

## Thalidomide – The Aftermath

by

K. I. MACDUFF

### INTRODUCTION

In 1956 the sedative Thalidomide was marketed in West Germany under the name of Contergan. In 1959 the same drug, alpha [N-Phthalimido] glutarimide, was marketed as Distaval in England. Initial tests carried out on the drug, principally in West Germany, indicated that Thalidomide gave a rapid and prolonged sedative effect, but even high dosages did not cause disturbances in the motor co-ordination of laboratory animals. No cardiac, blood pressure, or respiratory effects were observed and Thalidomide appeared to have no chemotherapeutic or cytostatic effect (i.e. there were no apparent metabolic or cellular changes).<sup>1</sup> Laboratory tests on human patients also produced only favourable results. Attempted suicides failed and inadvertent overdosages resulted in no untoward effects other than extreme somnolence.

Lacking the usual side effects of other sedatives, Thalidomide achieved rapid popularity. The first indications of untoward effects came with the drug's association with peripheral neuritis in a number of users. Only a relatively small number of users suffered in this way, but the problem was nevertheless a serious one as the damage in many instances appeared to be irreversible. Even after treatment with the drug was discontinued, the patients continued to suffer muscle atrophy.<sup>2, 3</sup>

Not until November 18, 1961, was the drug associated with its more serious consequences. In West Germany, Dr Lenz, linking the increasing number of cases of phocomelia<sup>4</sup> with the use of the drug,

<sup>1</sup> G. W. Mellin and M. Katzenstein, "The Saga of Thalidomide", (1962) 267 New England Journal of Medicine, 1184, 1238.

<sup>2</sup> Fullerton and Kremer, "Neuropathy after intake of Thalidomide (Distaval)" (1961) British Medical Journal, 855.

<sup>3</sup> A. L. Florence, letter to (1960) B.M.J. 1954.

<sup>4</sup> In phocomelia, the foetus is born with only rudimentary hands or fingers: the bones between the hand and shoulder are defective or absent. Legs and feet are similarly affected.

warned the German manufacturers of his suspicions. On November 26, the manufacturers, Grunenthal Chemie, withdrew the drug from the West German market and issued public warnings.

In England, the manufacturers, Distillers Co. (Biochemicals) Ltd, appeared less willing to accept the medical reports. Indeed, even the British Medical Journal was prepared to concede the drug's right to stay on the market despite growing suspicions.<sup>5</sup> However, the early suspicions related only to the incidence of peripheral neuritis. When the reports appeared of the drug's effect on the foetus in early pregnancy the serious nature of the problem was clear. On December 2 the drug was withdrawn from the English market.

Since those early days, medical practitioners have compiled an impressive list of anomalies caused by Thalidomide: for example, malformations of the cranium, hydrocephalus, meningomyelocele and lumbosacral-spine anomaly and various cardiovascular anomalies.<sup>6</sup>

On July 30, 1969, the first two children in England to be awarded damages received, as the result of a settlement, a total of £32,800. Although some 400 children in England were affected by Thalidomide, it appears that the terms of the settlement cover only sixty-two of them. The decisions in *S & others v. Distillers Co. (Biochemicals) Ltd., J & others v. same*<sup>7</sup> may well provide the guidelines for those cases covered by the settlement. In Germany the first case shows no immediate signs of solution, but when finally decided will be the model for some 2,500 similar cases.<sup>7A</sup>

The aim of this paper is, first, to comment on the highly unsatisfactory English decision, secondly, to discuss possible heads of liability, and thirdly, to discuss drug control legislation generally (but not with reference to narcotic drugs).

### I. *S & others v. Distillers Co. (Biochemicals) Ltd, J & others v. same*

A preliminary point which could be raised in a New Zealand action is a matter of conflict of laws: whether the court has jurisdiction. Understandably, the question was not raised in the English case as the manufacturers concerned were an English company. The issue did, however, concern the Australian Court of Appeal in *Thompson v Distillers Co. (Biochemicals) Ltd*:<sup>8</sup> indeed, the court was so preoccupied with the issue of jurisdiction that it merely assumed the incidence of

<sup>5</sup> B. Inglis, *Drugs, Doctors and Disease*, London, 1965, p. 181.

