Products Liability in the Pharmaceutical Industry at Common Law

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Introduction

Discussion of the shortcomings of the common law action for negligence in England — as in the Commonwealth generally — has been overwhelmingly concerned with injuries arising out of employment and road accidents. Products liability, in the sense of a manufacturer's strict liability to the consumer for defective goods, has received scant treatment.[1] The citadel of privity may have been taken by storm in America;[2] the Englishman's castle seemingly survives intact.

However, whether the narrow conceptualism which denies the consumer a right of action against the manufacturer in the absence of negligence or contract will hold sway for much longer is seriously in doubt. Law reformers in England are at last beginning to focus attention on the implications of a products liability approach for these matters. The Law Commission is currently examining the subject[3] and a Royal Commission established in 1972 to investigate the whole field of civil liability and compensation for personal injury includes in its terms of reference "death or personal injury (including ante-natal injury) suffered ... through the manufacture, supply or use of goods or services".[4]

Undoubtedly one major precipitating influence has been the thalidomide disaster, which, because of its catastrophic dimensions and much-publicised protracted negotiations, has generated discussion of key issues bearing on products liability. A private member's Bill was introduced in Parliament in 1972[5] specifically to impose

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1 See Legh-Jones, *Products Liability: Consumer Protection in America,* (1969) 27 Camb. L.J. 54; Jolowicz, *The Protection of the Consumer and Purchaser of Goods under English Law,* (1969) 32 M.L.R. 1; Pasley, *The Protection of the Purchaser and Consumer under the Law of the U.S.A.,* (1969) 32 M.L.R. 241.

2 Prosser, *The Assault upon the Citadel,* (1960) 69 Yale L.J. 1099 and Prosser, *The Fall of the Citadel,* (1966) 50 Minn.L.Rev. 791.

3 See the Law Commission: Seventh Annual Report (1971-72), H.M.S.O., 14, para. 60.

4 The Pearson Commission. See H.C. Deb., Vol. 84, col. 1119-20, Dec. 19, 1972.

5 Dangerous Drugs and Disabled Children Bill, first reading, Nov. 29, 1972.

strict liability on the manufacturer of an unsafe drug, expressed to be retroactive and to cover ante-natal injuries. Because of reservations voiced about possible anomalies in piecemeal legislation responding to a particular situation and in view of the subsequent course of the negotiations, the Bill was withdrawn. It will, however, be suggested that in several respects the thalidomide tragedy provides an unusually compelling demonstration of the potential benefits of applying a products liability test to the pharmaceutical industry.

Important underlying reasons for a reappraisal of the basis of liability in this area are the steady erosion of fault liability elsewhere in the common law world, reflecting mounting dissatisfaction with the negligence action in general, and a parallel shift towards greater consumer protection. The unwonted eagerness with which English appellate courts are now articulating policies hitherto masked by the all-purpose criterion of reasonable foreseeability has exposed the artificiality and inherent contradictions of the negligence action, while encouraging a more realistic attitude towards the role of insurance.[6]

At the same time, "consumer law" is emerging as an area of study in its own right, gradually being freed from that total identification with the world of commercial contracts which has sustained an unreal formal framework. The statutory recognition of the "consumer" in the *Supply of Goods (Implied Terms) Act*, 1973,[7] which makes exclusion clauses in "consumer sales" void, and in the *Fair Trading Act*, 1973,[8] which will enable the Director-General of Fair

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[6] See, *e.g.*, Symmons, *The Duty of Care in Negligence: Recently Expressed Policy Elements*, (1971) 34 M.L.R. 394, 528; *Morris* v. *Ford Motor Co. Ltd.*, [1973] 2 All E.R. 1084, 1088; [1973] 2 W.L.R. 843, 846 *per* Lord Denning,M.R. The House of Lords rejected this approach in *Morgans* v. *Launchbury*, [1973] A.C. 127; [1972] 2 All E.R. 606 (H.L.).

[7] S.4(7) provides that:

> In this section "consumer sale" means a sale of goods (other than a sale by auction or by competitive tender) by a seller in the course of a business where the goods —
> (a) are of a type ordinarily bought for private use or consumption; and
> (b) are sold to a person who does not buy or hold himself out as buying them in the course of a business.

[8] S.137(2) states that:

> ..."consumer"...means any person who is either —
> (a) A person to whom goods are or are sought to be supplied (whether by way of sale or otherwise) in the course of a business carried on by the person supplying or seeking to supply them, or
> (b) a person for whom services are or are sought to be supplied in the course of a business carried on by the person supplying or seeking to supply them, and who does not receive or seek to receive the goods or services in the course of a business carried on by him....

Trading to take injunctive action against manufacturers who consistently produce shoddy goods, exemplify the first stages of a program designed to transform this area of the law.

This recognition of an imbalance in bargaining power, coupled with rising consumer expectations, reinforces the protection provided by the *Misrepresentation Act*, 1967 and the *Trade Descriptions Act*, 1968, which went some way towards diminishing the purchaser's vulnerability in the face of sophisticated marketing techniques. In addition to these legislative developments, the judicial creation of liability for negligent mis-statement in *Hedley Byrne* v. *Heller*,[9] with its implicit revival of non-contractual warranty, has provided an as yet untapped source for strengthening the position of the consumer. Our purpose is to examine the application of these trends to products liability, with particular reference to prescription drugs.[10]

Products Liability in America

The development of products liability in America has been fully documented.[11] Though its details need not detain us, the routes which have been followed and the emerging rationales contain invaluable lessons for any common law country embarking on a similar venture. We are fortunate in being able to draw on their experience in three different lines of approach: raising the standard of care imposed on the manufacturer in negligence; providing an action in breach of warranty; and finally developing a strict liability doctrine in tort.

The judicial development of negligence in America, as in other common law jurisdictions, has gone some way towards meeting those critics who advocate a more comprehensive products liability system. It is often claimed that the combination of higher standards of care imposed on manufacturers and the doctrine of *res ipsa loquitur* obviate the supposed need for reform. But this assertion is surely unduly complacent, partly because the precise effect of *res ipsa loquitur* remains unclear, but also because the litigation or bargaining process may be profoundly influenced by the need to prove negligence. Even if the onus of proof is shifted to the defend-

[9] [1964] A.C. 465; [1963] 2 All E.R. 575. See also Stevens, *Hedley Byrne* v. *Heller: Judicial Creativity and Doctrinal Possibility*, (1964) 27 M.L.R. 121, 160: "[*Hedley Byrne*] may herald a whole new area of protection for the consumer."

