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The Modern Drug Industry's Increased Exposure to Damages

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NOTES

THE MODERN DRUG INDUSTRY'S INCREASED EXPOSURE TO DAMAGES

I. THE PROBLEM

A. The Current Drug Market

Thirty or forty years ago when the number of new drug products was small, and distribution facilities were slower and more limited, pharmaceutical houses produced, for the most part, drugs which had withstood the test of time. Under these circumstances, when an infrequent case of injury resulted, an error in the manufacturing process could likely be blamed. Further, when a new product was marketed, wide acceptance among the medical profession and by the public was likely to be years in coming. The result was that there was ample time to correct production and testing difficulties and to discover any unforseen reactions on human users while the number of consumers who might be affected was relatively limited.[1]

Modern technology and the incursion into every facet of day-to-day living is apparent to all. Thus, it is not surprising to discover that today's drug industry has incorporated many of the advanced techniques of manufacturing and marketing in dispensing their various products to an ever growing number of consumers. Technological advances have produced countless new products to aid the fight against disease. In 1965, it was estimated that as much as 90% of prescriptions being filled called for drugs which were nonexistent fifteen years ago.[2] In the twenty-four years from 1940 to 1964, the amount spent on prescription drugs increased from $150 million to $2.2 billion.[3] In 1957, half the sales volume of the Eli Lilly Company consisted of products which were introduced within the preceding five years.[4] In addition to

1. Willis, *Product Liability Without Fault: Some Problems and Proposals*, 15 FOOD DRUG COSM. L.J. 648, 655-56 (1960) (hereinafter cited as Willis).

2. Statement of George P. Larrick, Commissioner of Food and Drugs, *Hearings on Drug Safety Before Subcomm. on Intergovernmental Affairs, House Committee on Governmental Operations*, 88th Cong., 2d Sess. 14 (1964).

3. *Id.*

4. ELI LILLY & CO., REPORT TO THE SHAREHOLDERS 7 (1957).

emphasizing the fruits of modern research, these figures illustrate the tremendous advances in production and distribution methods of the modern drug industry. All of this sophistication has brought with it an increased risk of liability to the manufacturer in the products liability field. "Thus, in a very real sense, the American drug industry is in danger of becoming a victim of its own excellence."[5]

B. The Manufacturer's Exposure to Liability

Judicial handling of products liability suits has, in general, brought about that curious mixture of tort and warranty law known as strict liability. The courts have generally been cautious in this area because of the important policy considerations involved, especially the need to balance protection of the consumer against the possible economic consequences of strict liability to manufacturers.[6]

Liability without fault was first introduced in the drug industry in 1960 in *Gottsdanker v. Cutter Laboratories.*[7] A California jury found specifically that Cutter had not been either directly or indirectly negligent, but that in producing and marketing its polio myelitis vaccine which contained live polio virus, it had impliedly warranted that the vaccine was both merchantable and fit for its intended purpose.[8] On appeal, it was contended by Cutter that, as a matter of public policy, if drug makers are held strictly liable for the drugs they produce, further development of new products would be retarded. The court's answer in rejecting this argument was that the warranty in question was not one for a cure, but merely that the vaccine would not cause the disease that it was designed to prevent.[9] This decision infinitely broadened the spectrum of the drug manufacturer's liability for his product, and to the extent that the *Gottsdanker* holding is applied in other jurisdictions, the economic consequences to the drug manufacturer can

5. Willis, *supra* note 1, at 649.

6. Note, *A Federal Consumer Products Liability Act,* 7 HARV. J. LEGIS. 568, 568-69 (1970).

7. 182 Cal. App. 2d 602, 6 Cal. Rptr. 320 (1960); 13 STAN. L. REV. 645 (1961) [hereinafter cited as 13 STAN. L. REV.]. *Gottsdanker* was the appeal by Cutter Laboratories of a jury verdict for two young children who had contracted polio after being vaccinated with the Salk-type polio vaccine made by Cutter. The cause of the accident was live polio virus in the vaccine itself.

8. *Id.* at 323.