<sup>6</sup> Mellin and Katzenstein, *op. cit.*

<sup>7</sup> *The Times*, July 30, 1969.

<sup>7A</sup> It now appears that the German manufacturers have offered a lump sum settlement of one million marks (*Time*, Feb. 9, 1970, p. 38).

<sup>8</sup> (1968) 88 W.N. (Pt. 2) (N.S.W.) 219.

liability, principally on the basis of *Donoghue v. Stevenson*,<sup>9</sup> and *Grant v. Australian Knitting Mills*.<sup>10</sup> The Court of Appeal accepted *in toto* the opinion of Taylor J. in chambers:<sup>11</sup>

Once it is accepted, as it must be, that the English company owed a duty to the plaintiff or to the plaintiff's mother not to injure them by its product, then it follows in my opinion that the plaintiff has a cause of action in this State against the English company. In this State there has been that concurrence of breach of duty and damage which is the ground to any action based on negligence. The English company, on the evidence before me, supplied as safe a drug which in fact was harmful and which injured the plaintiff. All this took place in New South Wales and thus the plaintiff's cause of action arises in this State.

On the jurisdictional issue, the New Zealand courts would necessarily turn to R. 48 (a) of the Code of Civil Procedure and the cases thereon. On the question of liability the courts would do well to avoid the Australian attitude and seek instead a firmer basis for the imposition of penalties.

Whereas the court in *Thompson* presumed liability, the English court merely failed to discuss it. In this feature, the English decision is also distinguishable from the present German proceedings, in which all possible aspects of liability are apparently being discussed. The English case was concerned solely with assessing damages and even on this point it is less than satisfactory. The case concerned two boys, David, born without arms or legs, and Richard, born without arms, who will, because of the terms of a compromise approved by the court, receive only 40 per cent of the total of £84,000 damages assessed by Hinchcliffe J. Under the compromise the plaintiffs withdrew all allegations of negligence on the part of Distillers Co., the latter agreeing to pay 40 per cent of damages assessed.

It is submitted that, for two reasons, this decision will be of little assistance in similar cases. In the first place, the assessment of damages as far as quantum is concerned, is not a concept which tends to create binding precedents. Secondly, the lack of legal substance in this decision means that though Distillers Co. accepted liability in this instance there is no guarantee of them doing so in other cases.

By this unfortunate choice of words, Hinchcliffe J. leads the reader to wonder what criteria were used in assessing damages. Though the plaintiffs withdrew all allegations of negligence, the judge was nevertheless moved to note that:

Where a person has been severely injured by the negligence of another, the assessment of damages is not easy; mathematical accuracy was impossible—and there was no yardstick to measure the disability.

Indeed, his task was so much more difficult lacking even the concept of

<sup>9</sup> [1932] A.C. 562.

<sup>10</sup> [1936] A.C. 85.

<sup>11</sup> Cited at (1968) 88 W.N. (Pt. 2) (N.S.W.) 221–222.

a specific category of liability. It may be assumed that his Lordship bore in mind the concept of negligence—though as will be discussed subsequently, there were clear alternatives to this head of liability. On the other hand, it could well be argued that whatever category of liability is relied upon, it is the judge's attitude to the concept of damages *per se* which is decisive. Clearly, there are difficulties in substituting an amount of money for the loss of a physical amenity, and particularly the problem would be more difficult in cases such as the present in which the plaintiff never possessed the arm or leg for the "loss" of which he is to be compensated. The cases to which Hinchliffe J. referred contain statements of general principle, but in the final analysis such cases lend little more than moral support: the judge still has the choice of assessing damages subjectively or objectively. The alternatives may be seen clearly in the recent decision of *Baker v. Willoughby*<sup>12</sup> in which the plaintiff, seeking damages for injuries sustained to his leg in a car accident, failed in the Court of Appeal as the first accident had been obliterated by a subsequent accident: he was shot, during an armed robbery, in his injured leg, which then had to be amputated. The trial judge did not see the amputation as reducing the prospective loss suffered in the first accident, but the Court of Appeal held that the second accident had obliterated the effect of the first:<sup>13</sup>

Damages are intended to compensate the plaintiff for his loss arising out of the tortious act and no more. The consequences of a tortious act may continue to cover damage during the whole of the plaintiff's life, but if in fact they come to an end before trial, whether by recovery, or supervening disease, or further injury, I do not see why the defendant's liability should continue. Once damages are assessed, of course, they are not liable to be reopened, but this merely emphasises the importance of correct assessment initially.