[10] Also known as ethical drugs, *i.e.*, drugs not advertised directly to the public.

[11] See articles cited in f.n.1 and f.n.2, and also Kessler, *Products Liability*, (1967) 76 Yale L.J. 887. The American literature is voluminous. In relation to drugs, see especially Rheingold, *Products Liability — The Ethical Drug Manufacturer's Liability*, (1964) 18 Rutgers L.Rev. 947.

ant, considerations of cost and delay will dissuade many claimants from pursuing an action. Nor, in any event, does it seem particularly healthy for the law to perpetuate as the basis of liability a system out of touch with reasonable consumer demands and the economics of modern marketing methods.

Breach of warranty has been a more fruitful source of development. There is a wealth of case law, reinforced by section 2-318 of the Uniform Commercial Code and similar legislative provisions, imposing liability on manufacturers for breach of express or implied warranty in the absence of privity and in the face of purported disclaimers.

Yet however beneficial this approach may have been in particular cases, because it was rooted in contract, inconsistencies and fictitious elements emerged. If it entails classifying the supplier as a fictional agent of the manufacturer or consumer, requiring the consumer to give notice and indulging in over-elaborate argument on the precise ambit of exclusion clauses, it is not easy to see the merit of asserting even an attenuated contractual nexus between manufacturer and consumer. This is especially the case when there are strong historical grounds for the belief that the breach of warranty concept was tortious in origin.[12] To adopt the same model would be to invite the same consequences, with predictably more unfortunate results in England, where traditionally there has been a marked opposition to loosening the hold of privity.

It is certainly unsatisfactory to stress contractual elements in the context of prescription drugs (at least where a *Sale of Goods Act* model is relied on) since under the National Health Service there is no technical "sale" to the patient, even where he pays a nominal sum for the prescription.[13] The same problem is posed by free hospital treatment, free drug samples and public vaccination programs. In these situations recourse must be had to the device of relying on the initial sale of the drug.[14]

It was due to such theoretical weaknesses that a strict liability in tort theory eventually emerged. In three cases in 1913-14[15] concern-

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[12] See Stevens, f.n.9, *supra*, 162.

[13] *Pfizer Corp.* v. *Minister of Health*, [1965] A.C. 512; [1965] 1 All E.R. 450 (H.L.).

[14] *Cf.* the American cases on blood transfusions, where liability was originally denied because there was no sale, *e.g.*, *Perlmutter* v. *Beth David Hospital*, 123 N.E. 2d 792 (1954). But see now *Cunningham* v. *MacNeal Memorial Hospital*, 47 Ill. 2d 443; 266 N.E. 2d 897 (1970).

[15] *Mazetti* v. *Armour & Co.*, 75 Wash. 622; 135 P. 633 (1913); *Parks* v. *G.C. Yost Pie Co.*, 93 Kan. 334; 144 P. 202 (1914); *Jackson Coca Cola Bottling Co.* v. *Chapman*, 106 Miss. 864, 869; 64 S. 791 (1914).

ing impure and adulterated food and drink, manufacturers were held liable on broad grounds of public policy. The famous *Henningsen* decision [16] in 1960, ostensibly based on breach of warranty, effectively relied on changes in marketing techniques to justify strict liability for all products, and was soon followed by a clear statement of strict tort theory in *Greenman* v. *Yuba Power Products Inc.*[17] A few years later, in 1965, the Second Restatement of Torts [18] made far-reaching provision for strict liability in respect of "unreasonably dangerous" products. By 1971, approximately 30 States subscribed to strict liability for manufacturers in general.[19]

A tort framework has several advantages. It minimizes uncertainty on whether a court will adopt a liberal or restrictive attitude towards non-contracting claimants, and disposes of the requirement of sale. It also makes it easier to ignore exclusion clauses, on the basis that they are contractual terms which should protect the defendant only in the context of contractual liability.[20] Perhaps above all, it acts as a reminder that the principles governing liability for personal injury in a sphere where the parties are not at arms length should not be unthinkingly identified with those which regulate commercial loss, particularly at the very time when, as indicated above, consumer law is freeing itself from such identification.[21]

The Current Position in English Law

How far does existing English law fall short of a strict liability system?[22] The consumer will not normally be in a position to sue the manufacturer in contract, and third party proceedings are acknowledged to be inefficient and costly, if not ruled out altogether because of the insolvency of an intermediary or lack of jurisdiction. A collateral contract has occasionally been invoked,

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[16] *Henningsen* v. *Bloomfield Motors Inc.*, 32 N.J. 358; 161 A. 2d 69 (1960).

[17] 59 C. 2d 57; 377 P. 2d 897; 27 Cal. Rep. 697.

[18] Section 402A.

[19] Noel, *Strict Products Liability Compared with No-Fault Automobile Accident Reparations*, (1971) 38 Tenn.L.Rev. 297-98, n.4.

[20] See, *e.g.*, *Vandermark* v. *Ford Motor Co.*, 61 C. 2d 256; 37 Cal.Rep. 896 (1964); and Legh-Jones, f.n.1 *supra*, 73.

[21] Compare the Report of the Ontario Law Reform Commission on Consumer Warranties and Guarantees in the Sale of Goods (1972), where an implied warranty approach is advocated which would lead to "a substantial narrowing of the gap between Ontario and American products liability law". Ziegel, (1973) 22 I.C.L.Q. 363, 364.

[22] See Atiyah, *The Sale of Goods* 4th ed. (1971), chap. 13.

most notably in *Wells* v. *Buckland Sand and Silica Co.*,[23] but this has never been envisaged as encompassing widespread manufacturer liability. The *Wells* case itself rested on an express warranty given to the purchaser by the manufacturer: "It clearly emerges as being quite fortuitous that ... the defendants did not themselves sell direct to the plaintiff."[24] Moreover, collateral contracts and third party proceedings are confined to plaintiffs who have bought the product in question, thus retaining the disadvantages of contractual solutions as outlined above.