9. *Id.* at 326.

be severe or even fatal. An examination of three disastrous incidents of the recent past involving drug side effects demonstrates the impact of broadened products liability on the drug industry in terms of staggering numbers of plaintiffs and catastrophic damage awards. The three incidents involve the Salk vaccine produced by Cutter, and MER-29 (triparonol) and thalidomide produced by the Richardson-Merrell Company.

The discovery of the polio vaccine by Dr. Jonas Salk brought relief to parents across the nation who lived in fear of the summer-long rampages of infantile paralysis which left countless people, mostly children, crippled and disabled. Innoculations with the Salk vaccine made by Cutter Laboratories of California began in the summer of 1955. However, as a result of using Cutter's product, some of those vaccinated contracted the disease itself, and were crippled in varying degrees. Before the legal proceedings ended, Cutter was the subject of some sixty law suits for its role as the manufacturer of the vaccine.[10] The *Gottsdanker* decision was only the beginning, and the award of $147,000, only a small indication of things to come.[11] In one case alone, a Los Angeles jury awarded an eleven-year-old boy $675,000.[12] All claims filed against Cutter totaled about $11.8 million.[13] Like all substantial drug manufacturers, Cutter carried large amounts of products liability insurance, but by June 1961, it was apparent that its insurance would soon be exhuasted.[14] At that time, claims had been paid totalling $1,226,900 in the twenty-eight suits in which settlement had been reached.[15] In February 1962, Cutter reported that it had settled fifty-four suits for $3,049,000 in which $11,800,000 in damages was originally asked, and only six suits of relatively low settlement value remained.[16] This ended Cutter's difficulties for all practical purposes. Of the slightly more than three million dollars paid out, insurance covered only two million dollars, leaving Cutter to pay the remainder.[17] To do so, the company arranged bank loans.[18]

10. Wall Street Journal, Feb. 16, 1962, at 14, col. 4.
11. Gottsdanker v. Cutter Laboratories, 182 Cal. App. 2d 602, 6 Cal. Rptr. 320 (1960).
12. Wall Street Journal, June 28, 1961, at 12, col. 4.
13. Wall Street Journal, Feb. 16, 1962, at 14, col. 4.
14. Wall Street Journal, June 7, 1961, at 15, col. 3.
15. *Id.*
16. Wall Street Journal, Feb. 16, 1962, at 15, col. 3.
17. *Id.*
18. Wall Street Journal, Nov. 14, 1961, at 32, col. 4.

Though not a complete indication of the financial impact of the vaccine suits on Cutter, a look at the company's sales and net income figures from 1958 through 1964 is useful:

Year	*Sales*	*Net Income*[19]
1958	$18,744,928	$785,492
1959	21,319,989	978,858
1960	23,034,294	537,463
1961	24,807,774	697,862
1962	29,934,227	1,144,380
1963	32,238,399	1,390,594
1964	36,405,445	1,684,010

During each year in this period Cutter experienced a significant increase in sales; however, it is apparent that in 1960 and 1961, the two years during which nearly all of its damage claims were settled, the company's profits suffered sharp declines. Further, it is also apparent that with its legal problems rectified, Cutter was able to rebound from its declines in earnings. More important is a comparison of the amount of the damage claims to Cutter's total asserts. The $11.8 million dollars in claims equalled about two-thirds of the company's 1961 assets of $18,376,696,[20] the year in which most of the burden was felt. It is doubtful that a corporation the size of Cutter could survive so serious a loss.