Hinchliffe J, unlike the Court of Appeal in *Baker*, adopted a subjective attitude to the assessment of damages:

Actuarial aids were sometimes helpful, but they were not the be all and end all of the difficult matter. In the long run it was the court which took into consideration all the circumstances—the deprivation, the loss of earning capacity and the special expenses—and then decided what was fair compensation to both parties. The assessment of the global sum was based on experience and by the application of reasonable common sense and according to social standards as reflected in the general level of awards.

In adopting such an attitude, Hinchliffe J. is in good company, notably that of Diplock L.J. in his dissenting judgment in *Wise v. Kaye*.<sup>14</sup> Unlike those of the "objective school," the subjectivists took less at the actual physical needs of the plaintiff as the primary criterion, but rather adopt an almost Benthamite attitude in seeking damages as compensation for the difference between that which would have been

<sup>12</sup> [1969] 2 W.L.R. 489.

<sup>13</sup> *ibid.*, 494, per Widgery, L. J.

<sup>14</sup> [1962] Q.B. 638.

enjoyed without the accident, and the happiness or unhappiness that in future would be experienced as a result of the injuries.

. . . The Court is seeking, however imperfect the attempt may be, a just proportion as between the damages awarded to one plaintiff and those awarded to another. . . . The only rational basis on which it can do it is by assessing the only factor common to all kinds of personal injuries and their different consequences, namely, the difference between the happiness which the victim would have enjoyed if he had not been injured and the happiness or unhappiness he has experienced or will experience as an injured man.<sup>15</sup>

The difficulty with this approach is, as Diplock L.J. himself recognised, that it is<sup>16</sup>

an attempt to equate money with something with which money is not commensurable—prospective happiness.

Nevertheless, the High Court of Australia in *Teubner v. Humble*,<sup>17</sup> chose not to adopt the objective attitude of the majority in *Wise v. Kaye*. The opinion of Windeyer J. in *Teubner* exemplifies the less satisfactory consequences of the subjective approach, in that he refused to accept that damages should not be awarded beyond the amount which the injured person could in any way enjoy or which could be used to provide him with comforts or amenities:<sup>18</sup>

So far as his injuries consist of loss of enjoyment, I do not see that money that he cannot use and which cannot be used for him, and the possession of which can mean nothing to him, is compensation.

For this reason, then, an objective approach which considers the needs of the plaintiff as paramount, may be more satisfactory. The weight of current judicial opinion is, indeed, in favour of such an objective approach, the clearest objection to the subjective approach being expressed by Lord Pearce in *H. West & Son v. Shephard*:<sup>19</sup>

The loss of happiness of the individual plaintiffs is not, in my opinion, a practicable or correct guide to a reasonable compensation in cases of personal injury to a living plaintiff. . . . It would be lamentable if the trial of a personal injury claim put a premium on protestations of misery and if a long face was the only safe passport to a large award.

In fact, when it is borne in mind that the courts are seeking a “reasonable” award, the objective approach becomes all the more persuasive: the common law is steeped in the traditional objectivity of the reasonable man. Though the objectivists lay no premium on a long face, they are, of necessity, still concerned with a concept of enjoyment of life, but only to the extent that it may be assessed objectively:<sup>20</sup>

<sup>15</sup> *ibid.*, 669.

<sup>16</sup> *ibid.*, 664.

<sup>17</sup> (1962) 108 C.L.R. 491.

<sup>18</sup> *ibid.*, 507.

<sup>19</sup> [1964] A.C. 326 at 368–369.

<sup>20</sup> *McGrath Trailer Equipment Pty Ltd v. Smith* [1956] V.L.R. 738, 741, per Herring, C. J.