If the contractual routes are unsatisfactory, is it nonetheless possible to maintain that the existing law of negligence is adequate to cater to the consumer's legitimate demands? The argument runs as follows.[25] In a negligence action you must prove three things: that the product was defective; that the defect was present when the product left the manufacturer's premises; and that its defective nature was due to the negligence of the manufacturer. The first two requirements would have to be proven even under a products liability system; the third — negligence — is, it is said, largely satisfied nowadays by the readiness of the courts to apply the doctrine of *res ipsa loquitur* in manufacturer/consumer disputes.

Unfortunately, however, the fault concept is still so deeply entrenched that even in cases where it appears on the facts to have been abandoned, as in *Grant* v. *Australian Knitting Mills, Ltd.*[26] and *Mason* v. *Williams & Williams, Ltd.*,[27] the decisions have been explained in accordance with orthodox negligence theory, and the applicability of *res ipsa loquitur* has been denied. Further, the effect of that doctrine in the English case law is far from settled.[28] Often

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[23] [1965] 2 Q.B. 170; [1964] 1 All E.R. 41.

[24] *Ibid.*, at 177 and 43 respectively.

[25] See Prosser, *The Assault upon the Citadel, supra*, 1114-1119.

[26] [1936] A.C. 85; [1935] All E.R. 209.

[27] [1955] 1 All E.R. 808; [1955] 1 W.L.R. 549.

[28] See Street, *The Law of Torts* 5th ed. (1972), 138.

The effect of *res ipsa loquitur* in Canadian law is not fully settled, but the weight of opinion leads to the conclusion that once its requirements are met, the plaintiff has succeeded, if only temporarily, in satisfying the onus of proof. The defendant then will have to respond or lose his case: *Temple* v. *Terrace Transfer Ltd.* (1966), 57 D.L.R. (2d) 631 (B.C. C.A.). However, it does not seem that the defendant has the "onus of disproof". Rather, the prevailing view is that he may satisfy the onus now resting on him with a mere explanation, consistent with the facts, of how the damage could have occurred without his negligence: *Temple* v. *Terrace Transfer Ltd.*

There are cases which have shifted the burden of proof more forcefully to the defendant. Thus in *Zeppa* v. *Coca-Cola*, [1955] O.R. 855 (Ont. C.A.) it

the courts maintain that it is not a distinct rule of law shifting the legal onus of proof onto the defendant, but merely permits an inference of negligence.[29]

However, in two recent House of Lords decisions, *Henderson* v. *Henry E. Jenkins & Sons* and *Colvilles, Ltd.* v. *Devine*, the onus was in effect shifted.[30] As long as any doubt remains concerning the full force of the doctrine, the most that can be said is that the courts *may* interpret it in a manner which places a heavy burden on the defendant. But even if they were to do this consistently, it would not remove a most serious impediment to an acceptable solution of any technically complex case in which negligence was in issue, namely, the ability of a powerful defendant to compel settlement on terms unfavourable to a plaintiff who cannot take the risks or endure the delay which *any* investigation of that issue might involve.

As Tobin put it:

> Our courts have not yet faced the difficult issues that are raised for instance by prescription drugs. When they do, it is submitted that it will be preferable to approach the question of the extent of manufacturer liability in terms of the social and economic reasons for holding product makers liable rather than in terms of "fault" alone.[31]

As long as a negligence framework is retained, many judges will inevitably approach consumer claims against manufacturers with a notion of individual fault uppermost in their minds.

The Choice of Rationales

Apart from specific criticisms of the negligence action, perhaps the three grounds most commonly cited in favour of a products liability approach are deterrence, the moral responsibility of the manufacturer and rational risk allocation. The deterrent argument is in essence the popular notion that the stricter the liability to

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was held that *res ipsa loquitur* had the effect of placing a burden on the defendant to actively disprove negligence. From the point of view of the consumer, this is an encouraging note, since it would clearly aid the consumer-plaintiff in actions against manufacturers. However, this case represents an exceptional departure from the more established rule in *Temple* v. *Terrace Transfer Ltd.*

[29] *Lloyde* v. *West Midlands Gas Board*, [1971] 2 All E.R. 1240; [1971] 1 W.L.R. 749.

[30] *Henderson* v. *Henry E. Jenkins & Sons*, [1970] A.C. 282; [1969] 3 All E.R. 756; *Colvilles, Ltd.* v. *Devine*, [1969] 2 All E.R. 53; [1969] 1 W.L.R. 475. See Atiyah, *Res Ipsa Loquitur in England and Australia*, (1972) 35 M.L.R. 337, 340-344.

[31] Tobin, *Products Liability: A United States/Commonwealth Comparative Survey*, (1969) 3 N.Z.L.R. 377, 401-402.

which he is subject, the more care the manufacturer will take to see that his production methods are safe. Moral responsibility primarily connotes his obligation to stand behind products which through advertising are aimed at consumers as a class. It is also implicit to some extent in the "hazardous enterprise" theory: "these *liabilities are the price which must be paid to society for the permission of a hazardous activity*".[32] On yet another level, it is the corollary of making profits under a free enterprise system.

The other major approach centres on a more clinical search for rational risk distribution.[33] Nice questions of allocation of responsibility are overriden. Accident losses are deemed an inevitable price of doing business and the manufacturer is normally able to calculate the risks more efficiently than the potential victim. Liability insurance and costing are brought out into the open, instead of being concealed within an apparently fault-based system.

However, the very process of labelling and separating these various justifications is quite artificial. It understates the essentially pragmatic way in which many cases are decided and may convey an impression of mutually exclusive or necessarily competing explanations. The outcome of particular cases may owe something to the emphasis placed on particular rationales, but one should not lose sight of the extent to which they reinforce one another. Public policy, moral obligation and risk distribution were all explicitly put forward as justifications in *Escola* v. *Coca Cola Bottling Co.*[34] In so far as products liability arguably provides a stimulus to safety in manufacture, however minimal, it can only add force to this argument.

