNOVATION (Peter W. Huber & Robert E. Litan eds., 1991); and W. Kip Viscusi & Michael J. Moore, *Rationalizing the Relationship Between Product Liability and Innovation, in* TORT LAW AND THE PUBLIC INTEREST: COMPETITION, INNOVATION, AND CONSUMER WELFARE (Peter H. Schuck ed., 1991).

For a more general discussion of these linkages see PETER W. HUBER, LIABILITY: THE LEGAL REVOLUTION AND ITS CONSEQUENCES (1988).

[17] The data on R&D expenditures and sales are from the Compustat data base. This computerized data base provides information by firm and by year, which was matched to the firms in the federal court product liability sample.

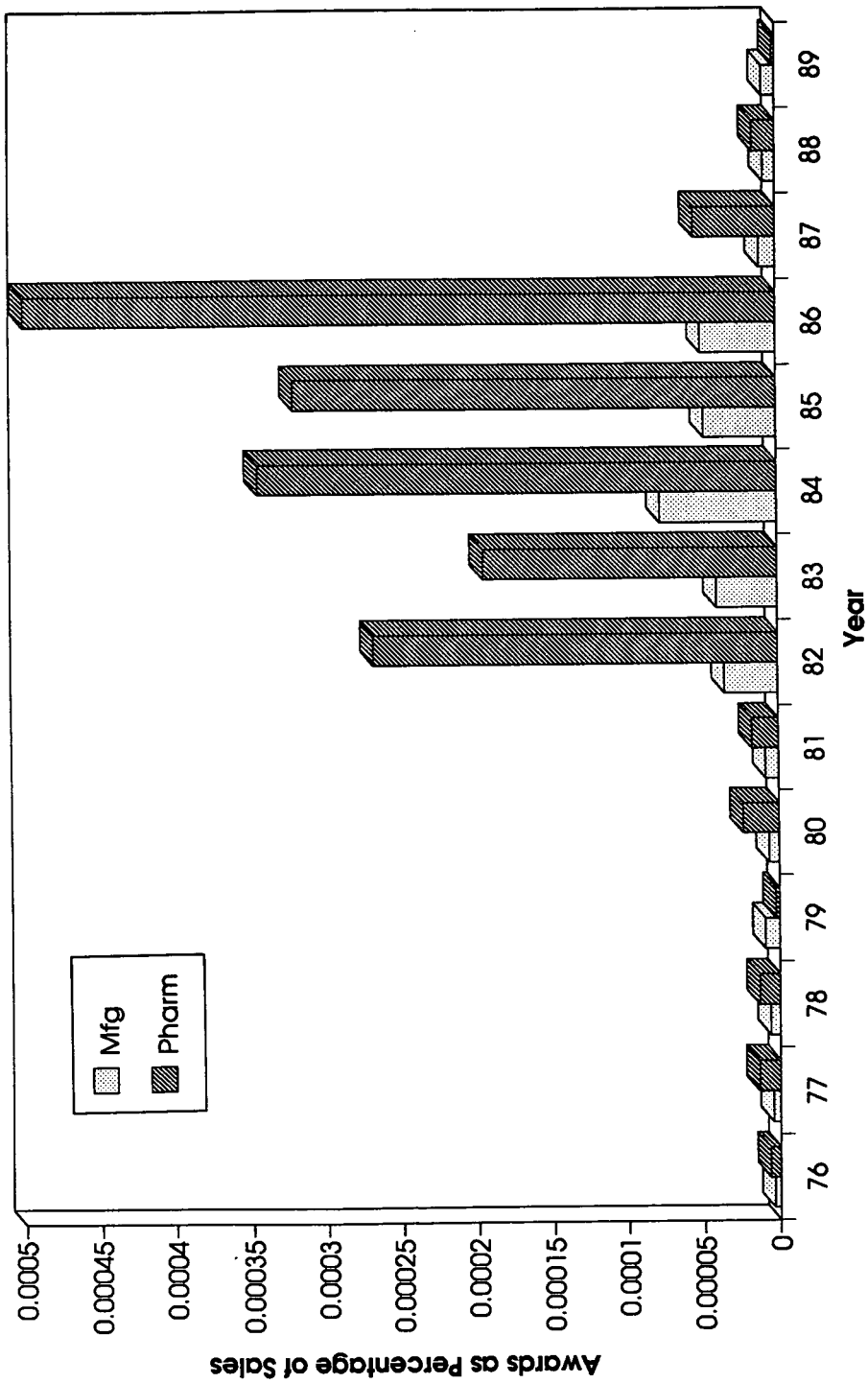

Figure 7
Awards over Sales:
Manufacturing and Pharmaceuticals

believed based on the widespread anecdotal reports regarding liability costs. The pharmaceutical industry, which is one of the most innovative industries in the economy, has been particularly hard hit by the surge in liability costs. The level of the awards borne by the industry, as well as the litigation rate more generally, are at a higher rate than for the rest of the manufacturing sector. This view is consistent with the hypothesis that tort liability costs fall disproportionately on the developers of new products with uncertain attributes as opposed to industries that have products whose designs change very little and are not much affected by product innovation.

The two most remarkable aspects about the patterns in these figures were the explosion of liability costs in the mid-1980s and the dramatic decline in the late 1980s. More specifically, in the years 1982 to 1986 there was a surge in the rate of liability claims and in award levels. Beginning in 1987, however, awards plummeted, as did litigation levels.

There are a number of possible explanations for this stark turnaround. One possibility is that the litigation environment changed after the enactment of liability reform measures in a large number of states, primarily in 1986 and 1987. These efforts imposed a variety of types of damages caps and other restrictions on liability.

There is little question that the imposition of constraints on awards and other pro-defendant changes in the liability regime will reduce liability costs. However, the patterns observed in the federal courts are quite pronounced, far beyond what even the most ardent proponent of liability reform may have expected. Recent research analyzing the specific effect of liability reforms on general liability insurance and medical malpractice insurance suggests that these measures did have a significant role in limiting liability costs.[18] Damage cap reforms appear to have been particularly influential. However, the effect on liability insurance costs is not as dramatic as the stark shifts in Federal litigation patterns in the late 1980s, which suggest that other aspects of the liability regime may be influential as well.

A second possibility is that companies adjusted to the shift in the liability climate and settled more cases out of court so that the mix of cases that were litigated changed. The establishment of trust funds for asbestos litigation and the Dalkon Shield, for exam-