The matter is to be treated objectively—what has the plaintiff lost as a result of his injuries, how great is the diminution of his capacity to enjoy life? The greater the injury, the less he is able to enjoy the normal human existence of men and women, the greater the loss he suffers.

One cannot say that Hinchcliffe J. was wrong in adopting a subjective approach, but an objective approach may well be conducive to the achievement of a more Aristotelian justice: attempts to equate financial gain with happiness can lead to little more than judicial frustration and confusion. Despite *Benham v. Gambling*<sup>21</sup> and the attempts to establish “a conventional sum”, there is no precise formula. Nevertheless, though damages awards are not binding in the sense of strict legal precedents, previous cases will, to a limited extent, be *indicia* of what is a reasonable assessment. This is clearly stated by Lord Denning M.R. in *Ward v. James*,<sup>22</sup> in a passage to which Hinchcliffe J. referred:

These recent cases show the desirability of three things: First, *assessability*: In cases of grave injury, where the body is wrecked or the brain destroyed, it is very difficult to assess a fair compensation in money, so difficult that the award must basically be a conventional figure, derived from experience or from awards in comparable cases. Secondly, *uniformity*: There should be some measure of uniformity in awards so that similar decisions are given in similar cases; otherwise there will be great dissatisfaction in the community, and much criticism of the administration of justice. Thirdly, *predictability*: Parties should be able to predict with some measure of accuracy the sum which is likely to be awarded in a particular case, for by this means cases can be settled peaceably and not brought to court, a thing very much to the public good.<sup>23</sup>

Noble sentiments, no doubt, and useful where cases are comparable, but in the Thalidomide tragedy there is extreme disparity between the individual cases. It is in such cases that the merits of the subjective approach may be seen most clearly, for here one may avoid the award of conventional or arbitrary sums, and instead increase the sum in the same proportion as the disability. The only difficulty lies in the assessment of a base figure on which to premise the award of higher sums: the problem seems eminently suited to circuitous argument. A child whose injury is microtia<sup>24</sup> clearly cannot rely on a case where the plaintiff's injury is the loss of a limb or limbs. Richard, lacking arms, nevertheless has normal mobility in that he can walk, run, kick, and climb stairs without difficulty. Are the damages awarded to him to be any less than those awarded to a similarly afflicted child merely because Richard is able to brush his teeth by holding the toothbrush with his foot and the other plaintiff may not be able to do so? Similarly, Hinchcliffe J. may have set a trap for the unwary by stating that it was doubtful that Richard would get to University—he had an IQ of 124—

<sup>21</sup> [1941] A.C. 157.

<sup>22</sup> [1967] 1 Q.B. 272.

<sup>23</sup> *ibid.*, 299–300.

<sup>24</sup> Abnormal smallness of the ears or of one ear: in some instances the external ear is missing and the internal auditory canal is abnormally low.

but he might get to technical college. Are future judges to have regard to the intellectual capabilities of similarly afflicted children? Research into the effects of the drug have indicated its teratogenic effects but the vast majority of afflicted children are of normal mentality.<sup>25</sup>

A further problem is that the cases to which his Lordship referred were concerned with the *loss* of a limb or enjoyment of life. In cases such as *Owen v. Sykes*,<sup>26</sup> where an athletic doctor claimed that he was not able, as a result of his injury, to pursue his athletic interest, the court has an amenity which has been of value to the plaintiff in the past. It is the value of this lost amenity, be it a limb or expectation of life, which provides a basis for actuarial calculations. Indeed, even in the present case, Hinchcliffe J. noted that

A fair and moderate value had to be placed on the disability and the consequential loss.

One wonders whether, in cases where the plaintiff has never had the limb, the damages should be assessed on a different basis. It could, on the one hand, be argued that damages should be greater because the plaintiff was deprived of even having had the use of the limb. On the other hand, it may be an equally tenable argument that damages should be lower, drawing an analogy with dicta in *H. West and Sons Ltd v. Shephard*<sup>27</sup> in which an unconscious person was seen as not entitled to damages for pain and suffering as she was not aware of that disability. If the person has never had the use of his feet, can the court accurately assess the possible value of those non-existent feet to the plaintiff? It would, however, be a perverse analogy with *West v. Shephard* to suggest that the Thalidomide victims were not aware of their disability.