Products Liability and the Pharmaceutical Industry

Assuming that legal deterrence in the pharmaceutical industry is felt by manufacturers, a change from a negligence to a products liability system would hardly be more inhibiting to them. Both systems are in practice underpinned by insurance. The first line of attack would surely be more stringent governmental requirements prior to marketing. Such controls are most notably evident in the United States' Federal Drug Authority regulations.[35] Britain, which

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[32] Ehrenzweig, *Negligence Without Fault* (1951), 54.

[33] No attempt has been made here to illustrate the range and complexity of risk distribution theory. For a recent analysis see, *e.g.*, Calabresi & Hirschoff, *Towards a Test for Strict Liability in Torts*, (1972) 81 Yale L.J. 1055, 1071.

[34] 24 C. 2d 453, 461-462; 150 P. 2d 436, 440-441 (1944) *per* Traynor,J.

[35] The American regulations are arguably too inflexible. Under the Food Additives Amendments 1958 (as amended) — responsible for the ban on

in the past relied on a voluntary system, has now introduced a measure of compulsion.[36] Safety procedures in most countries have been tightened up considerably since the thalidomide disaster.[37]

More generally, however, there is a familiar and more plausible explanation of safety levels than the fear of civil actions, or indeed of any legal intervention. Just as one drives safely in order to stay alive, so a company's degree of care in production methods is largely dictated by its wish to survive and create goodwill, and as such is governed by the ordinary controls implicit in running an effective business.[38]

A more convincing case for products liability can be made out on grounds of moral obligation and risk distribution. But here also their detailed application raises serious difficulties. In the case of prescription drugs, the consumer/patient is to a large extent relying on the middleman/doctor, for a product not directly advertised to the public. This necessarily complicates the issue if one is emphasizing responsibility for marketing the product. A comparable problem is posed when a drug manufacturer abroad grants a licence for the distribution of a compound containing its product, yet retains a measure of control over the sales promotion techniques employed. This, in fact, was how thalidomide was distributed in several countries.

If, on the other hand, one adopts a resource allocation model and takes as a starting point the proposition that for maximum efficiency the pharmaceutical industry should pay its own accident losses, several key issues are left in the air. What products are involved? If we confine strict liability to drugs, how do we define "drug"? If we extend liability to pharmaceutical products in general, is it feasible to work out a rational domestic form of risk distribution when dealing with huge, multi-national, highly diversified concerns, which can vary their production and marketing methods

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cyclamates in 1969 — any substance found to be carcinogenic in animals is prohibited. Hence saccharin, used for nearly 100 years without the slightest evidence that it is cancer-producing in man, is in danger of being taken off the market, regardless of the potentially more harmful consequences of increased sugar consumption.

[36] *Medicines Act*, (1968) 16 & 17 Eliz. II, c.67.

[37] In Canada, increased concern is reflected in the Federal Government's QUAD (Quality Assessment of Drugs) Program. See *Comments on Drug Quality and the Quad Program*, Hon. Marc Lalonde, Minister of National Health and Welfare, 13 March 1973 (News Release).

[38] This does not rule out fear of the possible impact of civil liability on trading reputation as *one* motivating factor. See Linden, *Tort Law as Ombudsman*, (1973) 51 Can. Bar Rev. 155.

so as to take advantage of national tax laws which are most favourable to them?

Even those American States which have gone "all the way" with products liability have encountered intractable problems with drugs. It is true that the historical progression from impure and adulterated food and drink to animal food to products for external bodily use would suggest that drugs and medicines have strong claims if an order of priority were to be drawn up for strict liability treatment. But this does not allow for the special market structure of the industry, the unique method of distribution in the case of ethical drugs and the complex nature of the products and their effects. Even the simplest drug transaction is apt to involve problems of causation which far outweigh the difficulty of deciding whether the plaintiff lost his finger because of a faulty machine.

What bearing does the economic structure of the pharmaceutical industry have on the degree of liability to which it should be subject? The plea is occasionally heard that this is an industry working uniquely for the benefit of mankind, as selfless dedicated healers, and as such must not be discouraged from carrying out its creative rôle by harsher laws. But antibiotics are not discovered every day and the bread and butter, routine work involves slight changes to established formulae, the end product being just sufficiently dissimilar to obtain a patent — the "close copy" products born of molecular roulette. Indeed, to the extent that consumers are being wooed with promises of "instant relief", the process is more insidiously commercial than many other industries.

Intense commercial pressures operate at every stage of marketing a drug. Patent life under English law lasts for sixteen years,[39] but in practice profitable patent life is no longer than ten or twelve years, since much time may be absorbed in developing the product — pharmacological and toxicity testing, clinical trials and registration — and the final years are undermined by competitive developments which force the price down shortly before the patent expires. On the other hand, the goodwill created by strong brand promotion lives on, especially if the product has enjoyed a near monopoly of the market.

Producing a genuinely new drug, as distinct from a close copy product, requires a vast initial outlay, recently estimated at £3 to £4 million in the United Kingdom and at £6 to £9 million in the United States.[40] Only one in approximately five thousand compounds

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[39] *Patents and Drugs Act*, (1949) 12 & 13 Geo. VI, c.62, s.22(3).

[40] See Beckett, "The cost of safety in medicines" in Teeling-Smith (ed.), *The Pharmaceutical Industry and Society* (1972), 19.

tested will ultimately find its way on to the market. There is then an immense pressure to produce one's product first and a psychological as well as commercial drive to market it rather than abandon costly research, reinforced by a resistance to removing it from the market until *conclusive* evidence of harm has been provided. It is therefore hardly surprising that the promotional element looms large in the manufacture of drugs.[41]

The profit ratio of pharmaceutical products is very high in comparison with industry in general and with other parts of the chemical industry in particular.[42] To what extent such profits are necessary to recoup past research and development expenditure and to provide adequately for future innovation is the central issue in the current litigation between the British Government and Hoffmann-La Roche.[43] Certainly there seems to be little evidence of a direct relationship between successful innovation and specific levels of research and development spending. Britain's efficiency record has recently been calculated as two and one half times that of the United States, proportionate to the amount invested in pharmaceutical research.[44]

Indeed beyond a certain level research expenditure could unjustifiably prejudice existing patents for the sake of speculative future gains. We simply do not have an objective basis for deciding proper pricing and research funding criteria for pharmaceuticals,[45] and in practice we lack the financial data to make an adequate evaluation when dealing with diversified, multi-national companies.

