Articles

Drug Injury Compensation Plans

JOHN G. FLEMING*

Three countries have enacted statutes to compensate victims of the Thalidomide tradgedy. The author not only canvasses these drug injury statutory plans but looks also at the different compensation techniques and their justification in light of the question whether preferential treatment should be awarded to this group of accident victims.

Afin de compenser les victimes de la thalidomide, on a promulgé des bis comportant cette tragédie dans trois pays. L'auteur non seulement examine à fond les dispositions statutaires, mais il étudit également les techniques de compensation diverses en tant que justification au problème d'accorder des traitements préférentiels à ces victimes.

The Thalidomide tragedy of the early 1960's left a searing and cataclysmic impression on the public mind throughout the world.[1] In its aftermath, public sorrow and anger became widely engaged over the question of compensating the pitiful victims of the ill-fated drug and helped to mobilize concern for the future provision of drug-related injuries.[2] So far three countries — West Germany, Sweden and Japan — have enacted special statutes to this end.

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*Editor-in-Chief. This is an expanded version of the Vicount Bennett Lecture, delivered at the University of New Brunswick, Canada on March 30, 1982. Shannon Cecil Turner Professor of Law, University of California, Berkeley; formerly Dean and Robert Garran Professor of Law, Canberra University College; of Lincoln's Inn.

[1]Inside Team of the Sunday Time of London, *Suffer the Children: The Story of Thalidomide*, (1979), Sjöstrom and Nielsson, *Thalidomide and the Power of The Drug Companies*, (1972).

[2]"Their plight and their impact on public opinion, have probably done more to cause a re-examination of some of the basic features of our legal system than any other recent single disaster." Dworkin, "Pearson's Implications for Severely-handicapped Children and Products Liability." Allen, Bourn & Holyoak, *Accident Compensation After Pearson*, (1979) 160. In Britain, public reaction prompted the request to the Law Commission to consider products liability (1971) and prenatal injury (1972) as well as the appointment of the Pearson Commission (1972). In the U.S. thalidomide was a major factor behind the 1962 amendments of the Food, Drug and Cosmetic Act, introducing *inter alia* the requirement of "effectiveness": Temin, *Taking Your Medicine: Drug Regulation in the U.S.* (1980) 123-24.

I propose to discuss, first, these three special plans, each of which reflects a different compensation technique typical of the country's legal culture, and second, the transcendent question as to the legitimacy of singling out for preferential treatment this, jarticular group of the disabled.

THE SPECIAL PLANS

The experience in settling the thalidomide claims cast a long shadow on future planning. Most pervasive seems to have been the recognition that public sentiment will not in the long run condone the heavy expenditures of adversary litigation or indeed protracted settlement negotiations. In Sweden, the Astra firm disclaimed at an early stage any desire to dispute the controversial issues of causality and forseeability, but in most of the other countries the longer delays in effecting settlements (from 1961 to the early 70's) were not uninfluenced by dickering over legal responsibility. Indeed, in England, the first batch of settled claims was originally discounted to 40% in the light of legal infirmities, including doubts concerning responsibility for prenatal injuries,[3] but the subsequent intense public agitation surrounding an additional 250 claimants eventually forced the defendants to a quick and fairer resolution.

In Germany where the number of victims was largest, residual public responsibility to the victims was reflected in two subsequent governmental contributions to the compensation fund which the manufacturer had set up to the absolute limits of its financial capacity.[4] In Japan, the state was implicated from the start as legally responsible for licensing the drug and, as such, participated in the settlement itself with many claimants.[5]

West Germany

West Germany was at once the center of the thalidomide affair and the scene of the strongest European pharmaceutical industry. The originator of the drug was a German firm (though its distributors and licensees were spread among several countries) and the number of victims (2,500) associated with this firm was by far the largest. The prolonged criminal

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[3]Bennett, "Liability of Manufacturers of Thalidomide", (1965) 39 *Austr. L. J.* 265. Since resolved by the Congenital Disabilities (Civil Liability) Act 1976.

[4]*Supra*, footnote 1, *Suffer the Children*, at 126; *Arzneimittelprobleme in Deutschland und Japan*, (1980), at 98 [hereinafter cited as *Arzneimittelprobleme*]. The federal government gave two reasons: first, that the federal republic was a social welfare state (*Sozialstaat*); second, that the time of marketing thalidomide such pharmaceutical injuries had been unforseeable and that this accounted for the failure to pass a stricter licensing law. The latter reason explains why the benefits were limited to this special group of victims, without violating the constitutional requirement of equal protection. See Wartensleben, *Arzneimittelprobleme* at 123 (summary of discussion).

[5]The State's legal responsibility in the drug cases is explained by Abe, "Probleme der Arzneimittelgesetzgebung in Japan," *Arzneimittelprobleme* at 63-70.

proceedings against the firm[6] continued to focus the attention of the public and the affected industry on the physical and financial risks of novel drugs. Not surprisingly, Germany also became the scene of the first serious efforts to rethink the problem of compensating drug victims. This process yielded important insights, both into alternative structurings of a compensation scheme and into the substantive problem of defining the scope of the compensable risks.

Structure

Several proposals preceeded the eventual compensation scheme.[7] The firsts draft, submitted in December 1973 by the federal Ministry of Health, proposed a three-tracked scheme: ordinary tort liability for negligence, a new strict liability limited by maxima but including non-pecuniary loss, and a compensation fund in case the claimant could not plausibly obtain satisfaction from a legally responsible defendant or an insurer. The idea of no-fault liability in limited amounts followed the traditional German pattern of strict liability statutes for selected "abnormally dangerous activities",[8] such as railways, utilities, automobiles and nuclear installations.[9] In turn, the idea of a subsidiary fund financed by the pharmaceutical industry followed the familiar model of uninsured motorist funds in France[10] and Germany[11] and had gained some academic support for the general problem of products liability.[12]

Not surprisingly, the industry did not welcome this proposal. It objected both to the extra financial burden implicit in strict liability and to the absence of any participation by the state which the industry demanded because of the state's role as licensing authority for pharmaceutical products. This first proposal was therefore soon superseded, in June 1974, by a Cabinet draft which proposed a simpler, two-tracked pattern: aside from negligence liability, all claims based on no-fault were to be made against a fund financed by the pharmaceutical producers. This change was welcomed

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[6]The criminal trial against the manufacturers, Chemie-Grünenthal, lasted 2 $^1/_2$ years and was eventually suspended, as part of the settlement, on the ground (StGB. § 153(3) that culpability was small (*gering*) and that continuation was not in the public interest. See *JZ* 1971, 507.

[7]Wolter, "Die Reform der Haftung des pharmazeutischen Unternehmers und der Verbraucherschultz", *ZRP*, (1974) 260; and "Die Haftungsregelung des neuen Arzneimittelgesetzes", *DB*, (1976) 2001.

[8]The term used by A.L.I. Restatement, Second, Torts § 519. The original Restatement spoke of "ultra-hazardous".

[9]Germany has so far shunned any "general clause" (*Generalklausel*) on the lines of socialist legislation. See generally Will, *Quellen erhöhter Gefahr*, (1980).

[10]Since 1951 (*fonds de garantie*). See S. Tunc, "Establishment of 'Fonds de Garantie' to Compensate Victims of Motor Vehicle Accidents," (1953) 2 *Am. J. Comp. L.*, 232.

[11]Motorists' Compulsory Insurance Law (PflVG), 5 April 1965.

[12]*E.g.* Simitis, Gutachten zum 47, *D.J.T.*, (1968) C82.

by the industry for lowering their financial exposure by dispensing with individual strict liability and by excluding non-pecuniary losses from claims against the fund. The fund's role was here more analogous to workers' compensation as structured in Germany around trade associations. Instead of its marginal function, envisaged by the first draft as a mere guarantor of the fiscal responsibility of civilly liable individual defendants, the fund here assumed the central role of compensating all claims for development risks and other non-negligent injuries.

Yet this plan was no more destined to carry the day than its predecessor. In the course of its parliamentary progress and despite being initially sponsored by the government, it was wrecked by an unexpected initiative from the insurance industry now fearful of being squeezed from the market. Contrary to earlier intimations, the major insurers suddenly declared themselves prepared to underwrite individual producers' strict liability at reasonable rates. For reasons that have remained somewhat obscure, the Social Democratic government yielded to this overture.[13] Thus in 1976,[14] Germany once again conservatively deferred to its traditional pattern of strict liability statutes previously mentioned, with their typical, if controversial,[15] exclusion of non-pecuniary losses and their limitation of liability to amounts within the capacity of the insurance industry.[16] By adhering to the principle of individual liability, backed by compulsory insurance, its promoters also claimed the advantages of deterrence. On the other hand, by preserving the role of the insurance industry as intermediary, the plan substantially increased its overhead cost and was for that reason opposed by the pharmaceutical industry, which thought it could operate a fund of its own less expensively. While the general consumer public will in the end have to shoulder that extra cost, individual claimants would ordinarily be unaffected by the choice between fund and strict liability. Indeed, the latter was claimed to be superior on the dubious ground that claims could be addressed directly to the injurer. By the same token, however, it requires precise identification of the source of the drug, which experience has shown to be sometimes difficult, if not impossible.[17]

Coverage

The scheme, whatever its precise form, was never intended to provide insurance against all drug risks; rather, compensation was intended only

[13]The conservative opposition parties continued to espouse the fund solution. For a behind the scenes vignette see *Der Spiegel*, No. 18, (1976) at 86.