His Lordship perhaps had little alternative but to assess damages vaguely as “fair compensation”. Indeed, assessment of damages in such cases present a conceptual problem similar to that which occurs in the matter of suits for prenatal torts. To the extent that a foetus has a potential natural personality, so perhaps do the Thalidomide victims have potential limbs which the drug destroys.

One can sympathise with his Lordship in that

Never can there have been a case where there are so many imponderables. It is fair to say that the Court is asked to speculate upon every aspect of damages. If ever there was a case where a broad view should be taken as to what is just and reasonable compensation, this is it.

Had Hinchcliffe J. founded his consideration of the assessment of damages upon one or other of the possible heads of liability, he may

<sup>25</sup> H. B. Taussig, “A Study of the German Outbreak of Phocomelia” (1962) 180, *Journal of the American Medical Association*, 1107.

<sup>26</sup> [1936] K.B. 192.

<sup>27</sup> [1964] A.C. 326.

have relieved himself of the task of such broad speculation. We should, therefore, now turn to the issue which should rank first in priority: that of liability.

II. Before possible heads of liability can be considered it will be necessary to discuss two problems:

- (a) What is the nature of the duty, if any, owed to the unborn plaintiff?<sup>28</sup>
- (b) Could it be said that the injury to the foetus was of such a nature as to be classified as an idiosyncratic reaction? If so, the the question of a duty owed to the plaintiff is again relevant.

A. "A duty is a notional pattern of conduct"<sup>29</sup> and such a pattern can take shape only after consideration of the person on whom the duty is imposed, the mode of its performance, and the person to whom it is owed.

The issue immediately raised is "is a foetus a person to whom a duty can be owed?" The early position taken by the courts is clearly stated in *Drobner v. Peters*:<sup>30</sup>

No liability can arise . . . except out of a duty disregarded and the defendant owed no duty of care to the unborn child . . . apart from the duty to avoid injury to the mother.

This would result in the somewhat anomalous situation that were the child born alive but deformed, there would be no liability, but if the child were born dead and the mother suffered nervous shock as a consequence, she would be able to recover damages.

The law takes an inconsistent stand in the matter. Though as a general principle, legal personality begins at birth (whereas to religion and medicine life begins at conception), the unborn child may still have property rights, and it is possible to commit crimes, such as abortion, against the unborn child. Clearly Holmes J. assumed that unborn children not yet viable did not have legal status:<sup>31</sup>

If we should assume . . . that a man might owe a civil duty and incur a conditional prospective liability in tort to one not yet in being, and, if we should assume that causing an infant to be born prematurely stands on the same footing as wounding or poisoning, we should then be confronted by the question . . . whether an infant dying before it was able to live separated from its mother, could be said to have become a person recognised by the law as capable of having a *locus standi* in court, or of being represented there by an administrator.

A similar scientific error was perpetrated by Judge Boggs in *Tursi v. New England Windsor Co.*<sup>32</sup> in stating that a *viable foetus* which is

<sup>28</sup> cf. J. M. Priestley, "Personality and Status in the Womb", 1967, A.U.L.R. 33.

<sup>29</sup> Dias, "The Duty Problem in Negligence", [1955] C.L.J. 198, 202.

<sup>30</sup> 232, N.Y. 220, 224 (1921).

<sup>31</sup> *Dietrich v. Inhabitants of Northampton* 138 Mass. 14, 16 (1884).

<sup>32</sup> 19 Conn. Supp. 242; 111. A. 2d. 14 (1955).



negligently injured while *en ventre sa mere* has, when born, a right of action. Ultimately, the law drew nearly level with scientific knowledge and rejected viability, namely that point in time in intrauterine development when the foetus is able to exist outside the womb, as the time of acquisition of *potential* legal personality. Medical science showed indeed, that the foetus was most susceptible to environmental influences during the first trimester, long before viability. For present purposes this was a significant development as in every case of Thalidomide injury the foetus was not viable at the time of injury. The rejection of the viability requirement does therefore avoid a potential injustice.