The Hoffmann-La Roche litigation provides a classic illustration of these difficulties. The concern is the largest pharmaceutical dealer in the world, with a controlling centre in Switzerland and subsidiaries in many countries, including Canada, England and the United States. The company has a well-earned reputation for

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[41] Total expenditure on sales promotion of National Health Service prescription drugs in the United Kingdom for 1965 was calculated as 13.9 per cent of total sales: Report of the Committee of Enquiry into the Relationship of the Pharmaceutical Industry with the National Health Service, 1963-65 (the "Sainsbury Report"), H.M.S.O. (1967).

[42] In 1968-69 it was 8 to 10 per cent above the "total industries" average in the *Financial Times*' "Trend of Industrial Profits" table, and 12 per cent above the corresponding figure for the chemical industry as a whole.

[43] See *Department of Trade and Industry* v. *F. Hoffmann-La Roche and Co. A.G. and Ors., The Times,* 14 July 1973; *F. Hoffmann-La Roche and Co. A.G. and Ors.* v. *Secretary of State for Trade and Industry, The Times,* 31 July 1973.

[44] *Innovative activity in the pharmaceutical industry,* a Report by the Pharmaceuticals Working Party of the Chemicals EDC, H.M.S.O., 1973, 4, 25.

[45] Vaizey, in preface to *The Pharmaceutical Industry and Society,* see f.n. 40, *supra.*

innovation, quality of research and safety of its products. Its discovery some ten years ago of new sedatives — *Librium* and *Valium* — meant that doctors no longer felt compelled to prescribe barbiturates which have potentially more harmful side-effects.

When the Government was concerned at the price the company was charging for these tranquillizers, an investigation by the Monopolies Commission[46] revealed profits on sales of up to 60 per cent and rates of return on capital of over 70 per cent. Thus a highly-regarded company with a virtual monopoly of the market[47] and protected by patents[48] was subject to little or no direct consumer pressure on prices. At the same time it was able to maximize profits by adjusting its operations to take account of differing national taxation systems.

The Government ordered[49] the company to reduce the price of *Valium* to "not more than 25 per cent of the selling prices in 1970" (not more than 40 per cent in the case of *Librium*) and to repay alleged excessive profits. The company, which has appealed against the Order,[50] maintains that the Government's policy will stifle initiative at a time when research and development are becoming prohibitively expensive. Whatever its merits in this case, it is submitted that this argument is unconvincing as a general proposition. On-going research is of the essence of a pharmaceutical company's activities. Even when no specific breakthrough results, goodwill which helps the company to negotiate licences is maintained, and the continued production of close copy drugs is facilitated.

The overall picture of the pharmaceutical industry is therefore one of high profitability. The increasing costs of marketing and of research and development inhibit the entry of new companies into the market, and one might reasonably anticipate more and more concentration of resources among huge international concerns. Most companies would seem to be in a position to adjust relatively painlessly to a strict liability system (as the American ones already have) and insure for all but the most catastrophic of losses. Nor

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[46] *Chlordiazepoxide and Diazepam*, H.M.S.O., 1973.

[47] Approx. 99 per cent, *ibid.*, 57, para. 194.

[48] Its hold on the market was reinforced by the free distribution of *Librium* and *Valium* to hospitals and the armed forces, making their continued prescription highly probable.

[49] The Regulation of Prices (Tranquilising Drugs) Order, 12 April 1973, renewed on 18 May 1973 and 21 June 1973.

[50] *The Times*, 31 July 1973. See f.n.43, *supra*.

would the marginal increase in cost to the consumer, who in England spends on the average about one penny a day on National Health Service medicines, prove unduly burdensome.

Admittedly there is a problem when one considers new drugs with a potential for causing catastrophic loss. The actuarial process operates by reference to the past. It may be prohibitively expensive to insure against some drug risks if in fact they are insurable at all. This difficulty and its implications will be considered when assessing the outcome of the thalidomide negotiations.[51]

The special method of distribution of prescription drugs is another distinctive feature of the industry. One might in the abstract expect a drug manufacturer to be subject to strict legal control because of the intrinsic dangers of his products and the above average vulnerability of his clientele.[52] Is this argument substantially affected by the role of the doctor? He is not a mere conduit in the chain of supply, but has an independent, professional duty to evaluate. Even if the exigencies of general practice tend to make prescribing a rather mechanical process, there is still much greater reliance on the "seller" than is the case with most goods. Nor should a doctor be allowed to exculpate himself entirely by claiming that he prescribed on the basis of a company's misleading promotional material, for that is to abdicate his responsibility. In fact most doctors probably place more reliance on discussions with professional colleagues than on any other source as a guide to prescribing, although promotional material and medical sales representatives must exercise some influence.

Since it is the doctor who primarily determines which pills the patient consumes, the marketing of prescription drugs also appears to lack the important feature, from a moral obligation standpoint, of direct advertising to the public. But one cannot divorce a company's reputation as an ethical drug manufacturer from its general reputation, if doctors are to continue prescribing its products. The general motive of fostering reliance to increase sales remains.

Perhaps the most intractable problems which any system of liability for drug-induced injury must face relate to causation. Typically, drugs are taken by people who are already ill and often unusually susceptible to further ailments. Unlike many other products, they may cause injury in unpredictable ways, depending on the user's individual constitution. He may be allergic to a particular drug. On the other hand, what appears to be an allergy may in

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[51] At pp. 121-22.

[52] This also, of course, implies a high standard of care in negligence.

fact be a toxic reaction. Presumably a balance must be struck between a defence for the manufacturer based on allergy and the conflicting tort principle that you must take your victim as you find him.

Further difficulties stem from the ways in which drugs are taken. The synergistic effects of certain combinations (for example, barbiturates and alcohol, anti-histamines and cheese) may prove fatal. Harmful self-administration may take several forms, such as overdosage, unduly prolonged use, failure to inform one's doctor of a previous medical condition or taking drugs stored in medicine cupboards long after there has been publicity about their potential danger.