The drug MER-29 was developed by the Richardson-Merrell Company to be used to lower the level of cholesterol in the blood. About a year after its release, clinical reports began to appear in which patients taking MER-29 developed cataracts and other less-serious side effects such as hair loss and dermatitis.[21] On May 22, 1962, MER-29 was withdrawn from the market, approximately two years after its initial clearance for release by the Food and Drug Administration.[22]

Suits were filed throughout the country alleging damage as a result of taking MER-29. In the first suit to reach trial, a jury returned a

19. MOODY'S INDUSTRIAL MANUAL 213 (1966).

20. MOODY'S INDUSTRIAL MANUAL 775 (1962).

21. Rheingold, *Products Liability—The Ethical Drug Manufacturers Liability*, 18 RUTGERS L. REV. 947, n.4 (1964) [hereinafter cited as Rheingold]. MER-29 was used by about 500,000 persons during its two-year stay on the market. *Id.*

22. Toole v. Richardson, 251 Cal. App. 2d 689, 60 Cal. Rptr. 398 (1967). MER-29 was initially released in April 1960 by the FDA.

verdict for Richardson-Merrell,[23] but the company did not remain so fortunate. Judgments in substantial amounts were awarded various plaintiffs, e.g., $1,205,000 in a New York State Supreme Court,[24] $117,000 in a New York federal court,[25] $425,000 in a San Francisco Superior Court,[26] $150,000 in a Seattle federal court.[27] The number of damage claims based on the side effects of MER-29 was staggering, with the company reporting 1,410 claims as of March 1966.[28] At that time, 650 claims had been settled and 760 claims were still outstanding, of which 650 were in litigation.[29]

Thalidomide was a tranquilizer initially produced in Germany under various trade names.[30] The Richardson-Merrell Company undertook to produce thalidomide in the United States under the trade name of Kevadon, and on September 12, 1960, the company filed its new drug application with the FDA. Despite FDA findings that the new drug application was incomplete, the drug remained in limited use, although it retained its investigational status and was never cleared for use in the United States as a prescription drug.[31] Following reports of

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23. Wall Street Journal, June 19, 1964, at 15, col. 3.

24. New York Times, Nov. 9, 1966, at 41, col. 5.

25. Wall Street Journal, March 9, 1966, at 8 col. 4. The $100,000 punitive damages in the verdict was later reversed in *Roginsky v. Richardson-Merrell*, 378 F.2d 832 (2d Cir. 1967), leaving only the $17,500 compensatory award. More importantly, the court considered the implication of large punitive awards to the drug industry as a whole. It found the issue of large punitive damages to be one of

> extreme significance not only in monetary terms to this defendant in view of the hundreds of MER-29 actions and to the plaintiff as well, but from a longer range, to the entire pharmaceutical industry and to all present and potential users of drugs . . . . 378 F.2d at 838.

The court thought it was incongruous that the maximum criminal penalty in fines was only $10,000; whereas, punitive damages awarded to hundreds of plaintiffs could run into tens of millions of dollars. The court had the "gravest difficulty in perceiving how claims for punitive damages in such a multiplicity of actions throughout the nation can be so administered as to avoid overkill." 378 F.2d at 839.

26. Wall Street Journal, March 10, 1966, at 7, col. 1. The verdict was reduced from $625,000 by the trial judge, who cut punitive damages by half. *Id. See* Toole v. Richardson-Merrell, 251 Cal. App. 2d 689, 60 Cal. Rptr. 398 (1967), *aff'g* the trial court award.

27. Wall Street Journal, April 11, 1966, at 25, col. 3.

28. Wall Street Journal, March 10, 1966, at 7, col. 1.

29. *Id.* Total damages in the MER-29 cases will be discussed *infra* in conjunction with damages in the thalidomide cases.

30. Cavers, *Administering That Ounce of Prevention: New Drugs and Nuclear Reactors-I*, 68 W. VA. L. REV. 109, 113 (1966).

31. Campbell, *Civil Liability For Investigational Drugs: Part II*, 42 TEMP. L.Q. 289, 291-92 (1969), (hereinafter cited as Campbell).

many thousands of deformed infants born to mothers who had taken thalidomide during pregnancy, and after the withdrawal of the drug from the West German, British and Canadian markets, Richardson-Merrell voluntarily withdrew its product from FDA consideration on March 8, 1962.[32] Nevertheless, according to the FDA, 2,528,412 tablets of thalidomide were distributed to 1,267 physicians in the United States.[33] About three thousand clinical complaints alleging damage due to thalidomide were filed by parents and other adults.[34] In Philadelphia in the first such suit filed, parents asked for $2,486,050 for the deformities of their eighteen-month-old son.[35] Similar suits were brought in Cleveland and Cincinnati, asking $2.2 million for one child and $4.1 million on behalf of two children, respectively.[36]