However, as the principal issue in damages remains that of proving causation, and as legal personality still begins only at birth, the foetus having only potential natural personality, the courts will still concern themselves with a difference in medical and legal opinion.

A causal link may be clearly established between the act and the injury, but<sup>33</sup>

the broad general principle which should govern the assessment of damages . . . is that the tribunal should award the injured party such a sum of money as will put him in the same position as he would have been if he had not sustained the injuries . . .

Though damages may accrue from the date of the injury, can they be awarded to a still-born child? The causative approach does not recognise the foetus as having legal status until birth and therefore if it dies before term, though the cause of the death be the negligence of the defendant, no action can be derived through the foetus. (Though Viscount Simon L.C. may stigmatise the maxim *actio personalis moritur cum persona* as “a maxim which is both obscure in origin and inaccurate in expression”,<sup>34</sup> the parents or personal representatives of the foetus could hardly succeed to a right of action not enjoyed by the foetus itself.) Were the law to bring itself more truly in line with science, it would adopt a biological approach which, though still requiring proof of causation, would nevertheless see “life” as the donor of rights. As, in biological terms, life begins at conception, a foetus which dies before term would nevertheless be construed to have lived and legal rights would be transmitted to the foetus’ beneficiaries. It appears, however, that this level of medico-legal consensus is unlikely:<sup>35</sup>

A fundamental basis of tort law is the provisional compensation to an innocent plaintiff for the loss that he has suffered. Tort law is not, as a general rule, premised upon punishing the wrongdoer . . . [To] compensate the parents any further than they are entitled by well-settled principles of law, and to give them a windfall through the estate of the foetus is blatant punishment.

<sup>33</sup> D. A. Gordon, “The Unborn Plaintiff”, (1965) 63 Mich. L.R. 579 *et seq.*

<sup>34</sup> *Benham v. Gambling* [1941] A.C. 157, 160.

<sup>35</sup> Gordon, *op cit.*, 595.

In the Thalidomide injury cases, it appears that the courts should have little difficulty in accepting the existence of the duty relationship between tortfeasor and infant. Though still biologically naive the law, in rejecting the viability criterion, has progressed significantly from the opinion stated in *Drobner v. Peters*.<sup>36</sup> However, not only does the law persist in its conception of damages, but it further maintains the principle of foreseeability in negligence actions, and for so long as it does so this may prove to be a convenient escape for the negligent defendant. It appears that the law will continue to require subsequent birth as proof of life and proof of injury, but life will be considered potential from the moment of conception.<sup>37</sup>

As the [plaintiff] developed biologically from potentiality to reality the wrong developed too. It progressed as did he, from essence to existence. When he became a person the nature of the wrong became fixed.

It is "common sense justice" that if a child is to be considered in being at any time after conception, it should be considered in being from the exact moment of conception.<sup>38</sup>

However, this is, as it were, a "one-way justice" in that it can only work to the advantage of the plaintiff. To this extent it is relevant to consider an analogous problem: that of experimentation on humans. The Kefauver-Harris Amendments to the American Food, Drug and Cosmetic Act 1962,<sup>39</sup> which were largely precipitated by the Thalidomide tragedy, concern themselves, in part, with the matter of consent in experimentation. Could the manufacturer of an experimental drug (and surely any drug which is new on the market is, to that extent, experimental) which later turned out to be detrimental to health, say that all those who used it were consenting users and therefore *volenti non fit injuria*? Further, could it be said that pregnant mothers, aware of their condition, in using the drug thereby consented for themselves and for the child? Such would surely be a perverse form of estoppel. Conversely, could it be argued that the foetus, having potential legal personality, consented through his agent, his mother? It is conceded that these are basically semantic issues, but are nevertheless relevant. The Amendment defines consent in the following manner:

"Consent" or "informed consent" means that the person involved has legal capacity to give consent, is so situated as to be able to exercise free power of choice, and is provided with a fair explanation of all material information concerning the administration of the investigational drug, or his possible use as a control, as to enable him to make an understanding decision as to his willingness to receive said investigational drug. This latter element requires that before the acceptance of any affirmative decision by such person the investigator should make known to him the nature, duration, and purpose by which it is to be administered; all inconvenience and hazards reasonably to be

<sup>36</sup> 232, N.Y. 220, 224 (1921).