[14]Arzneimittelgesetz, 24 August 1976, §§ 84-94.

[15]A reform proposal emanating from the Ministry of Justice in 1967 (*Referentenentwurf*) proposed deletion of this feature but has not so far been acted upon.

[16]The maximia for injury or death to any individual claimant are DM 500,000 ($210,000) or an anuity of DM 30,000 ($12,600), for all injuries caused by the same drug DM. 200 mill. ($84 mill.) or anuities of DM 12 mill. ($5 mill.): § 88.

[17]*Infra*, text at footnote 69.

for personal injury (and death) resulting from *defective* drugs. The statutory definition of the covered risks marks out the respective spheres of responsibility as between producer and user.

A claim may be made if the injury was caused by a prescription drug "whose harmful effects in the course of its prescribed use objectively exceeded acceptable limits in the light of medical scientific knowledge."[18] This postulates a hindsight test to cover "development risks", in order to reach the very situation illustrated by the thalidomide disaster. But it also reaches exceptional (non-negligent) manufacturing defects, and (expressly) failures to warn. The consumer forfeits all protection by use not conforming to the manufacturer's instructions, and is accountable for contributory fault in accordance with the customary regime of apportionment (comparative negligence).[19]

So far as is known, not a single claim has yet been made under the new act.

Sweden

Swedish reform followed close on the heels of the German.[20] A government committee appointed in March 1973 to consider the general problem of products liability (hence called the Product Liability Committee) decided at the start to confine itself to the drug industry. Taking a leaf from the contemporary German plan for an industry-financed fund, the Committee in 1976 proposed a basically similar scheme for legislation in Sweden. However, the one eventually adopted, which came into force in July 1978, was a voluntary group insurance set up jointly by the pharmaceutical manufacturers and importers with the major insurance companies, under the threat of alternative legislation by the Ministry of Justice. This informal (or private) method of "legislation" is occasionally encountered elsewhere, as illustrated in the United Kingdom by the Motor Insurance Bureau for uninsured motorist claims.[21] In Sweden, however, this

[18]*Supra*, footnote 14, at § 84.

[19]*Supra*, footnote 14, at § 85.

[20]Dufwa, "A No-Fault or Strict Liability Scheme in Action — Sweden" (1970, unpub.); Dufwa, "Product Liability Legislation. General Problems and Techniques. The Swedish Experience", (1980) *Tidskrift, Jur. For. Finland*, pt. 1-2; Dufwa, "Responsibilité du Fait des Produits en Droit Suédois," (1977) 29 *Rev. Int. Dr. Comp.*, 525.

[21]Atiyah, *Accidents and the Law*, (1970) 274-80.

procedure seems to have become habituated as a more general device for replacing tort liability with group insurance.[22]

The first experiments of that sort occurred in the fields of work accidents[23] and medical mishaps.[24] In both instances, the victim's safety net would be social security but any recovery over and above (especially non-pecuniary loss) would have to be sought *via* tort damages (at least in the absence of private insurance). The tort system, with its adversary posture, long delays and high transaction costs, had aroused public concern especially in the above-mentioned fields. A more efficient substitute was first-party insurance to bridge the gap between social security benefits and full compensation, financed in the case of work injuries by the employers and in the case of patient insurance by the county councils which in Sweden are responsible for health care.[25] Both schemes are administered by syndicates of the largest insurance companies.

The advantages of first-party insurance are of course recognized also by the promoters of no-fault automobile plans in the United States and Canada.[26] But there is this fundamental difference:[27] our no-fault plans (despite their considerable variation in benefits) purport to cover only *basic* losses which in Sweden are taken care of by social security; the Swedish insurance schemes on the other hand cover the *top* losses which even in no-fault jurisdictions in North America are still left to the tender mercies of the tort system.[28]

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[22]The Swedish preference for "private legislation" is clearly articulated: greater flexibility, ease of changes in the light of experience, preference for arbitration, *etc.* Hellner, "Schweden," *Haftungsersetzung durch Versicherungschutz*, (1980) 24. Quite aside from the below-mentioned plans dealing with accidents, Sweden had previously committed itself to a "2-step" system of comprehensive income replacement for disability: social security, augmented by nonstatutory industry-wide group insurance financed by employers both for white collar and blue collar employees. Only the automobile accident scheme is statutory: Hellner, "The Swedish Traffic Damage Act of 1975," 2 *Harmonization of Insurance Risk*, (Antwerp, 1981) 269.

[23]Introduced in 1974. See Hellner, "Geborgenheitsversicherung," *Festschrift Klingmüller*, (1974) 159.

[24]Introduced in 1975. Cohen and Korper, "The Swedish No-Fault Patient Compensation Program: Provisions and Preliminary Finds", (1976) *Ins. L.J.* 70; Oldertz (Skandia Int'l Symposia), *Unexpected Complications in Medical Care*, (1979) at 237. Weyers, *"Gutachten zum"*, (1978) 52 *D.J.T.*, 74-78. The English analogues are more obscure or arcane (*e.g.* the government was afraid that a legislative scheme for victims of crime would implicitly acknowledge an obligation to protect citizens against crime).

[25]Channeling is further ensured by (1) compelling deduction of both types of benefits from tort damages and (2) denying reimbursement to either fund from tortfeasors.

[26]The prototype was developed by Keeton and O'Connell, *Protection for the Traffic Victim*, (1965).

[27]*Supra*, footnote 22, at 37.

[28]*Cf.* the still-born proposal by Morris and Paul, "The Financial Impact of Automobile Accidents", (1962) 110 *U. Pa. L. Rev.* 913 for an automobile plan that would cover the top rather than the bottom losses in view of the well-documented phenomenon that the smaller injuries are typically over-compensated due to collateral benefits while the severer injuries are progressively under-compensated. See also Conard, "The Economic Treatment of Automobile Injuries", (1964) 63 *Mich. L. Rev.* 279 at 291.

A characteristic of prevailing Scandinavian practice,[29] is that disputes are relegated to non-judicial procedures — in the first instance, to an eight-member board (Drug Injury Committee)[30] and as a last resort, to arbitration. Compensation which includes pain and suffering, disfigurement and general inconvenience in accordance with prescribed tariffs, is ordinarily in the form of lump sums, but in the case of longer-lasting and severer disability, in the form of indexed periodical payments.[31] As under the German scheme, there are maxima but more generous ones. Individual awards are limited to SKr 2 mill. (U.S. $300,000), total awards for the same kind of drug to 75 mill. ($13 mill.) and total liability for injuries in any one year to 150 mill. ($25 mill.)[32]

Coverage

Unlike the German scheme, the Swedish is not limited to *defective* drugs but proceeds on a wider insurance principle. Covered are all "drug-related injuries", including injuries due to a subsequent change in the composition of a drug or to the action of third parties, such as a physician's misdiagnosis and consequent prescription of the wrong drug. Excluded are any mere ineffectiveness of a drug,[33] relatively minor disability,[34] side effects which, given the patient's health and medical prediction, should reasonably be endured,[35] and wilful misuse or knowing violation of drug regulations.[36] No doubt because of its more generous scope, the number of applications have not been insubstantial, though less than expected, and the largest proportion has been denied.[37]

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[29]Bengtsson, "Personal Injury Boards in Sweden", (1970) 18 *Am. J. Comp. L.* 108.

[30]There are no legal members as such, and legal representation by the parties is discouraged by denying legal aid.

[31]§ 8 and two annexes.

[32]§ 9.

[33]§ 3.

[34]§ 5.

[35]§ 6.

[36]§ 4.

[37]In the first two years, out of about 250 claims 50% were denied, 26% still pending and 24% allowed. Of the 86 unsuccessful claims, 20 were denied for lack of causality, 7 for triviality, and 59 because of "risk-evaluation" (§ 5). Dufwa "A No-Fault Scheme", *supra*, footnote 20.