It was estimated that the amount of claims against Richardson-Merrell for both MER-29 and thalidomide was in excess of 355 million,[37] with thalidomide claims making up an estimated $25 million of that figure.[38] Of course this astronomical amount of claims was substantially reduced by settlement. Richardson-Merrell refused to state the exact amount spent in settlement; however, an attorney coordinating claims against the company estimated in March 1966, that $10-15 million had been paid out.[39] The company refused to disclose the amount of its products liability insurance coverage; however, it did state that its coverage was exhausted in February 1967, and as a result it incurred unindemnified settlement costs of $6,860,827 in fiscal 1967.[40]

Unlike Cutter, Richardson-Merrell's earnings growth was not impeded.[41] A look at the company's net sales and net income for the years 1960 through 1968 bears out this statement:

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32. *Id.* at 292.

33. *Id.* at 293.

34. *Id.* at 292.

35. Wall Street Journal, Oct. 8, 1962, at 4, col. 2. The suit was subsequently settled about six and a half years later for an undisclosed amount. *See* Wall Street Journal, March 13, 1969, at 20, col. 3.

36. New York Times, March 24, 1964, at 17, col. 1; New York Times, Dec. 16, 1964, at 33, col. 8.

37. Wall Street Journal, March 10, 1966, at 7, col. 1.

38. Campbell, *supra* note 31, at 292.

39. Wall Street Journal, March 10, 1966, at 7, col. 1.

40. Wall Street Journal, Sept. 18, 1967, at 32, col. 2. The exhausted coverage situation applied only to insurance coverage for the years 1961 and 1962. Other years were said to have ample coverage, but this coverage would take effect only after Richardson-Merrell had paid some of its own funds. *Id.*

41. *See* Wall Street Journal, March 10, 1966, at 7, col. 1.

Year	Sales	Net Income[42]
1960	$132,288,297	$14,380,848
1961	151,509,885	17,025,139
1962	161,886,539	17,263,303
1963	169,867,334	18,324,659
1964	180,305,858	17,744,426
1965	213,401,397	21,147,847
1966	247,831,316	24,971,335
1967	269,029,329	25,713,850
1968	301,013,697	26,120,623

Although more than $6.8 million in excess of insurance coverage is a tremendous deficit to absorb, it is not unmanageable for Richardson-Merrell when compared to its 1967 earnings of $25.7 million, the year of the deficit. However, the initial claims of more the $355 million exceeds the 1967 assets of $255,761,302 by nearly $100 million, clearly enough to destroy the company if such claims could be sustained.[43] Such exposure to liability is likely to have an inhibiting effect on the progressive policies of drug manufacturers as a whole. This fear of liability to a patient has already caused the Veteran's Administration (VA) some difficulty in securing equipment and drugs for research purposes. Research was delayed for several months on one occasion because the producer of a plasma expander refused to allow the expander's use on human subjects without some protection from liability.[44] In an attempt to balance the rights of the deserving victim against possible economic chaos in the drug industry, the following possible solutions are discussed as alternatives in coping with the problem.

II. POSSIBLE SOLUTIONS

A. Limitation of Damages

Traditionally, when it has been felt that damages in a particular type of litigation have become excessive, either as a windfall to the plaintiff or as too great a burden for the defendant, legislative bodies have set arbitrary limits on maximum recovery.

The best-known examples of such a limitation are state wrongful death statutes which establish an arbitrary ceiling on damages recover-

42. MOODY'S INDUSTRIAL MANUAL 2021 (1969).
43. *Id.*
44. Campbell, *supra* note 31, at 349.

able for the life of a person killed by the wrongful act of another. At present, eight states have such limits.[45] An example of concerted activity on the part of an industry to limit damages with respect to its particular risk is the airline industry. There is a growing move to limit damages recoverable in commercial airline crashes since these crashes have obvious potential for very large damage claims.[46] The introduction of planes with larger and larger passenger capacity increases this possibility. Arguments against limitation in the airline industry have some application to the drug industry, and, of course, the drug industry has its own factors mitigating against limitation.