Even when properly administered, many drugs will have possibly harmful side-effects but be deemed medically acceptable because on balance their use is beneficial. This peculiarity raises a problem concerning the definition of "defect", the hallmark of products liability. The American Restatement (Second) [53] concluded that drugs which are typically unavoidably unsafe, yet socially indispensable, should not be considered "defective". But as Mr Justice Traynor has pointed out, we should arguably be *more* ready to impose liability where the product's norm is danger, this being classic enterprise theory, and in particular where a reasonably safe substitute exists.[54]

Finally we might note in passing the anomalous position of the patient who has become addicted to a drug, or in the case of cigarettes who has contracted lung cancer. In these situations it is precisely as a consequence of using the manufacturer's product over a period of time that the injured party is often prevented from protecting himself. The addiction model is illuminating in that it illustrates, in an extreme form, the vulnerability of drug consumers as a class. One possible inference is that defences such as disclaimer, *volenti* and contributory negligence should be construed very strictly against drug manufacturers.

It is tempting to conclude that as products liability is no better equipped to cope with the above kind of causal problems than negligence, a wider criterion still is needed on the lines of a state insurance scheme of the New Zealand type.[55] This alternative

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[53] American Restatement (Second), Torts, para. 402A, comment k.

[54] *The Ways and Meanings of Defective Products and Strict Liability*, (1965) 32 Tenn.L.Rev. 363. *Cf.* Ehrenzweig, f.n.32, *supra.*

[55] Accident Compensation Act, 1972. See also *The Report of the Royal Commission of Inquiry: Compensation for Personal Injury in New Zealand*, N.Z. Government Printer, 1967 (the "Woodhouse Report").

cannot be dealt with in detail here, but it should be borne in mind when considering the history of the thalidomide dispute in England as elsewhere.

The Thalidomide Dispute

Thalidomide is a sedative invented by the West German company, Chemie Grunenthal. In England it was manufactured and distributed by Distillers Company (Biochemicals) Ltd. (DCBL) in 1958 under the trade name of *Distaval,* and under licence from Chemie Grunenthal. In 1961 DCBL withdrew the drug from the market following evidence that if taken in the early stages of pregnancy it could cause serious injury to the embryo.

Sixty-two actions were brought against the company within the limitation period (*i.e.,* within three years of the birth of the children). But before they were heard, the plaintiffs withdrew all allegations of negligence and settled on the basis that the defendants would pay 40 per cent of the damages awarded to all plaintiffs who were not statute-barred. In 1968 Hinchcliffe, J. approved settlement on these terms in principle, but since an agreement was not reached on quantum, two cases were tried in 1969[56] in the nature of representative actions. A child described as in the middle category of injured was awarded £32,000 (and his mother £7,500) and a child in the most serious category received £52,000. In both cases 60 per cent was deducted.

The judgment exemplified some of the features of the existing common law action which are most open to criticism. The judge regretted that so much time had been taken up in dealing with questions of actuarial evidence.[57] The view that inflation and interest should be deemed to cancel one another out was adopted.[58] A global sum was awarded, based on experience and calculated to be fair to the plaintiffs and to the defendants.

Meanwhile many more cases were gradually coming to light, and by 1971 it appeared that there were more than 400 claims not covered by the 1968 settlement. In November, 1971 DCBL proposed to set up a charitable trust fund of £3¼ million for these children,

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[56] *S.* v. *Distillers Co. (Biochemicals) Ltd.,* [1969] 3 All E.R. 1412; [1970] 1 W.L.R. 114.

[57] [1969] 3 All E.R. 1412, 1421. On the basis of actuarial evidence submitted, the awards (subject to the 60 per cent deduction would have been approximately £78,500 for the middle category and £135,000 for the most serious category. See Prevett, *Actuarial Assessment of Damages: The Thalidomide Case — II,* (1972) 35 M.L.R. 257, 263.

[58] *Cf. Mallett* v. *McMonagle,* [1970] A.C. 166, 177; [1969] 2 All E.R. 178, 190.

provided that *all* the parents concerned accepted. Five families refused the offer, and an application to have them replaced by the Official Solicitor as next friend was dismissed by the Court of Appeal.[59] The negotiations were resumed.

In September, 1972 the *Sunday Times* published the first of a proposed series of articles on the subject. Two months later an injunction was granted restraining publication of one of these articles, which purported to show that DCBL had not exercised due care to see that *Distaval* was safe before it was put on the market. The basis of the decision was that the article formed part of a deliberate campaign intented to influence the course of the litigation and amounted to contempt.[60] Towards the end of November, coverage of thalidomide in the press was at its height and the campaign to provide a better settlement for the children had reached national proportions. On 28 November, the day before Parliament was to debate the issue and hear the First Reading of the Dangerous Drugs and Disabled Children Bill, the company increased its offer from £3¼ to £5 million.

In January, 1973 it seemed that the Privy Council was about to be called upon to decide whether a child has a right of action in tort for ante-natal injury, as the Supreme Court of Victoria had held in *Watt* v. *Rama*,[61] but the defendant did not appeal. In the same month the Law Commission expressed a preliminary view in favour of such a right.[62] Also, the company substantially increased its offer to £20 million.

In the following month the Court of Appeal discharged the injunction against the *Sunday Times*, mainly on the ground that the litigation was dormant.[63] However, the House of Lords subsequently allowed an appeal from this decision,[64] stressing that negotiations for a settlement were being actively pursued and that the proposed article contained material expressly aimed at establishing that the company was negligent.

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[59] *Re Taylor's Application*, [1972] 2 Q.B. 369; [1972] 2 All E.R. 873.

[60] *Att.-Gen.* v. *Times Newspapers Ltd.*, [1972] 3 All E.R. 1136; [1972] 3 W.L.R. 855. But *cf. Att.-Gen.* v. *London Weekend Television*, [1972] 3 All E.R. 1146; [1973] 1 W.L.R. 202, where a television program shown one week later was not deemed to create "a *serious* risk that the course of justice would be interfered with".

[61] [1972] V.R. 353.

[62] Law Commission Working Paper No. 47: *Injuries to Unborn Children.*

[63] *Att.-Gen.* v. *Times Newspapers Ltd.*, [1973] 1 All E.R. 815; [1973] 2 W.L.R. 452.