Japan

Japanese reform was propelled as much by public opinion aroused over the long delays in the settlement of the thalidomide[38] and SMON[39] disasters as by a government anxious to avoid in the future the stigma of culpability in respect of its licensing role.[40] Thus, promptly after the fourth SMON decision in 1978, the government submitted a bill which was eventually passed into law in September 1979.[41] Its model was neither the German one of strict liability nor the Swedish one of group insurance, but rather that of a legislatively enacted special compensation fund with social security overtones. In many respects its prototype was the compensation plan for pollution victims set up in 1973 in the wake of the Minimata, Toyama, and similar catastrophes.[42]

Benefits are prescribed by tariffs on social security lines and cover medical expenses, medical allowance, disability pension (two degrees), pensions for bringing-up injured children and death benefits. The level of benefits is substantially higher than under National Health Insurance, but well below tort damages by excluding non-pecuniary loss and limiting compensation for economic loss.[43] Entitlement is defined on a no-fault basis but victims remain free to pursue their tort remedy; indeed no benefits are payable if it appears that someone's negligence was responsible for the injury. Critics on the plaintiffs' side complain about the prejudicial effect of the latter provision in its tendency to delay compensation or force a reluctant victim to engage in tort litigation. They deplore even more the refusal to replace negligence with strict liability as a basis for tort recovery.

The fund is financed by manufacturers and importers of drugs according to a prescribed formula (having regard to the number of drugs sold, their price and their risk rate) and finally by discretionary government subsidies. The fund is entitled to reimbursement from anyone culpable of negligence.

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[38]Litigation between 1962 and 1973 in eight different district courts eventually terminated in a settlement, October 1974, in which the state and the manufacturer confessed liability. Adachi "Der Thalidomid-Fall: Aspekte und Ergebnisse", *Arzneimittelprobleme* at 89, 99-100.

[39]The SMON litigation, involving the drug chinoform, was launched in 1971. Later split among several courts, the Tokyo district court rendered the first decision in 1976. Judge Kabe, after holding the manufacturers and the government liable for negligence, proposed standards for a settlement of the various claims. Nearly 40% of the plaintiffs accepted a settlement within those standards. Later, the nine other district courts followed these guidelines.

[40]*Supra*, footnote 5.

[41]*Drug Side-Effect Injury Relief Fund Act*, 7 Sept. 1979. Morishima, "On the Bill of Drug Injury Relief Act", (1979) 696 *Jurist* 51; Ishibashi, "Some Problems of the Drug Injury Relief Act", (1979) 51 *Horitsujiho* 63. I am indebted to Professor Katsumasa Hirabayashi's help with these materials.

[42]Gresser, Fujikama & Morishima, *Environmental Law in Japan*, (1981) ch.6 [hereinafter cited *Gresser*].

[43]Present maxima are Personal Injury Pension of annually ¥ 1,760,400 ($7,000), Bereaved Family Pension ¥ 1,539,600 ($6,160). For similar standards of benefits under the Pollution Compensation scheme see *Gresser, supra*, footnote 42 at 294-95. For comparison see the lump-sum standards set by Judge Kabe in the Tokyo SMON case: *Hanreijiho* (1977) No. 838, (the State) 29, No. 846 (manufacturers) 48. The Confirmation was published in (1979) 5 *Hortisujiho* 517. See also translation of judgement and settlement terms by the Hiroshima court in (1979) 12 *Law of Japan* 99.

JUSTIFICATION FOR SPECIAL COMPENSATION PLANS*

Special or tailored compensation plans which focus on a particular set of accidents rather than on accidents generally are not a new idea. Workers' compensation was the first and remains the most prominent experiment of this sort, assuring compensation for work injuries and increasingly for industrial diseases. In more recent years a rapidly growing number of other programs have followed that inspiration: compensation plans for auto accidents,[44] aircraft accidents,[45] nuclear accidents,[46] pollution,[47] and black lung victims,[48] victims of violent crimes,[49] of medical mishaps,[50] of vaccination,[51]

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*This section draws on a study by myself and Professor Steven D. Sugarman for the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research on the subject of compensation for human medical research subjects (unpub. 1981).

[44]*E.g.* "no-fault" automobile plans in the U.S., Sweden, Israel and the recommendation by the Pearson Commission in Britain (1978). In this list one could include also statutes imposing a special strict liability, as in Germany and Switzerland. See generally Tunc, "Traffic Accident Compensation Law and Proposals", *Int'l Encycl. Comp. L.* XI ch. 14; and *Pour Une Loi Sur Les Accidents de la Circulation* (1981).

[45]The Warsaw convention for international flights and legislation for domestic flights in many countries.

[46]Ollier, "Nuclear Energy", *Int'l Encycl. Comp. L.* XI Ch.5, §§ 214-225. *Cf.* the Price-Anderson Act 1956 in the U.S. (*infra.* footnote 105).

[47]*E.g.* the Japanese scheme, *supra,* footnote 41. See also Soble, "A Proposal for the Administrative Compensation of Victims of Toxic Substance Pollution: A Model Act", (1977) 14 *Harv. J. Leg.* 683. *Gresser* (*supra,* footnotes 42, at 497-8, 195) suggests several reasons why the problem of pollution compensation has been ignored for so long in the U.S. But note "Superfund" legislation for cleaning-up chemical waste dumps, Comprehensive Environmental Response, Compensation and Liability Act of 1980 (Superfund), P.L. 96-510, 42 U.S.C. § 9601 ff.; Note, "Conscripting Industry Support for Environmental Cleanup," (1981) 9 *Ecology L.Q.* 524.

[48]U.S.: *Black Lung Benefits Act,* 30 U.S.C.A. § 901 ff., upheld against constitutional attack by mine operators for denial of "substantive due process": justified as serving to spread costs in a rational manner by allocating to the operator the actual cost of its business. *Usery* v. *Turner Elkhorn Mining Co.,* (1976) 428 U.S. 1 U.K.: British National Coal Board Scheme 1974 (*Pearson Report* 1 § 790).

[49]See Stoll, "Compensation in the Context of Criminal Law," *Int'l Encycl. Comp. L.* XI ch.8, §§ 49-62; Schafer, *Restitution to Victims of Crime* (1960). Atiyah, *Accidents, Compensation and the Law* (1970), at 319-26 questions at length, the justification for preferential treatment of such victims. But the Pearson Commission considered it "morally justified as in some measure salving the nation's conscience at its inability to preserve law and order" (§ 588). In New Zealand it was absorbed into the general scheme of Compensation for Personal Injury (*infra,* footnote 90).

[50]The Swedish scheme *supra,* footnote 24.

[51]The *Pearson Report* ch. 25 recommended strict liability, following special schemes in France (Law, No. 75-401 of 26 July 1975: see *Pearson Report* III §§ 429-435), West Germany (Law of Epidemics, No. 53, 22 July 1961 §§ 51-61 see *Pearson Report* III §§ 511-12), Switzerland and Denmark. In Britain the Vaccine Damage Payments Act 1979 gave formal authority to the practice since 1948 of government tax-free grants of £ 10,000 in case of death or serious disablement. *Cf.* McIntosh, "Liability and Compensation Aspects of Immunization Injury: A Call for Reform", (1980) *18 Osg. H.L.J.* 584. Franklin & Mais, "Tort Law and Mass Immunization Programs: Lessons From Polio and Flu Episodes", (1977) 65 *Calif. L. Rev.* 754 also advocates "internalizing" by the government. In the U.S., under existing law, the manufacturers alone bear strict liability for defective vaccine (*i.e.* a vaccine that causes the very disease against which it was designed to protect): *Gottesdanker* v. *Cutter Laboratories* (1960), 182 Cal. App. (2d) 602 (Salk: implied warranty); *Grinnell* v. *Charles Pfizer & Co.* (1969), 284 Cal. App. (2d) 424 (Sabin: strict liability). A compensation plan financed by manufacturers is recommended by Ladimer, "Legal and Regulatory Perspectives in Mass Immunization Programs," (1976) *Ins. L.J.* 459.

of medical experiments,[52] and even of sporting activities.[53] Compensation plans for victims of pharmaceutical drugs are thus only the latest arrivals along a well beaten track.

Compensation plans are typically justified by one or more complaints as to why tort law peculiarly fails to cope adequately with the class of accidents in question. The literature is rich with the writings of law reformers whose studies of a particular kind of accident had convinced them that a compensation scheme was needed to cure the shortcomings of tort law. The Pearson Commission Report, a latter-day kind of Doomsday survey of the British accident compensation scene, abounds in such recommendations.[54]

However, the complaints about tort law vary from one such plan to another. One claim is that the tort treatment is especially unjust. For example, workers' compensation arose in response to the harsh application of assumption of risk and other defenses which, at the time, virtually precluded successful tort recovery.

A second claim is that the tort system of dealing with the problem is not only administratively too costly but is also beset with fraud. This position has been emphasized in the debate over auto no-fault.

A third claim is that the tort solution requires unusually difficult determinations of causation (as in pollution and drug cases) or of negligence (as in auto accidents).

A fourth and related claim is that tort law in action takes on a lottery aspect as similarly situated victims are treated unequally by juries — a claim often made about auto and medical accident victims.

A fifth justification rests on the claim that the compensation plan will better deter socially undesirable conduct; and a sixth and related claim is that the compensation plan will better promote the efficient allocation of resources. With a rise in popularity of law-and-economics, these latter justifications are heard with increasing frequency.