In the first place, where there is fault, a limitation on damages counters the tort law notion that the tortfeasor must bear the burden of his wrongful act.[47] Directly in point is the negligence of Richardson-Merrell in its production and marketing of MER-29. Even when the recovery is based on implied warranty, as against Cutter in *Gottsdanker,* there remains the idea of a promisor who has broken a promise (albeit implied in law), and thus should bear the resulting burden of injury and damage.

Second, the argument that individual states already impose a maximum recovery in wrongful death actions and that therefore such a limit should exist in drug injury cases is not compelling. The number of states maintaining such limits has decreased to the present number of eight mentioned above.[48] In addition, existing ceiling amounts have been increased,[49] thus demonstrating the general disfavor of limitations.

Third, the victim must be considered. An arbitrary limitation on damages bears no relation to actual damage caused by a defective drug. A rough indication of this is demonstrated by the MER-29 cases. Where liability was found, damage awards ranged from $1.2 million[50]

45. Kriendler, *Limitation on Liability In Aircraft Crashes,* 36 J. AIR L. & COM. 467, n.9 at 468 (1970). The states are Kansas ($35,000) Massachusetts ($40,000), Minnesota ($35,000), Missouri ($50,000), New Hampshire ($60,000), Virginia ($75,000), West Virginia ($110,000), and Wisconsin ($35,000). *Id.*

46. *Id.* at 467.

47. *Id.* at 468.

48. *Id.* at 468.

49. *Id.* at 469. For example, West Virginia increased her damage ceiling from $20,000 in 1961 to $110,000 in 1969. *Id.* at n. 10 at 469.

50. *See* note 24 *supra.*

to $117,500[51] in litigated cases. Adequate compensation is based on a myriad of independent variables interacting in countless combinations too complex to be realistically governed by a damage ceiling.

Finally, even with an artificial limitation, the drug industry has no way of predicting the number of plaintiffs it will encounter. This is because the extent of distribution of a problematic drug is not easily predicted.[52] It may reach millions of patients or just a few thousand, depending on when the injurious side effect manifests itself in damage to a consumer.

There remains to be considered a more flexible limitation analogous to the one used in admiralty for more than a century. The purpose in admiralty was to encourage the shipping industry by limiting the risks of loss from major marine disasters.[53] The thought was that the risk of catastrophic loss was so great that it must be limited to avoid discouraging investment in a socially useful field.[54] In general, the federal statute limits the liability of the shipowner for all claims arising out of a marine mishap, including personal injury and property damage, to the owner's investment in the ship or up to $60 per ton if the investment is insufficient to cover damages.[55]

In the drug industry, the damage could be related in some way to the product involved. One procedure would be to limit liability for non-negligent injury to a given percentage of the manufacturer's net sales of the liability-causing product in the year in which the injury occurred. Alternatively, the damage ceiling might be set at the figure beyond which is no longer possible or economically feasible to insure against loss.[56] Such a limitation would apply only in cases of catastrophic loss due to injuries caused by a particular product. The objective of this plan would be to provide a source of reasonable recovery for injured consumers, but at the same time make the manufacturer's risk finite and calculable.[57] If this finite number of dollars was distributed pro rata to all bona fide claimants, individual recoveries might be diminished to

51. *See* note 25 *supra.*
52. Willis, *supra* note 1, at 662.
53. *Id.*
54. Id.
55. *Id.* at n.35. *See* 42 U.S.C. § 183 (1970).
56. *Id.* at 662.
57. *Id.*

some extent, but at least a first few enormous awards would not leave later claimants with no drug company to proceed against.[58]

In short, a static statutory limitation on damages is undesirable from the point of view of the seriously injured consumer, while a flexible statute geared to the financial status of the drug company could provide adequate recovery for injury while insuring continuation of a progressive drug industry.