[64] *Att.-Gen.* v. *Times Newspapers Ltd.*, [1973] 3 All E.R. 54; [1973] 3 W.L.R. 298 (H.L.).

In April, 1973 the company put forward an offer which constituted the basis of the final settlement,[65] and which has been accepted by 95 per cent of the parents — accounting for 433 children. Each child who qualifies,[66] but did not share in the 1968 settlement, is to recover 40 per cent of the value of his claim assessed as of 1970, at a rate comparable to the 1968 cases, plus 33 per cent to take account of inflation and interest. *All* the children, including those in the 1968 settlement and any who later qualify, will share in a charitable trust fund of £14 million, to be paid in seven yearly instalments of £2 million, protected against inflation by up to 10 per cent compound interest. In addition, each pair of parents is to receive £5,000. On average this settlement currently[67] represents approximately £54,000 for each family — as compared with £8,000 on the basis of the £3¼ million offer made in November, 1971.

In one sense, the end of a long, painful and tortuous path has been reached, resulting in awards which will be "virtually equivalent to a settlement on a full liability basis".[68] But there is little cause for complacency when one reflects on the inordinate delay (without prejudice to responsibility for it in the instant case) which must have contributed to the family breakdowns and disruptions experienced by many thalidomide families;[69] the risk that a few families took in holding out against the £3¼ million offer; the apparent necessity of an intensive press campaign; and the fact that it may still be several years before individual settlements are finalized. Not least disconcerting from a legal point of view is the absence of any guidelines in the event of a comparable future disaster.

What then are the legal issues involved in drug-induced catastrophes of this kind?[70] If pleading negligence, a claimant would have to show that a cause of action exists in respect of ante-natal

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[65] *Allen and Ors.* v. *Distillers Co. (Biochemicals) Ltd., The Times,* 31 July 1973.

[66] *I.e.,* broadly speaking, anyone who is accepted as a thalidomide child by DCBL or satisfies a judge that his injuries were caused by any pharmaceutical preparation manufactured by DCBL in the United Kingdom, containing thalidomide.

[67] A residual problem concerns over 100 disputed claims which, if they were all ultimately acknowledged as valid, would reduce the average award by about £9,000.

[68] See f.n.65, *supra.*

[69] H.C. Deb. Vol. 847 No. 22 col. 470.

[70] See Bennett, *The Liability of the Manufacturers of Thalidomide to the Affected Children,* (1965) 39 A.L.J. 256.

injury and that the manufacturer (or distributor, as the case may be)[71] was in fact negligent in marketing the drug.

Little needs to be said here about ante-natal injury.[72] There is no authoritative English case law on liability for it in tort, and the Irish case, *Walker* v. *Great Northern Ry. Co. of Ireland*,[73] denying a right of action, is hardly persuasive, influenced as it was by unscientific fears about the difficulty of proving causation.[74] A growing body of Commonwealth authority,[75] and the general trend in the United States[76] are now in favour of a remedy. The cumulative effect of professional and academic support,[77] public sympathy and the Pearson Commission's terms of reference[78] suggests that such a right will soon be definitively established by legislation.

It is on the fundamental issue of negligence that the thalidomide litigation has proved most revealing. As negotiations and proceedings in several countries have shown,[79] any claimant faces

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[71] The theoretically possible but much weaker case against the prescribing doctor will not be considered.

[72] A useful summary is to be found in the Law Commission Working Paper No. 47, see f.n.62, *supra.*

[73] (1891), 28 L.R. Ir. 69; 8 Digest (Repl.) 618.

[74] (1891), 28 L.R. Ir. 69, 82.

[75] *E.g., Montreal Tramways* v. *Léveillé*, [1933] 4 D.L.R. 337 (Que.); *Duval* v. *Seguin* (1972), 26 D.L.R. (3d) 418; *Watt* v. *Rama*, [1972] V.R. 353; *Pinchin* v. *Santam Insurance Co. Ltd.* (1963) (2) S.A. 254 (W).

[76] Twenty-one states now allow recovery and only two deny it. See also *White* v. *Yup*, 458 P. 2d 617, 620-621 (1969): Law Commission Working Paper No. 47, *supra.*

[77] The Law Society has added its support to the Law Commission's provisional recommendation: *The Times*, 11 June 1973. See also Winfield, *The Unborn Child*, (1942) 4 U. of T. L.J. 278.

[78] At p. 102.

[79] The German criminal proceedings (including preliminary investigations) lasted for eight and a half years before being suspended, as their continuation was deemed contrary to the public interest. For an interesting account of these proceedings and of thalidomide generally see Sjostrom & Nilsson, *Thalidomide and the Power of the Drug Companies* (1972).

In Canada, many settlements were reached in 1968, allegedly worth from £100,000-£150,000 (*Sunday Times*, 22 April 1973). Parents who did settle were obliged not to disclose the amounts. But other suits alleging negligence have been filed quite recently in United States' jurisdiction on behalf of children from Quebec, where limitation provisions prevented them from suing.

In Australia, after some seven years of negotiations, the company has made offers averaging £51,000 to 13 claimants, plus £5,400 for each set of parents: *Sunday Times*, 15 July 1973.

In Japan, actions begun in 1965 are still continuing. The company marketing the drug has denied that thalidomide causes deformity: *Sunday Times*, 6 May 1973.

the prospect of a prohibitively costly and unendurably lengthy action. One could not construct a more vivid model to confound those critics of products liability who maintain that it already exists in all but name. For in the thalidomide cases, unlike prenatal injury claims based on nervous shock, *causation* in the vast majority of cases is beyond dispute,[80] so precisely are the consequences calculable. Proving *negligence*, on the other hand, would be a long drawn-out, expensive struggle. Even if *res ipsa loquitur* is interpreted as placing the burden of proof on the defendant, he could mount a highly technical case,[81] asserting the adequacy of his safety precautions and tests in the light of the then current procedures, and invoking as evidence of reasonableness the degree of governmental sanction which attached to the drug in question.[82]

Clearly a products liability system would greatly enhance the plaintiff's prospects of success, and at the very least make litigation a practical proposition, with the further likelihood that a realistic settlement might be achieved without undue delay. A possible objection to liability along the lines envisaged by the Second Restatement, para. 402A comment k ("new or experimental drugs as to which because of lack of time and opportunity for sufficient medical experience, there can be no assurance of safety") could be rebutted where (as in the case of thalidomide) acceptable, safe substitute drugs are in existence.