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[52]The *Pearson Report* §§ 1340-41 recommended strict liability. So did Havighurst, "Mechanisms for Compensating Persons Injured in Human Experimentation,"*HEW Secretary's Task Force on the Compensation of Injured Research Subjects*, (1977) Appendix A 81, embracing Calabresi's theory of internalizing the risk. The Report by the present writer and Professor Sugarman (*supra*, p. *) to the "successor" committee was more skeptical. On an earlier occasion (*ibid*, at 105) Havighurst advocated that subjects be paid on a scale corresponding to the gravity of the risk. But unless first-party insurance against medical costs and income maintenance is available (clearly, at least the latter is not) or it be assumed (against all evidence) that only deliberate risk-takers are involved, it would seem better to use the extra cost for compensation purposes.

[53]*Sporting Injury Insurance Act*, 1978 *(N.S.W.)*.

[54]*Royal Commission on Civil Liability and Compensation for Personal Injury, Report* (3 vols. 1978). See generally, Fleming, "The Pearson Report: It's Strategy", (1979) 42 *Mod. L. Rev.* 249; Marsh, "The Pearson Report", (1979) 95 *Law Q. Rev.* 513, Allen, Bourn & Holyoak, *supra*, footnote 1.

A seventh argument focuses on the insolvent wrongdoer: for example in plans for victims of violent crimes.

An eighth justification is the desirability of compensation itself. It is sometimes linked with the claim that tort damages overcompensate, for example in auto nuisance claims and, for some critics, in all awards for pain and suffering. Usually, however, the driving concern is the failure of tort law to compensate victims adequately — in particular, its failure to compensate some victims at all. This justification — but only this one — is nearly universally invokes by compensation supporters.

In considering the desirability of a compensation scheme for a new area, it may advance analysis to consider which of these justifications is applicable.

Coverage

Many of the complaints against the tort system are applicable to the drug problem. As to the first, it is probably the case that the theoretical conditions of recovery are no more formidable for drug victims than for those injured by other injurious products.[55] In most countries, the plaintiff would be required to establish negligence, but the trend is to relax that standard, whether by shifting the burden of proof to the defendant (as in Germany[56]) or by imposing outright strict liability (as in the United States[57]) for all "defective" products. This preference over the generality of other accident victims is justified principally on the grounds that the injured consumer is at a disadvantage in access to evidence and information compared to the manufacturer, and that such liability tends to "internalize" the accident cost and thereby promote a more efficient allocation of economic resources through specific or "general" deterrence.[58] However, in the three

[55]Indeed in the U.S. the drug victim has been traditionally favored. The "privity requirement" in actions for negligence was relaxed long before *MacPherson* v. *Buick Motor Co.* (1916), 217 N.Y. 382 by bringing drugs under the "inherently dangerous" exception: *Thomas* v. *Winchester* (1852), 6 N.Y. 397. Later, drugs joined food and drink as candidates for strict liability before its extension to products generally: *e.g. Gottsdanker* v. *Cutter Laboratories*, *supra*, footnote 51.

[56]Federal Supreme Court (BGH, 26 Nov. 1968) *BGHZ* 51, 91. See Lorenz, "Zur Entscheidung des Bundesgerichtshofs im Hchnerpestfall", (1970) 34 *RabelsZ.* 14; generally, Kötz, *Deliktsrecht* (1976), at 187-207. A similar tendency has been observed in the Japanese drug and pollution cases of the '70s. The first case to invoke an "inference" of fault ("as long as an adequate rebuttal is not forthcoming") against a drug manufacturer was the "Hokuziko" SMON case: *Arzneimittelprobleme* at 83, 84.

[57]Merrill, "Compensation for Prescription Drug Injuries", (1973) 59 *Va. L. Rev.* 1. "Impure" drugs, like the uncooked batch of vaccine in *Gottsdanker* v. *Cutter Laboratories*, *supra*, footnote 51 entail strict liability. But dangerous "pure" drugs raise the question of design defects, liability for which is as a rule tested by a negligence standard. *Infra*, foonote 60 on the question of hindsight vs. "state of the art." On products liability generally see Restatement, Torts, Second §§ 402A; Noel and Phillips, *Products Liability* (2nd ed. 1980); R. Epstein, *Modern Products Liability Law* (1980).

[58]Owen, "Rethinking the Policies of Strict Products Liability", (1980) 33 *Vand. L. Rev.* 681; Cowan, "Policy Bases of Products Liability", (1965) 17 *Stan. L. Rev.* 1077; Symposium "Products Liability: Economic Analysis and the Law", (1970) 38 *Chi. L. Rev.* 1. "General deterrance," a notion explored by Calabresi, *The Cost of Accidents: A Legal and Economic Analysis* (1970) is pursued in greated detail, *infra*, text, footnote 80.

countries that have so far adopted special plans for drug victims, the prior law was based on negligence so that the reform could be regarded as a first and most urgent step towards no-fault liability for all products.[59] For that matter, in countries which have already adopted strict liability for all defective products (like most United States jurisdictions) or are preparing to do so (like Great Britain), the need of a special regime for drugs is less keenly felt. Nowhere does the interposition of a licensing authority appear to deflect the drug developer's responsibility.[60]

Perhaps the most important practical limitation on liability for negligence is that it does not cover "development risks", *i.e.*, risks which the manufacturer neither knew or should have known at the time of marketing in the light of existing scientific knowledge. Even under strict liability there is strong support for excluding such risks which, it is feared, would expose industry to an impossible burden that is practically uninsurable, would uneconomically tie up enormous reserves and would be difficult, if not improper, to pass on to the consumer public.[61] Others, however, argue no less persuasively that reform is needed precisely to provide this extra protection both as an incentive to even greater investment in prophylactic research and because the victims of development risks are especially deserving in that they are, so to speak, sacrificed for the sake of medical progress much like experimental research volunteers.[62] Here, compromise between these opposing views can be found in extending coverage to development risks but subject to financial limits within the capacity of the affected industry and its insurers. This solution is embodied in the EEC

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[59]While the manufacturers of thalidomide and SMON were actually found culpable, the burden of proving negligence contributed greatly to the delay in reaching a decision. Thus what aroused public anger was the inefficiency of the tort system more than its doctrinal inadequacy.

[60]The *Pearson Report* I § 1260 specifically opposed any exception from strict liability for "officially certified" drugs. So did the Ontario Law Commission [*Report on Products Liability* 90 (1979)] and the English Law Commission [*Report No. 82* para. 612 (1977)]. For a contrary argument see Page Keeton, "Products Liability — Drugs and Cosmetics", (1972) 25 *Vand. L. Rev.* 131. The *Uniform Product Liability Act* § 108 would create a resumption that a product conforming to legislative or administrative regulatory safety standards relating to design and performance was not "defective." Several states have legislated a "state of the art defense", making conformity with governmental standards either a complete defense (Ariz., Ind., Wash.) or a rebuttable presumption (Utah, Colo.). See Note, "State of the Art Defense in Products Liability: 'Unreasonably Dangerous' to the Injured Consumer", (1980) 18 *Duquesne L. Rev.* 915.

[61]Thus the *Uniform Product Liability Act* § 106(B) postulates "the state of scientific and technological knowledge at the time of manufacture". According to the accompanying Analysis, "this approach has been followed by the common law courts throughout the United States." See *e.g. Brochu* v. *Ortho Pharmaceutical Corp.* (1981), 642 F. 2d 652 at 657 (1st Cir.). But see *Barker* v. *Lull Engineering Co.*, (1978) 20 Cal. (3d) 413, which seems to espouse a hindsight test.

[62]See *e.g. Pearson Report* I §§ 1258-59; English Law Commission, *supra*, footnote 60 at para. 105. Among American advocates: James, "Products Liability", (1955) 34 *Texas L. Rev.* 192 at 215; Rheingold, "Products Liability — The Ethical Drug Manufacturer's Liability", (1964) 18 *Rutgers L. Rev.* 947 at 1001; Wade, "On the Nature of Strict Liability for Defective Products", (1973) 44 *Miss. L. J.* 825 at 835-6; Pratt and Parnon, "Diagnosis of a Legal Headache: Liability for Unforseeable Defects in Drugs", (1979) 53 *St. J. L. Rev.* 517.

draft directive on products liability[63] and, to some extent,[64] in the three drug plans here being considered.[65]

Plaintiffs in ordinary civil litigation often face additional special problems in drug cases. Most prominent perhaps is the difficulty of proving causation. However, experience at least in the United States indicates a general acceptance of statistical proof and, in practice, a less than rigorious standard of persuasion.[66] The first German draft for a drug compensation scheme expressly postulated an even lesser standard,[67] but this concession was later dropped. In the result, all three schemes condition compensation on the regular standard of proof of drug-related injury, though, as already observed, the extent of coverage varies from one scheme to another. At one end is the cautious German definition which excludes foreseeable risks that must be tolerated in the light of medical knowledge; at the other end is the Swedish scheme which includes even misapplication by medical personnel.