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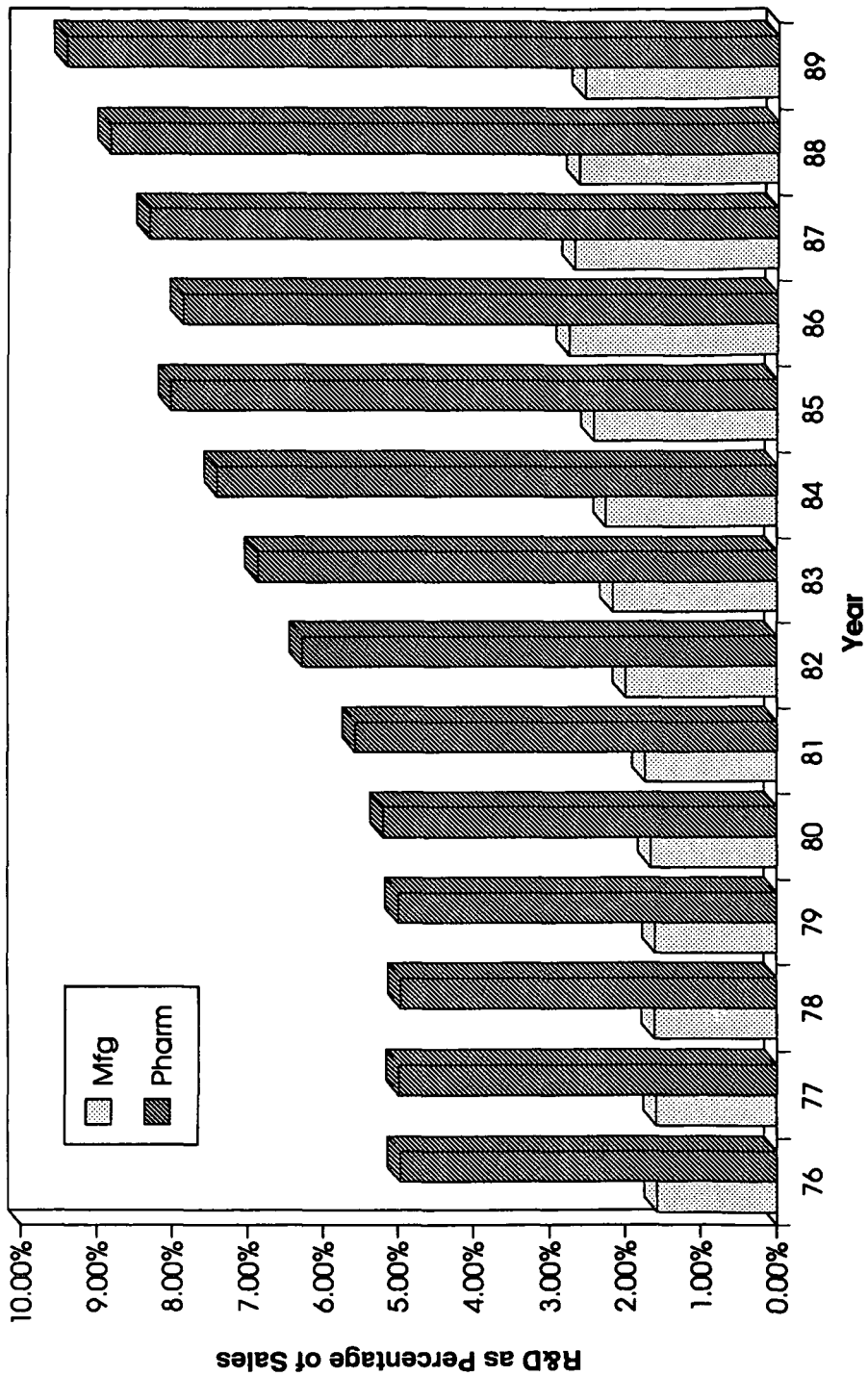
[18] *See* Viscusi & Born, *supra* note 1.

Figure 8
R & D Expenditures over Sales:
Manufacturing and Pharmaceuticals



ple, established the administrative compensation approach as an alternative to litigation. The National Childhood Vaccine Injury Act of 1986 similarly served to remove many vaccine death-related cases from the courts as well.

Perhaps the most telling statistic with respect to the factors driving the changing pattern of litigation is the dramatic drop in the plaintiff success rate in pharmaceutical industry cases between 1986 and 1989. Whereas plaintiffs won one-third of all cases in 1986, by 1988 and 1989 plaintiffs were winning fewer than ten percent. Such changes cannot be explained solely by a liability regime shift. Most of these reforms focused on damage limits rather than liability rules. Moreover, if liability laws were structured in a manner that increased the advantage of defendants relative to plaintiffs, then we would expect the mix of cases settled out of court to adjust, and the plaintiff success rate to remain unchanged. Reactions by plaintiffs and defendants to the new regime will consequently eliminate any effect on the observed plaintiff success rate as parties will anticipate the effect of the tort reform laws on outcomes and adjust settlement behavior accordingly.

What can explain this precipitous drop in plaintiff success rates is a change in out-of-court settlement patterns. There was an escalation in the cost of losing cases for defendants, relative to the stakes facing plaintiffs, due to the rise of mass torts involving entire pharmaceutical product lines in which pattern-setting liability awards had broad ramifications. Faced with such large stakes, companies became increasingly willing to settle cases out of court. Many marginal cases, and even cases in which the company has a better than even chance of winning, become attractive to settle once the stakes for the company are sufficiently large. The litigation patterns are consequently consistent with a situation in which fewer cases reach the federal courts because of a rise in out-of-court settlements.

As a result, one should be cautious in interpreting the federal court statistics. Although these data indicate an abatement of litigation rates and award levels in federal courts, they do not necessarily imply that the overall liability burden has abated to the same degree. The data are also strongly consistent with the possibility that out-of-court settlements have risen as well. Data based on the federal courts may induce a false sense of complacency. What we observe in the federal courts may not be representative of the liability system as a whole.