<sup>37</sup> *Zepeda v. Zepeda*, 190 N.E. 2d. 849, 855 (1963) per Dempsey, J.

<sup>38</sup> *Williams v. State*, 46 Misc. 2d. 824, 260 N.Y.S. 953 (1965).

<sup>39</sup> Pub. L. No. 87-781, 76 Stat. 780.

expected, including the fact, where applicable, that the person may be used as a control; the existence of alternative forms of therapy, if any; and the effect upon his health or person that may possibly come from the administration of the investigational drug. Said patient's consent shall be obtained in writing by the administrator.

For obvious practical reasons no court, bearing such a definition in mind, could conceivably hold that a foetus had consented to treatment with investigational drugs. To this extent, the unborn plaintiff is placed in the rather enviable position of having the law invariably smile favourably on him.

It may safely be concluded that, in view of the increasing concensus of medical and legal opinion, a court faced with a Thalidomide injury claims could look to *Montreal Tramways v. Leveille*<sup>40</sup> as enunciating the general concept of causation:<sup>41</sup>

. . . The relation of cause and effect must exist with certainty between the fault and the injury. As soon as that relationship exists the injury must be compensated, however remote it may be . . . It is not a question of proximity in time and space, but merely of the existence of a chain of causation.

*B.* The medical utility of a drug depends on the margin between the desired toxic action and that which is excessive, and also on the nature of the less desirable manifestations of its toxicity.<sup>42</sup>

Where a drug has been in use for some time, its effects and side effects are generally well known. But where a new drug is introduced, though animal experiments may indicate the probable therapeutic value of the drug, such experiments are less likely to reveal all the probable side-effects which the drug may have when administered to humans. This was clearly the case with Thalidomide: laboratory experiments indicated that it was the safest and most effective sedative to be released on the market. It was only subsequent use which revealed the teratogenic effect of the drug on the foetus. But this effect was clearly limited to a specific category of cases; similarly, the drug caused peripheral neuritis in some, but by no means a substantial number of users. Were the manufacturers to claim merely that this was a toxic reaction not predictable from tests (and not only necessarily involving an idiosyncratic reaction to the drug), there would be clear grounds for admonition and imposition of a penalty for failing to test their product adequately. But, it might be agreed that the adverse reaction suffered was demonstrably different, quantitatively and qualitatively, from the effect of the drug on the majority of users, and was attributable only to an allergic reaction. Should the manufacturer of what is ostensibly a safe product be held accountable for the individual allergies

<sup>40</sup> (1933) 4 D.L.R. 337.

<sup>41</sup> *ibid.*, 369, per Cannon J.

<sup>42</sup> G. E. Paget, "The Safety of New Drugs", (1960-61) 1, *Medicine, Science and the Law*, 153.

of the consuming public? Though such a case might be less forceful in the instances of injury to the foetus, it would be clearly arguable that the reaction which caused peripheral neuritis could not be predicted from any laboratory study available at the time and therefore must remain a hazard faced by users of any new drug.

The findings of a number of American decisions have been summarised in the following manner:<sup>43</sup>

Although there are decisions to the contrary, generally it has been held that in an action by the buyer of a product against the seller for breach of warranty to recover damages for injuries resulting from the use of the product, there is no liability upon the seller where the buyer was allergic or unusually susceptible to injury from the product. In action by the buyer or user of a product, based on negligence, against the manufacturer, jobber, or seller for damages resulting after the use of the product, it has been held that there is no liability upon the manufacturer, jobber, or seller, where the buyer or user was allergic or unusually susceptible to injury from the product.

A similar opinion was expressed in *Bennett v. Pilot Products*<sup>44</sup> in which the plaintiff showed an allergy to ammonium thioglycolate, an ingredient in the defendant's permanent wave solution and fixative. In drawing an analogy with allergy to strawberries—"a commodity honoured so frequently by the authorities in illustrating difference in liability to the allergic in contrast to the normal individual"—the court concluded that the plaintiff's ailment was, in fact, an allergy, and as such was not compensable as a matter of law. The court expressed its sympathy with the plaintiff's predicament but refused to place the manufacturer in the position of an absolute insurer against physiological idiosyncrasy.<sup>45</sup>

To do so . . . would invest the elusive ordinary prudent man with a quality of foreseeability that would take him out of character completely. Every substance, including food which is daily consumed by the public, occasionally becomes anathema to him particularly allergic to it. To require insurability against such an unforeseeable happenstance would weaken the structure of common sense, as well as present an unreasonable burden on the channels of trade.