Another causation problem illustrates the difference between the tort and the fund models. The received tort theory, whether based on negligence or strict liability (like the German drug act), requires identification of the source of the particular drug that caused the injury. Whether cases of multiple pollution[68] or generic drugs[69] justify a lesser standard, at least once the defendant's culpability has been established, remains highly con-

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[63]Jolowicz, "Product-Liability — the EEC and the House of Lords", (1980) *Camb. L.J.* 263. By contrast the Strassbourg Convention (1975), on which the draft Directive is based, omitted maxima: see Fleming, "Draft Convention on Products Liability (Council of Europe)", (1975) 23 *Am. J. Comp. L.* 729; Lorenz, "Some Comparative Aspects of the European Unification of the Law of Products Liability", (1975) 60 *Cornell L.Q.* 1005; Harland, "Products Liability and International Trade Law", (1977) 8 *Syd. L. Rev.* 357.

[64]The German and Japanese schemes contain maxima, the Swedish is limited to the slice above social security benefits.

[65]The *Pearson Report* I § 1264 opposed the idea on administrative grounds.

[66]*Reyes* v. *Wyeth Laboratories* (1974), 498 F. 2d 1264 (5th cir.).

[67]*I.e.*, that causal responsibility was "credible" (*glaubhaft*) rather than probable. *Cf.* the presumptions under the *Black Lung Act* § 413(b), unsuccessfully impugned in *Usery* v. *Turner Elkhorn Mining Co.* (1976), 428 U.S. 1, *supra*, footnote 48.

[68]Japanese courts pioneered highly innovative approaches in the major pollution cases: see *Gresser*, *supra*, footnote 42, ch. 3 at 128-30.

[69]In the celebrated case of *Sindell* v. *Abbott Laboratories*, (1980) 26 Cal. 3d 588, the California court applied the novel solution of market-share liability against all manufacturers of DES, a generic drug. Whether other courts are prepared to follow this lead remains to be seen. See *e.g.* Fischer, "Products Liability — An Analysis of Market Share Liability", (1981) 34 *Vand. L. Rev.* 1623. The German Civil Code, BGB § 840 I 2 provides for a shifting of the burden of proof to "participants" (*Beteiligte*) who, traditionally, had to be related to the accident by a "unity of place, time and fact" (*Alternativtäterschaft*). But lately the term has been interpreted more liberally: see Deutsch, *Haftungsrecht* (1976) 349-357. Japanese courts invoked a corresponding provision (Civ. Code § 719) against the three manufacturers of SMON and the government.

troversial. In contrast, the fund model would avoid this difficulty, since it is sufficient that the drug itself, regardless of its source, be identified.[70]

Deterrence

One of the most familiar claims for the tort system is that it deters accidents by giving the actor a choice between avoiding liability by exercising the requisite amount of care or exposing himself to the risk of liability by saving the expense of precautionary measures. Indeed, some enthusiasts argue that this constellation will result in the most efficient allocation of resources inasmuch as the actor, motivated by self-interest, will be likely to choose the — to him — less costly alternative, at any rate in the best of all possible worlds, which would afford him full information to guide his decision. Indeed, the market theorists go further, invoking the authority of Judge Learned Hand to suggest that only cost-*un*justified risks be treated as negligent (unreasonable).[71]

We may accept that the prospect of tort liability does enter into the calculations of manufacturers and other business enterprises more, perhaps, than of automobile drivers and the like, whose behavior is less planned and less sensitive to such a stimulus. Would a move from negligence to strict liability weaken this incentive of accident prevention? Though some critics have advanced this theory, arguing that rational people will invest less if they have no chance of avoiding the loss, experience and common sense suggests to the contrary that strict liability promotes the highest standard of care since they can no longer bank on benefiting from the forensic vagaries of fault finding.

Strict liability, like negligence, is geared to the individual producer. A compensation fund, on the other hand, represents collectivization of the cost among a larger pool, for example of all drug producers. It is therefore arguable that this may result in some individual or even collective lessening of inventives. Evidently, however, such a prospect has not deterred the widespread socialization of accident losses through liability and social insurance (often without subrogation rights[72]), let alone comprehensive ac-

[70]The problem of identification does not appear to have influenced the structure of the three existing drug schemes: see *e.g.* Wolter, "Haftungsregelung", supra, footnote 7, at footnote 36. The advantage of a fund is illuminated by the interesting French case of the two hunters who both negligently fired in the plaintiff's direction but it could not be determined who shot and wounded the plaintiff. While excusing the hunters individually, the Grenoble court nonetheless imposed liability on their common insurer; 1963 *Rev. trim. dr. civ.* 555 (note by Tunc). American and Canadian courts have held such hunters liable by imposing on them the burden of incrimination: *Summers* v. *Tice* (1948), 199 P. 2d 1 (Cal.); *Cook* v. *Lewis*, [1951] S.C.R. 830.

[71]Posner, "A Theory of Negligence", (1972) 1 *J. Leg. Stud.* 29. The reference is to Judge L. Hand's celebrated, if incautious, formula of negligence as meaning that the probability and gravity of the risk outweighs the burden of avoid it = B <PL: *U.S.* v. *Carroll Towing Co.* (1947), 159 F. 2d 169 (2d Cir.). The manufacturer would not in any event invest additional resources in accident prevention (in the absence of other coercion) even if the law held him negligent for failing to adopt cost-unjustified precautions). *Cf.* Coase, "The Problem of Social Cost", (1960) 3 *J.L. & Econ.* 1.

[72]As in Great Britain and Sweden: see Fleming, "Collateral Sources," *Int'l Encyl. Comp. L.* XI ch.11, §§ 63-73; Hellner, "Damages for Personal Injury and the Victim's Private Insurance", (1970) 18 *Am. J. Comp. L.* 126.

cident schemes like that in New Zealand[73] and the developing insurance scenario in Sweden.[74] Special funds limited to a particular industrial group, like the drug industry, do offer a plausible incentive to minimizing collective costs. In any event, there may be other safeguards. In the case of the drug industry, which certainly has its share of "bad eggs",[75] licensing authority such as the FDA in the United States, provides a screen between producer and consumer which might serve as effective a substitute as individualized loss bearing. Besides adverse publicity, which on occasion has proven a formidable ally of consumer protection,[76] there is finally a residual sanction in criminal proceedings which has also been shown in the past to be more than an empty threat.[77]

Over-deterrence can be as serious a problem as under-deterrence. A prominent motive of the pharmaceutical industry in supporting special plans was to secure dollar limitations on its potential liability as a trade-off for no-fault compensation. The thalidomide affair itself and drug litigation since has given cause for genuine alarm that the cost of adverse judgments based on unrestricted tort damages could overwhelm the industry.[78] or at least either discourage the development of new and potentially highly beneficial drugs or lead to over-investment in precautions. The need for industry protection obviously grows with increasing exposure to compensation claims as a result of progressively raising the standard of legal liability. This accounts for the limits on products liability proposed in the draft EEC directive[79] as a concomitant to the move from negligence to strict liability. Compensation plans limited to drug injuries can similarly provide needed protection for the industry no less than for its victims.

Related to deterrence is the theory of internalization.

Internalizing Costs

Lawyer-economists have argued that all costs ou to be debited to the activity that causes them so that they are reflected in the price of the

[73]*Infra*, footnote 87.

[74]See Hellner, "Haftungsersetzung," *supra*, footnote 22.

[75]Probably the worst case was mounted against Richardson-Merrell, Inc. in the MER/29 litigation which resulted in repeated awards of punitive damages against that firm: see *Toole* v. *Richardson-Merrell* (1967), 251 Cal. App. 2d 689; *Roginsky* v. *Richardson-Merrell* (1967), 378 F. 2d 832 (2d Cir); Rheingold, "The MER/29 Story — An Instance of Successful Mass Disaster Litigation", (1968) 56 *Calif. L. Rev.* 116 at 117-21.

[76]On the other hand, tort litigation tends to focus public attention on harmful products: see Linden, "Tort Law as Ombudsman", (1973) 51 *Can. B. Rev.* 155.

[77]*E.g.* Richardson-Merrell, and several of its employees implicated in the MER/29 scandal were convicted: Rheingold, *supra* footnote 75 at 124. Also, the German proceedings against Chemie-Grünenthal in Aachen were criminal.

[78]Claims in the current DES litigation are believed to exceed $6 bill.

[79]*Supra*, footnote 63.

resulting product or activity.[80] The cost of accidents, in short, is properly an item of the overhead costs of a particular enterprise. In this way activities with higher accident rates will have lesser attraction in the marketplace and will thus be carried out to a more socially desirable extent. By contrast, it is claimed that if activities do not bear their accident costs they are in effect subsidized and will thus be over-produced. This creates both an inefficient allocation of resources and excess accidents to boot. In sum, the market mechanism can be enlisted in the pursuit of "general" deterrence of accidents.