B. Insurance

Drug companies do carry products liability insurance and in very large, though sometimes inadequate amounts as shown by the Cutter and Richardson-Merrell experiences. Obviously, no company would deliberately under-insure if it thought it would probably incur inordinate losses, but there is a point at which extra amounts of insurance are not an economically justifiable corporate expense when balanced against the probabilities of catastrophic damage awards. The private insurance industry, too, has its problems with products liability insurance; it must determine the probability of liability and set its premiums accordingly.

The insurance company and its actuaries must operate on the premise that the future will be much like the past, containing the same rough number of usual and unusual events,[59] or more simply, insurance is based on hindsight. In dealing with abnormally large claims of a business, as where a business has one $100,000 claim when its normal is $1,000, the large claim is minimized by the actuary and reduced to a lower figure, since he must consider the one abnormal claim to be the product of chance.[60] To this extent, it seems that the risk is predicted without full regard for the large sum, an important consideration in an expanding research-oriented drug industry. Still, the drug industry has relied heavily on products liability insurance, and for the most part the standard coverage has been satisfactory, with Cutter and Richardson-Merrell standing as notable exceptions. However, the size of claims that insurance companies must now meet has alarmed the

58. *Id.* at 663.

59. Morris, *Enterprise Liability and The Actuarial Process—The Insignificance of Foresight*, 70 YALE L.J. 554, 574 (1961) (hereinafter cited as Morris).

60. *Id.* at 562.

insurance industry. Thus, it may become increasingly difficult for drug companies to obtain adequate coverage for the possible $10 to $20 million claims that are within the realm of possibility.[61] The only alternatives for the insurance companies are higher premiums or lower limits of liability,[62] neither of which accommodates the drug industry's problem. Although some solution may be feasible through a reappraisal and revision of traditional products liability insurance, "in the final analysis, insurers will cover only calculable risks, while the risk of products liability appears to be getting less calculable every year."[63] Without commercial insurance, self-insurance may be necessary if the drug company's assets permit; however, many producers, like Cutter, will find this impossible because of inadequate assets.[64]

The problem inherent in trying to cover catastrophic damage claims against drug producers by using commercial insurance alone presents economic conflicts that seem basically insoluble. For this reason, some form of government indemnification must be considered as an alternative to allowing reputable drug companies to be destroyed by damage claims involving only one problem product.

Such a solution has been enacted at the federal level concerning indemnification of victims of possible disastrous nuclear reactor accidents. In 1956, the Atomic Energy Commission (AEC) commissioned a study to determine the extent of damage, and hence liability, in the event of a large scale nuclear reactor accident.[65] Though it discounted the findings as somewhat overly-pessimistic, Congress enacted the Price-Anderson amendments to the Atomic Energy Act.[66] The Act now requires every nuclear reactor operator, each a licensee of the federal government, to carry insurance in the amount of $74 million. Coupled with this is $486 million of governmental indemnity to cover liability

61. Willis, *supra* note 1, at 657.
62. *Id.*
63. *Id.*
64. *See* note 20 *supra; See* 13 STAN. L. REV. at 648.
65. Cavers, *Administering That Ounce of Prevention: New Drugs and Nuclear Reactors-II,* 68 W. VA. L. REV. 233, 234 (1966) (citing *Theoretical Possibilities and Consequences of Major Accidents in Large Nuclear Power Plants,* 1 CCH ATOM. EN. L. REP. 4031 (1957)) (hereinafter cited as Cavers-II).
66. Cavers-II at 234; *See* 42 U.S.C. §§ 2014 & 2210 (1970).
67. Cavers-II at 235, nn.5 & 6; *See* 42 U.S.C. § 2210 (1970).

in excess of insurance. Finally, a maximum liability ceiling of $560 million is established.