The instinctive popular reaction to the thalidomide tragedy was essentially based on the notion of moral responsibility. It was reiterated in the Commons Debate:

> ... the powerful and wealthy Distillers Company, with assets of £64 million, has had no compunction in fighting these children for no less than 10 years... a display of moral irresponsibility which has seldom if ever been surpassed.[83]

As we have seen, the moral obligation approach derives much of its force from the view that a manufacturer ought to stand behind his products. Thus it was suggested in the Debate that "[t]he Company aggressively marketed thalidomide",[84] and much atten-

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[80] Apart from an equivocal reaction from Japan's Health Ministry, every drug-controlling authority has recognized this in respect of thalidomide.

[81] As happened in the German criminal proceedings; see f.n.79, *supra*.

[82] As was pointed out in the Parliamentary Debate, thalidomide had been classified under "New remedies of proved value", by the Standing Joint Committee on the Classification of Proprietary Medicines. H.C. Deb. Vol. 847 No. 22, col. 435.

[83] *Ibid.*, col. 434.

[84] *Ibid.*, col. 433.

tion has focused on the advertisement current in October, 1961 that "*Distaval* can be given with complete safety to pregnant women".

From the perspective of risk, one might simply argue that the individual should not bear losses of this order because he is not in a position to calculate the risk as efficiently as the manufacturer. If it be said that the manufacturer may not be able to calculate the risk either, a compromise solution would be possible using Ehrenzweig's "typicality test"[85] (imposing liability where the injury is broadly typical of the kinds of hazard to which the enterprise gives rise). No doubt there are difficulties concerning the precise level of generality covered by such a test, but the basic idea is clear. Damage to the foetus resulting from the use of a particular drug may be wholly unexpected, but should still import liability, being a side-effect of a specifically medical character. Such a test can be justified in that it requires separate enterprises to bear their own accident losses, and emphasizes the desirability of calculating costs as far as possible prior to engaging in an enterprise, so that one may then insure accordingly.[86]

However, while the general financial state of the pharmaceutical industry is probably healthy enough for it to absorb and insure against normal losses, thalidomide has reminded us that the scale of mass-production of drugs is such that a single error can affect vast numbers of people throughout the world and that there is no guarantee that a given company will be able to insure against, or even obtain coverage for, such an eventuality. The argument for at least partial public responsibility in such situations can be supported on the ground that a government seal of approval should import a measure of financial responsibility.[87]

Products liability is not the only alternative to negligence. If one regards such injuries mainly as a price of technological advance and stresses the benefits of medicine to the public in general,[88] a

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[85] Ehrenzweig, *Negligence Without Fault* (1951).

[86] See James, *The Untoward Effects of Cigarettes and Drugs: Some Reflections on Enterprise Liability,* (1966) Cal.L.Rev. 1550.

[87] *Cf. The Pharmaceutical Journal,* (1973) Vol. 211, No. 5727, 84: "the government should accept at least joint responsibility with a manufacturer, whose product has met standards of safety set by the government, but from the use of which any injury or loss has arisen".

[88] "[I]n the case of vaccinations, compulsory or recommended, the state under German law, is liable for damages": Bundesseuchengesetz, July 18 1961, (1961) 1 BGBL 1012. Quoted, Caemmerer, chap. 4 of *Aspects of Comparative Commercial Law,* Ziegel & Foster (ed.)(1969).

social security model of risk allocation based on general taxation might seem most appropriate. Certainly where there are losses of massive proportions, some governmental backing would be justifiable to meet the needs of the injured and to prevent reputable firms from going bankrupt.

The introduction of a partial or total state compensation scheme would obviously raise large issues of social and political philosophy, but its desirability would also partly depend on how effectively the industry could function under a products liability system. In 1964 Rheingold said that "[t]his subject is badly in need of a socio-economic study to determine factually what the impact of strict liability would be upon the drug industry".[89] The current investigation into the affairs of Hoffmann - La Roche is one aspect of what should be an on-going process of analysis, and itself demonstrates the difficulty of formulating objective criteria to resolve the problem.

Conclusion

Whether in respect of normal or catastrophic loss the negligence action for injury caused by drugs has proved to be inefficient, primarily for procedural reasons. There is therefore a cogent case for introducing a system of products liability. While in itself this may not sound very startling, it must be remembered that the concept is one which, when first introduced into a legal system, is likely to encounter strong opposition not only from the industry, but also from those who would see in it an unacceptable abdication of individual responsibility.[90]

Further, available financial data suggests that the industry is capable of bearing the increased burden which this would entail in the ordinary course of events. To provide for catastrophic losses, it might be possible to make compulsory insurance up to a given amount a prerequisite of the right to market a drug, with the government underwriting any excess.

This discussion has been largely concerned with prescription drugs. The conclusions, therefore, are open to the objection that they would lead to piecemeal reform producing yet further anom-

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[89] (1964) 18 Rutgers L.Rev. 947, 1015, n.359. See the "Sainsbury Report" (f.n.41, *supra*) for a detailed analysis of the industry in England during the period 1963-65.

[90] For a recent exposition of this view, see Stoljar, *Accidents, Costs and Legal Responsibility*, (1973) 36 M.L.R. 233.

alies.[91] However, always assuming that products liability is the preferred alternative to negligence, this form of criticism is not simply too perfectionist, but fundamentally misconceived. For it should be evident that there can be no all-purpose formula for products liability. The particular form it takes in any given industry will have to be worked out on the basis of as thorough an analysis as is practicable of the peculiarities of its market structure.

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[91] *Cf.* Richard Crossman (in an article on disabled children): "By the accident that a wealthy company could be held responsible (sic) for their misfortune, they (the thalidomide children) will become a tiny plutocratic elite while 8,500 children (many of them with disabilities just as grave as theirs) are condemned to lifelong incarceration in obsolete long-stay hospitals." *The Times,* 18 July 1973.