Although it has become fashionable to argue that tort law should — and some have contended that it actually does — serve to internalize costs, there are many problems with this line of analysis. First, negligence law does not in fact attempt to assign all accident costs to activities that cause them. Rather, it purports to assign only the cost of accidents that reasonably should have been avoided. To some, this is an indictment of negligence. To other it reveals a fundamental ambiguity about the internalization argument. What is the cost of what?

In many situations policymakers have acted as if there were no problem in attributing particular types of accidents to a specific activity. For example, work injuries are by general consensus regarded as part of the cost of industrial operations: "the product should bear the blood of the worker." But on closer examination, the problem can become very thorny indeed. Is an accident caused by failure of an industrial tool to be internalized by the maker or by the user of the tool? If mother mink eat their young when frightened by sonic booms, is this the cost of national defense or mink farming?

If internalization has the function of placing the cost on the best loss avoider and thus serve the cause of "general deterrence", it is plausible enough to allocate the cost of avoidable product injuries to producers who fail to invest to a socially desirable extent in accident prevention. But applying it to "development risks", which are unavoidable and preventable only by incurring socially undesirable costs (*e.g.* even longer periods of testing with resulting delay in marketing beneficial drugs), would result in a misallocation of economic resources. At best, "general deterrence" can then no longer point to the *production* of drugs rather than to their *consumption* as the activity to which the cost of such accidents should be internalized. In sum, compensation for development risks may be thought desirable for the sake of compensating the injured out of a deeper pocket, spreading the cost among a larger risk pool, *etc.*, but it cannot be justified on grounds of efficient resource allocation.

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[80]Especially Calabresi and his epigones. Calabresi, *supra*, footnote 58. Applied to the drug problem by Merrill, *supra*, at 87 ff.

A second reservation about the theory of internalization is that, given all the market imperfections otherwise existing in a modern complex economy, even if the tort system did achieve acceptable cost-attribution, there is no guarantee that it will have moved our economy closer to an efficient level of various accident-producing activities. For example, if a monopolist producer of a product (and this is especially relevant to drug manufacturers who usually enjoy a patent monopoly) otherwise underproduces a product as economic theory suggests then the *failure* to impose accident costs on that monopolist could be just the right subsidy needed to boost production to the socially desired level.

More important yet is that, in the real world, it is frequently impossible to internalize accident costs to the specific offending product or activity. For example, not only would a drug that eventually reveals itself as dangerous, in all likelihood be totally withdrawn from the market, but the cost of compensation will in any event probably be spread among all or most other products of the particular manufacturer, with the result that the consumers of the safe drugs will in effect be bearing the accident costs of the dangerous drug. In a theoretical free market, this "externalizing" of the cost might be blocked; but often — and prescription drugs are a good example — such a hypothesis is wholly unrealistic.[81]

Government Liability

The policy of deterrence has been invoked not only against the pharmaceutical industry but also against the government. Government has long played a critical role in the marketing of drugs through its licensing function. Increasing the pressure for maximum regulatory caution, it is argued, can be achieved by exposing the government to shared liability for its failures.[82] But others would question whether an appreciably larger margin of safety can be achieved in this manner, having regard to the fact that we are here concerned principally with so-called development risks (*i.e.*, unknowable risks) and to the controlling agency's dilemma of balancing the expected benefit of a new drug against the risk of harmful side effects.

An alternative argument for state participation in the cost of compensation is the public benefit derived from drug use and development. This is most obvious in the case of vaccines which inure not only to the benefit of the individual patient, but to the public in general by preventing the spread of disease.[83] Hence the proliferation of special compensation schemes

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[81]Teff, "Products Liability in the Pharmaceutical Industry," (1974) 20 *McG. L. J.* 102.

[82]Merrill, *supra*, foonote 57, at 68-87.

[83]Law-and-economic buffs would argue that rather than externalize the cost of free-loaders, that cost should be internalized by the general public: see Merrill *supra*, footnote 57 at 99-102.

financed by the public purse[84] for victims of publicly-sponsored vaccination programs. The public interest is also engaged in pharmaceutical and medical progress in general,[85] sufficiently it is argued, to warrant passing on at least part of the cost of compensation to public funds.[86] This would, in addition, somewhat relieve the financial burden of the smaller producers who are supposedly unable to spread the compensation cost among a wide range of products and their consumers.

In the past, governments have not been anxious to assume such a responsibility aside from the special case of vaccination. Governments in several countries did contribute to the thalidomide settlements, in some cases voluntarily (West Germany, Sweden), in others forced by legal process (Japan). But the special compensation plans, actual or proposed, do not (with the exception of Japan) envisage any public financial participation.

Transaction Costs

The most serious criticism that can be levied aggainst the tort system is its inordinate expense. Two recent American studies of different areas of tort liability tell the story. One dealing with automobile accidents concluded that it costs $1.07 in total system expenses to deliver $1.00 in net benefits to victims — plaintiffs' legal expenses being 23% and insurers' claim expenses (attorneys' fees, *etc.*) 25% of total operating expenses.[87] So also the Inter-Agency Task Force on Products Liability[88] estimated 40% for underwriting expense and profit and an additional 20% for loss adjustment expenses, leaving 40¢ of the premium dollar for the victim and his attorney. The combined legal expenses for plaintiff and defendant, as well as the underwriting expense and profit, each exceeded the claimant's compensation.[89]

These very high transaction costs of the tort system compare most unfavorably with the cost of compensation plans. In New Zealand, which abolished the tort system for personal injury in 1974 in favor of an accident

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[84]*Supra*, footnote 51. In the U.S. the responsibility surfaced in the Swine Flu Affair, *infra*, footnote 94. In *Gottsdanker*, *supra*, footnote 51, government pressure to speed up the production of Salk vaccine contributed to the marketing of a live batch.

[85]As evidenced, *e.g.* in the U.S., by the large budgetary support of the National Institute of Health (NIH).

[86]Wolter, "Reform," *supra*, footnote 7 at 266 argues for no more than half.

[87]Department of Transportation, *Motor Vehicle Crash Losses and their Compensation in the United States*, (1971) 47-52.

[88]Department of Commerce, *Final Report* (1976) V:23-25.

[89]The somewhat better statistics from the English scene cited by the *Pearson Report* I, § 261, *viz.* no more than 45% operating costs, are probably attributable to several factors among which a distinctly lower level of legal fees is only one. Others are the lesser incidence of litigation encouraged by the abolition of juries, virtual tariffs for damages and more willingness on both sides to compromise.

compensation scheme,[90] the cost of handling claims amounted to only 8%;[91] a similar experience is claimed for the Ontario workers' compensation scheme.[92] In New Zealand the savings from lower transaction costs accounts more than marginal limitations on non-pecuniary loss for the ability to provide compensation for *all* accident victims for the same price ticket.[93]

The high transaction costs of the tort system are inherent in the system itself. Primary is the adversary relationship between claimant and the compensation source. Liability to compensate is dependent on issues of causation and fault, which require investigation and are frequently contested. The assessment of damages, tailored to each case, invites additional controversy. In sum, the system is geared to individualized processing and does not favor economies of scale.

Moreover, these costs are incurred in the processing of all claims, not only those that are eventually successful. The reluctance of the drug companies and their insurers to participate in the 1976 swine flu program in the United States stemmed less from their fear of successful claims than from their concern over the cost of handling claims, spurious as well as meritorious. In the upshot, the government had to agree that, rather than indemnify the manufacturers (for successful claims), it would handle (defend) all claims directly with a mere right of reimbursement from negligent manufacturers.[94]

In the drug field, the defense costs under the tort system are unusually high. Even where, as in the United States, the basis is strict liability rather than negligence, the principal issue remains the highly controverted question whether the product was unnecessarily dangerous, *i.e.*, was suffering from an actionable "design defect". This depends, more often than not, on striking a cost-benefit balance which, in the opinion of many observers,[95] patently overtaxes the judicial system, especially juries. At all events, it causes mammoth trials and, since an adverse judgment condemns a whole product line, manufacturers have every incentive to invest the maximum

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[90]*Accident Compensation Act*, 1972. See Palmer, *Compensation for Incapacity* (1979); Ison, *Accident Compensation* (1980); Blair, *Accident Compensation in New Zealand* (1978).

[91]Ison, *supra*, footnote 90, at 122.

[92]Report of the Royal Commission of Inquiry, *Compensation of Personal Injury in New Zealand* (1968) 213. In contrast, American workers' compensation is disastrously inefficient, largely because of its litigious aspects. The Interdepartmental Policy Group reported that only 52¢ in the premium dollar reached the victim: *Workers' Compensation: Is There a Better Way?* (1977), 15.

[93]The average levy for employers is now only 1.07% of wages, which is $^1/_3$ of the average premium rate paid by employers in New South Wales (Australia) for worker's compensation and common law liability.

[94]42 U.S.C.A. § 2476(j)(i). See *Ducharme* v. *Merrill-National Laboratories* (1978), 574 F. 2d, 1307 at 1311 (5th cir.); Neustadt and Feinberg, *The Swine Flu Affair* (1978) 52-53. For a representative, recent claim under the program see *Overton* v. *U.S.* (1980), 619 F. 2d 1299.