Recognizing that drug companies are indeed subject to catastrophic losses, a plan similar to the nuclear accident coverage offers a viable alternative to commercial insurance.[68] Under such a plan, a drug producer would be required to obtain and maintain a certain amount of private insurance coverage based on some variable such as gross sales or quantity of drugs produced. If the insurer and manufacturer incurred liability in excess of the coverage, governmental aid would be available.[69] The prospect of some liability, which would naturally raise insurance costs, would encourage due care on the part of producers, but the availability of governmental aid in emergencies would prevent undue discouragement of new products research.[70]

Carrying the above proposal one step further, the government could accept full financial responsibility for injured parties through legislation affording compensation.[71] Such a proposal was made regarding the victims of the Cutter-Salk vaccine mishap.[72] Indeed, some drug manufacturers have considered some governmental aid as a possible solution in extraordinary risk situations.[73] A system of complete governmental indemnification would be socially expensive, although it would offer both plaintiff and the defendant the ideal outcome. The social expense is that, in the final analysis, the burden would be borne by the entire population in higher taxes. In addition, further governmental encroachment in the industry may be undesirable to drug manufacturers as a whole.[74] Lastly, the drug company is offered no incentive to use utmost care in its manufacturing and marketing.

A low-cost medical insurance is another possible alternative. Though it would not provide compensation comparable to the usual award in products liability litigation, most claimants would be able to

68. The drug manufacturers and AEC licensees are similar in the fact that the pharmaceutical products of the former must be licensed and approved for marketing by a governmental agency, the FDA.

69. 13 STAN. L. REV., *supra* note 7, at 652.

70. *Id.*

71. Campbell, *supra* note 31, at 346.

72. *Id.* (*citing* H.R. 8082, 85th Cong., 1st Sess. (1957)).

73. 13 STAN. L. REV., *supra* note 7, at n.39.

74. Campbell, *supra* note 31, at 349.

cover a large portion of their medical expenses from such insurance.[75] Such a plan would probably have to be compulsory to afford both the consumer and the drug company the desired protection. This might involve incorporating this insurance into Social Security or Medicare, an unlikely event at this time. Because this plan would probably not be able to provide complete or even sufficient protection to all consumers, and because it does not offer the traditional legal remedy of pain and suffering, it is not a satisfactory answer.

If insurance is considered the best solution to the drug industry's damage problem, it is submitted that some combination of commercial insurance coupled with governmental indemnification is the only workable solution. This alone minimizes the tremendous expense or unavailability of private insurance to cover disastrous losses while at the same time protecting the drug company against financial destruction or having to stifle its research efforts.

C. Enterprise Liability—Redistribution of Loss to the Consumer

Under the concept of enterprise liability, a producer of a product assumes the burden of injury and damage to another party caused by the producer's product. This burden is thought to be one of the costs of doing business.[76] Through the operation of this theory, a consumer's loss is shifted to the manufacturer, who is said to be in a unique position to bear the loss and ultimately redistribute it back to the consumer by raising prices.[77]

Advocates of enterprise liability contend that it causes little business dislocation while providing important service by offering financial recompense to the injured consumer or his beneficiaries. And since the entrepreneur's competitors are exposed to the same liability, no one suffers a competitive disadvantage.[78] To meet the judgement costs, the producer must either buy insurance or self-insure. The cost of either, like all costs of doing business, is reflected in prices. This price rise, having been spread over all of a company's products, is a negligible burden to the individual consumer who ultimately pays.[79]

75. 13 STAN. L. REV., *supra* note 7, at n.20.
76. Morris, *supra* note 59, at 555.
77. Willis, *supra* note 1, at 655.
78. Morris, *supra* note 59, at 555.
79. *Id.*

This "natural law-like" statement is an oversimplified approach. The crux of the theory is an assumption that an increase in a manufacturer's product's prices will enable him to recoup his liability losses from a fixed broad consumer base. This assumption ignores the fact that a price increase may significantly affect consumer demand and result in less sales. Consequently, there may be no relative improvement in the manufacturer's initial position of being saddled with excessive costs from products liability damages.[80] Thus, depending upon the industry's demand curve, the cost of enterprise liability will be divided between the consumer and the industry with the former suffering some increase in product price, and the latter, some decrease in sales volume.[81] If, instead, prices are not increased, sales would remain stable, but the industry would necessarily absorb a decline in earings. Some companies, e.g. Richardson-Merrell, might be able to live with this in the short run; however, the weaker components of the industry, e.g. Cutter, might be driven out of business.