[95]See especially Henderson, "Judicial Review of Manufacturers' Conscious Design Choices: The Limits of Adjudication", (1973) 73 *Col. L. Rev.* 1531.

in legal defense. The thalidomide,[96] SMON[97] and current DES[98] litigations bear ample witness to this diversion of resources from victims to "transactors".

Taking drug injuries out of the courts therefore looks especially propitious. The German model of individual liability is clearly the more expensive, since it involves participation of private liability insurers besides retaining the adversary posture of third-party claims, always prone to produce conflict and extra cost. By comparison, the fund model adopted in Sweden and Japan, and originally proposed in Germany, has greater attraction, though this might have to be balanced against competing considerations, such as the internalization theory previously canvassed.

Horizontal Equity

Another serious flaw of the negligence system is that it discriminates between different accident victims not according to their own deserts, but according to the culpability of the defendant: a claimant's success is dependent on his ability to pin responsibility for his injury on an identifiable agent whose fault he can prove. Put differently, negligence deems as deserving only those who can trace their harm to someone's wrongdoing. To critics, this causes unequal treatment in several ways: between victims of the same kind of injury, one of whom can but another cannot point to a responsible cause, *e.g.*, one who breaks his leg in a car accident and another who slips in the bathtub;[99] between one who does and one who does not succeed in proving fault in a defendant — a distinction exacerbated by the vagaries of jury trial long after the accident in question and by the fine line that often divides minimally acceptable and culpable conduct; between those with especially effective lawyers and those without and between those who are personally attractive victims and those who are not — both of which are thought by critics to influence juries unduly. Not least of all is the fortuitous exclusion of victims unable to collect from responsible defendants who turn out to be judgment proof, *i.e.*, lacking liability insurance or other financial resources.

Even among those fortunate enough to obtain some damages, studies show a capricious relation between the total amount of compensation recovered from all sources and the gravity of the injury.[100] Although slight

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[96]*Supra*, footnote 1.

[97]*Supra*, footnote 39.

[98]After several years of litigation over procedural issues, principally the issue of identification, only two or three cases out of hundreds have so far been tried on the merits. The *Sindell* decision *supra*, footnote 69, itself encourages vast legal expenditure in cross-claims over the issue of "market shares".

[99]Hence widely known as the "bathtub argument." Home accidents account for 50% of all injuries, industrial accidents for 12%, road for 10%, recreational and school for 8% each: Ries, "Episodes of Persons Injured: United Stattes, 1975," DHEW Pub. 78-1250, cited by Bernzweig, *By Accident Not Design* (1980) 15. Likewise the Pearson Commission (*Report* II t. 2 & 4) attributed 10% to road accidents, 25% to work and the remainder elsewhere ("bathtubs").

[100]*Supra*, footnote 28.

injuries tend to be over-compensated (because of medical insurance and other sources of compensation which do not set off each other or reduce tort damages and because of the nuisance value of small claims), yet the graver the injury the smaller the share of compensation. Among the reasons for this parlous state of affairs are the low liability insurance coverages held by many motorists and the gaps in tort recovery. With much justification, the process has been called a "forensic lottery"[101] in which a small minority obtain a pot of gold but the majority go empty-handed or obtain only tokens of solace.

By contrast, compensation plans avoid most, if not all, the preceding inequities by focusing not on the injurer's misconduct but on the victim's injury, by eliminating as many points of controversy as possible, and by assuring financial responsibility. Such preferential treatment in turn raises another question of horizontal equity: Why are they regarded as more deserving than others whose condition is in varying degree rather similar?

In the case of drugs, there are different plans of increasing scope: plans for experimental research volunteers, for vaccine victims, for all drug victims however variously defined, and for victims of all dangerous products, including drugs.[102] Preference for the first two classes is commonly justified by a special public responsibility. Research volunteers incur risk for the sake of scientific progress, and public immunization confers a benefit not only on the individual patient but on the public at large by reducing the spread of disease.[103] These subjects are therefore widely deemed deserving of public solicitude at the cost of those who benefit from their sacrifice. Are they not, in a sense, doing a job for the public welfare so as to become entitled to much the same benefits as members of the armed services? Yet there are also analogies pointing the other way. Not all victims of programs carried on under government sponsorship for the benefit of the general public fare so well. Indeed, governments have in the past notoriously resisted even ordinary tort liability,[104] and not infrequently seek to encourage publicly beneficial enterprises like nuclear power plants by reducing the protection of the public and so granting a subsidy at the cost of potential victims.[105] Why then should research volunteers and partici-

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[101]Ison, *The Forensic Lottery* (1967).

[102]*Supra*, at 17-18.

[103]*Supra*, footnote 83.

[104]*Immunities* still remain: *e.g.*, under the *Federal Tort Claims Act*, 28 U.S.C.A. § 2680(a) for any "discretionary function or duty." The FDA's licensing functions have been consistently held exempt as being "discretionary": *Gelley* v. *Astra Pharmaceutical Products* (1979), 610 F. 2d 558 (8th Cir.). In Germany, state liability is in any event subsidiary (BGB § 839). Only in Japan has the state been held liable in the drug cases.

[105]Thus a constitutional attack on the dollar limitation ($560 mill.) on compensation under the Price-Anderson Act was defeated on the ground that the Act bore a rational relation to Congress' concern to stimulate private industry development in nuclear energy. This provided an answer to the double attack based on due process and equal protection. *Duke Power Company* v. *Carolina Environmental Study Group, Inc.* (1978), 438 U.S. 59. See Green, "Nuclear Power: Risk Liability and Indemnity", (1980) 71 *M.L.L.R.* 479.

pants in publicly sponsored immunization programs have a better claim to compensation than victims of military jet sonic booms[106] or victims of a nuclear accident?[107] One probate answer is that is for the sake of encouraging participation; it is, if not a bribe, at least the reward for making a desired choice in a free society which prefers incentive to compulsion.[108]

In the case of ordinary drugs, the argument for preference is even more tenuous. Admittedly, we have seen[109] a case can be made for government sharing financial responsibility with pharmaceutical producers for the cost of drug injuries because of the public involvement in the marketing and development of drugs. But this assumption does not address the argument of inequity any more than making a distinction between victims of negligence and victims of innocent causes. In what way, one might ask, were the thalidomide children more deserving of public generosity in Britain than the 1,000 other handicapped children born every week or the 100,000 severely handicapped children under sixteen who must be content with the benefits of the general social security program?[110] For that matter, how are we to justify the disparity between the British government's grants since 1948 of £10,000 to serious vaccine victims[111] and the £54,000 that were eventually awarded to each of the thalidomide children?[112] And on what basis are we to prefer the credentials of cancer victims from drugs to those from leaking x-ray equipment or, for that matter, from microwave ovens? At any rate, the contemporary debate in Europe over adopting strict products liability has turned its back on any distinction between different classes of products because the need for protection seems the same for all.

Special compensation plans, then, suggest a potentially serious problem of injustice. If the current treatment of a given class of victims is altered so that it better conforms to that afforded some other similarly situated victims, the change will at the same time place the altered class out of harmony with yet another class of similar victims.

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[106]Such claims have been consistently rejected either on the ground that the activity is discretionary (*Abraham v. U.S.*, 465 F.2d 881 (5th Cir. 1972) or that the FTCA does not cover strict liability (*Laird v. Nelms*, 406 U.S. 797 (1972). On the other hand, claims for compensation up to $25,000 can be made by civilians against the military under the 10 U.S.C.A. § 2731.

[107]In the U.S. the *Price-Anderson Act* of 1957 set a dollar limit on the total liability for an accident but left the standard of liability (negligence or strict) to the varying perceptions of the individual States. Only belatedly did an amendment in 1966 introduce across-the-board no-fault liability for "extraordinary nuclear occurrences," for which however not even the Three Mile Island disaster qualified.

[108]This policy is well illustrated by our treatment of rescuers. While we are reluctant to compel rescue, we encourage it by "Good Samaritan" laws (which exempt doctors from liability for negligence) and other means. A plea for compensation of rescurers is made by Gregory, "The Good Samaritan and the Bad: The Anglo American Law", Radcliffe, ed., *The Good Samaritan and the Law* (1966) 23 at 38.

[109]*Supra*, at 313.

[110]Dworkin, *supra*, footnote 2 at 165.

[111]*Supra*, footnote 51.

[112]*Suffer the Children, supra*, footnote 1, ch. 14.

One way out of this dilemma is to argue that the proposed change is a politically ripe part of an evolving pattern that over the long haul is headed toward consistency. In short, when public and official attention is focussed on a specific class of injuries, the opportunity should be grasped for reform, even if it is only part of the package eventually desired.[113] This argument apparently assumes that the ultimate objective is a series of special compensation schemes that together cover most or all accident victims. Alternatively, the incremental accumulation of special plans might be seen as a halfway station on the way to a single comprehensive plan. The first prognosis could find support in the progressive evolution of tort-replacement in Sweden.[114] The second seems to have been the lodestar of the Pearson Commission in England.[115] But there is no similar target even dimly evident in other countries like Japan, Germany, or the United States, which on occasion have adopted isolated special plans "where the shoe pinched most".