The drug industry in particular may not be a good example of an enterprise subject to price-responsive demand fluctuations. A small price increase in an effort to absorb liability losses may not lead to a significant decrease in sales of a certain product or to the use of substitutes by consumers. One reason is that many drugs are patented and, therefore, are not available from another source.[82] Another reason is that the consumer often is not involved in any selection process between competing products. This is the case when a doctor prescribes a certain drug after diagnosing a patient's ailment. The patient does not know the merits of a drug or its price; he gets the prescription filled and takes it. But the drug industry presents a more fundamental problem to the enterprise liability advocate. The chain of events in the enterprise liability sequence is as follows: liability is incurred; the manufacturer pays the damages either with commercial insurance or through self-

80. The manufacturer's prices are determined by supply and demand factors. With a stable demand, a company will decrease its sales if it increases its prices. The extent of sales loss is determined by the slope of the demand curve. A relatively flat demand curve coupled with a rise in prices will bring about a sharp decrease in sales volume. However, if the demand curve is relatively steep, a rise in prices will have much less effect on sales. Morris, *supra* note 59, at 585.

81. *Id.*

82. Rheingold, *supra* note 21, at n.373.

insurance; the consumer pays, and the costs are covered. If the commercial insurance cannot be bought in the quantity desired, or if the price of insurance is too high so that the manufacturer either takes the risk or self-insures, the manufacturer may be out of business before a price increase can recoup his losses. Therefore, it is questionable whether or not the enterprise liability theory offers any solution at all to the ever increasing damage problem of the drug industry.

III. SUMMARY

The problem of how drug companies are to pay astronomical damages to consumers injured by their products is not hypothetical. The difficulty is compounded by judicial findings of liability without fault which make the incidence of liability unpredictable. The Cutter and Richardson-Merrell experiences demonstrate that dire financial consequences are neither impossible, nor improbable to the affected manufacturer. The social utility of a progressive, research-oriented drug industry cannot be seriously questioned, and some accommodation should be made to insure its continued progress. Conversely, the injured plaintiff should be adequately compensated. A denial of compensation to him out of regard for the industry's financial plight is antithetical to modern philosophy of the place of industry in society today. The thalidomide baby and the paralyzed polio victim are entitled to compensation for their suffering, inconvenience and extra cost of just being alive in this unfortunate condition.

It is submitted that an artificial limitation on damages recoverable by a drug victim is not workable from the victim's point of view. A static ceiling cannot adequately compensate every deserving plaintiff unless it is too high to offer the manufacturer the relief he is seeking. Even a formula related to the company's earnings or investment in a product, such as the admiralty analogy, is subject to this basic shortcoming.

Nor does enterprise liability offer a solution. Although interesting hypothetically, when applied to the drug industry's damage problem, it is likely that the company in question may be bankrupt before the enterprise liability logic will allow it to recoup its losses. Remaining

are plaintiffs who are short on compensation and a defendant who is out of business.

The prospect of covering all losses with private insurance alone is no more encouraging. Either the insurance company's liability coverage limit will be too low to afford adequate protection, or the price of adequate coverage will be so high as to be economically unfeasible for the manufacturer. The same reasoning applies to any form of medical insurance held by the consumer.

Complete government indemnification suffers from being socially expensive to the country as a whole, disagreeable to drug manufacturers who want no more government control, and lacking in incentive to the producer to exercise the most possible care.

It is suggested that the most complete solution is a system of insurance secured by drug producers from private sources, coupled with indemnification by the federal government for extraordinary losses. First, the consumer is protected. Second, the producer is inspired to use due care in his business since he must pay the cost of his private insurance. This insurance becomes more expensive if the producer becomes a bad risk. Third, the drug company is protected against financial destruction. And last, the progressive nature of a research-oriented drug industry is not stifled, and society as a whole can continue to share the fruits of the industry's progress.

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