On the other hand, there are those strenuously criticize special plans, not only for the horizontal inequity they entail, but for diverting efforts from enacting a system of comprehensive social insurance. Accident victims, in their view, present the same social concern as do the disabled generally; indeed their need is much the same as that of the retired, the unemployed, even the poor. For this set of critics, therefore, the basic reform strategy lies in reforming the social security system.[116] But pessimism about the public prospects of such a retorm has caused some reformers to narrow their focus. A first line of retreat would be to limit compensation to the disabled, to the exclusion of the unemployed, retired, *etc.*, but including victims of accident and disease, as recommended in 1974 by the Woodhouse Commission for Australia.[117] More practical, however, is to retreat one more step and focus on accidents alone, like the New Zealand scheme which came into force in 1974[118] on the recommendation of the celebrated original Woodhouse Report (1968).[119] The principal attractions of this more modest program include: (1) a sense by its supporters that accident victims (or

[113]Hellner, "Social Insurance and Tort Liability in Sweden", (1972) 16 *Scand. St. L.* 187, 194-7.

[114]*Supra*, footnote 22.

[115]See especially *Report* I, ch.11; *supra*, footnote 54. Even the New Zealand development (*supra*, footnote 87) was progressive, since the scheme as originally enacted in 1972 excluded non-earners except with respect to motor accidents. The exclusion was eliminated in 1974, the cost being borne by a supplementary fund: in 1978/9 13% of total claims and 11.2% of total costs were attributable to this category.

[116]This group has been particularly vocal in Great Britain in criticism of the *Pearson Report*. See e.g. Allan, Bourn and Holyoak, *supra*, footnote 2; Ogus Corfield & Harris, "Pearson: Principled Reform or Political Compromise", (1978) 7 *Indust. L.J.* 143; Ison, "The Politics of Reform", (1977) 27 *U. Tor. L.J.* 385; Lewis, "No-Fault Compensation for Victims of Road Accidents: Can it be Justified?", (1981) 10 *J. Soc. Pol.* 161; Lewis, "Tort and Social Security. The Importance Attached to the Cause of Disability", (1980) 43 *Mod. L. Rev.* 514 deploring the recommendation to retain the industrial injury preference.

[117]Report of the National Committee of Inquiry, *Compensation and Rehabilitation in Australia*.

[118]*Supra*, footnote 92.

[119]Report of the Royal Commission of Inquiry, *Compensation for Personal Injury in New Zealand* (1968).

perhaps the disabled generally) are specially deserving as compared with others; (2) a political judgment that this package is more saleable (injury is the cause of incapacity in at most 10% of cases[120]); and (3) a conviction that the most urgent need and most practical first step is to replace the tort system and, essentially, extend workers' compensation coverage around the clock.[121] Rather than get into the deeper waters of national medical care and income maintenance for all, the New Zealand approach stays within the general scope of experience with accidents.[122]

The advantages of such broad-based schemes are several. Perhaps most important is that they finally shed all vestiges of concern with the source of the victim's accident, in contrast to special plans whose limited coverage still compels inquiry into the precise nature of the accident, not dissimilar to the tort system's inquiry into fault and causal responsibility. They therefore promise relatively few "boundary" issues. Bitter experience with workers' compensation testifies to the persistent problem of determining whether a given injury was suffered as a result of an "accident arising out of and in the course of employment" rather than some extraneous cause. Compensation plans for medical injury have foundered on the difficulty of devising administratively workable tests for excluding claimants whose worsening condition was due merely to the unavoidable progression of disease.[123] That the dividing line between accident and illness is particularly perplexing in the area of medical treatment also emerges from the brief New Zealand experience.[124] It likewise affects the scope of defining the coverage of drug compensation plans.[125] If general compensation plans largely avoid such inquiries, they offer administrative saving which can sharply reduce overhead costs.

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[120]Of these 10% occur on the road, 25% at work and the remainder elsewhere ("bathtubs") according to the *Pearson Report* II, t. 2 & 4.

[121]Extension of workers' compensation to 24 hours coverage for employees was advocated by R. Henderson, "Should Workers' Compensation be Extended to Non-Occupational Injuries", (1969) 48 *Tex. L. Rev.* 117. In 1978, 76% of all accidental deaths and 59% of injuries occurred off the job (National Safety Council, *Accident Facts* (1979) 25). Bernzweig, *supra*, footnote 99, makes the case for comprehensive injury reparation against the background of the present very inadequate social security.

[122]Not that the exclusion of disability from sickness has passed without criticism or resentment. Why, it is asked, should one who has suffered an accident through his own fault, perhaps even a criminal act, fare better than one who is stricken by a crippling disease? Palmer, *supra*, footnote 90, ch. XIX, and Ison, *supra*, footnote 90, ch. 2, both argue in favor of extending the scheme to include diseases or at least upgrading sickness benefits under social security.

[123]The *Pearson Report* I § 1348 ff. rejected a no-fault plan for all medical injury on this ground. The problem is explored by R. Keeton, "Compensation for Medical Accidents", (1973) 121 *U. Pa. L. Rev.* 590; Havighurst, "Medical Adversity Insurance: Has its Time Come?", (1975) *Duke L.J.* 1233.

[124]"Medical Mishap" is specifically included in the definition of "accident." See *e.g.*, Hughes, "Accident Compensation and Childbirth", (1981) *N.Z.L.J.* 79; Osborne, "Informed Consent to Medical Treatment and the Accident Compensation Act 1972", (1979) *N.Z.L.J.* 198. The difficulty of attributing birth defects to medical mishaps led the Australian Commission, *supra*, footnote 114, to recommend the inclusion of all "congenital defects" in the Australian scheme: Luntz, *Compensation and Rehabilitation*, (1975) 49.

[125]*E.g.* should it cover misprescription by physicians? See *supra*, footnote 33.

Special plans are sometimes claimed to be preferable to general compensation plans because they concentrate the cost of accidents on the sources that ought to bear them. This cost internalization is then said to promote social values we have already canvassed: stimulating safety, achieving the optimum amount of accident-causing activity and serving justice by making those pay who benefit from the activity. But as already pointed out, it is very doubtful that most special plans can effectively further these goals in a world such as ours where regulatory regimes, market pressures, and market imperfections largely obliterate whatever marginal impact such a plan might otherwise have had on safety and general allocative efficiency. Besides, the financing mechanisms of general accident compensation plan could be used to promote the same objectives.[126] Some plans envisage that charges be levied on particular accident-causing activities, and over time the agency in charge presumably could refine its targeting in both sensible and fair ways. Such a general plan would then begin to look very much like a fully integrated and complete series of separate plans, in genuine contrast to one that simply looked to payroll tax for its financing. The lesson here is that financing arrangements are a vital aspect of this debate.

CONCLUSION

Special compensation plans for drug injuries have been the result of strong public emotion over specific calamities like the thalidomide tragedy, rather than expressions of a comprehensive public policy program for disability compensation. Indeed the credentials for singling out these unfortunates for preferential treatment are hardly impressive. It is at best arguable that the traditional tort regime, especially the negligence doctrine, suffers from more than average defects in its application to drug injuries because of difficulties over causation, access to evidence, the exclusion of development risks. More debatable still is whether such a reform would appreciably advance the cause of accident prevention or the efficient allocation of resources. Its most troublesome aspect, is how to justify preferential treatment to victims of drug injuries over other, somewhat similarly situated victims of accident or disease.

From a compensatory point of view, the traditional tort system is most vulnerable to criticism for conditioning compensation on the fault of the injurer rather than the merits of the victim. But while special compensation

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[126]See Craig, "Deterrence and Accident Compensation", (1978) 17 *U.W. Ont. L. Rev.* 111. In New Zealand, for example, the Motor Vehicle fund is administered and financed separately from the Earners' Fund. In other respects, howeveer, the New Zealand planners have evinced little faith in the efficacy of financial deterrents. Thus contributions to the Motor Vehicle fund are at a flat rate and even levies on employers for the Earners' Fund (principally for industrial accidents) ignore experience rating: Ison, *supra*, footnote 90 at 127-34. This skeptical attitude is also shared by and large in Britain: see *e.g.*, Atiyah, "Accident Prevention and Variable Premium Rates for Work-Connected Accidents", (1975) 4 *Indus. L.J.* 1, 89. However, Berkowitz, an American economist advocates variable rates: *The Economics of Work Accidents in New Zealand* (1979).

plans eliminate this horizontal inequity, they create a new one by confining their preferential treatment to victims of a specific cause, in this instance to victims of drugs alone. Advocates of comprehensive accident compensation must therefore view special plans for drug victims, as for any other limited category of claimants, with mixed enthusiasm.