One can well imagine that, were peripheral neuritis the only side effect of Thalidomide, a similar argument to that above might be presented to avoid liability in the event of such injury. The chances of the success of such an argument would, however, be proportionately diminished by the fact that the drug had far more serious consequences. The drastic effect of the drug on the foetus may well lead the court, and, more particularly, a jury, to conclude that it was an inherently dangerous product, the manufacturers of which, in the event of injury, should be punished—allergy or otherwise. Indeed, *Bennett v. Pilot Products*<sup>46</sup> was not concerned with an inherently dangerous product. It may, however, prove to be a difficult problem to decide what, in

<sup>43</sup> 26 A.L.R. 2d. 966, cited in *Bonowski v. Revlon. Inc.*, 100 N.W. 2d. 5, 8 (1959).

<sup>44</sup> 235, P. 2d. 525 (1951).

<sup>45</sup> *ibid.*, 527.

<sup>46</sup> 235 P. 2d. 525 (1951).

fact, is a dangerous product. It may well be argued that any drug, be it the humble aspirin or Thalidomide, is inherently dangerous. On the other hand,<sup>47</sup>

A loaded gun will not go off unless someone pulls the trigger, a poison is innocuous unless someone takes it, gas will not explode unless it is mixed with air and then a light set to it . . .

Almost any drug contains the potential for injuring the consumer, though in many cases, particularly where barbiturates are concerned, there is the intervening factor of the individual who gives himself the overdose which proves fatal. On this latter point it may, therefore, be argued that drugs are *not* inherently dangerous if properly labelled and tested, and if the correct dosage is taken. The problem remains, however, of the individual whose allergy is not anticipated and therefore not provided for in prescribing dosages or in giving warning on the label.

The liability of the manufacturer in such cases may well prove to depend on a quantitative assessment of evils and benefits, to be obtained from the product. Indeed, in this matter the manufacturer truly sails between a fearsome Scylla and Charybdis. In *Merrill v. Beaute Vues Corp.*<sup>48</sup> some 500 million articles of the type which injured the plaintiff had been sold with only very rare ill-effects. There was medical knowledge of a certain toxic reaction to the product,<sup>49</sup> but there was no knowledge of the possibility of the plaintiff's particular injury, optic neuritis. The Court held that it did not follow that because the plaintiff suffered this particular reaction the product was inherently dangerous. Therefore the manufacturer who places a product on the market, knowing that some unknown few, *but not an identifiable class which could be effectively warned*, may suffer allergic reactions or other isolated injuries not common to the ordinary or normal person, need not respond in damages to such persons.<sup>50</sup>

It appears to be wisdom after the event to say that pregnant women were an identifiable class which could be effectively warned of the dangers of Thalidomide. It is necessary, however, to determine whether, in fact, the defect was known: it will be a question of liability for negligence if the defect should have been known and would have been revealed by adequate testing. On this point, Asprey J.A. fell into error in *Thompson v. The Distillers Co. (Biochemicals) Ltd*<sup>51</sup> in stating that:

The English company knew of the dangerous qualities of the Thalidomide which it purchased in bulk from the German manufacturer and incorporated in its own preparation known as Distaval.

<sup>47</sup> *Dominion Natural Gas Co. v. Collins* [1909] A.C. 640, 646, per Lord Dunedin.

<sup>48</sup> 235, F. 2d. 893 (1956).

<sup>49</sup> Again, ammonium thioglycolate in a permanent wave solution.

<sup>50</sup> 235 F. 2d. 893, 897.

<sup>51</sup> (1968) 88 W.N. (Pt. 2) (N.S.W.) 219, 227.

In view of the fact that Mrs Thompson did not use Distaval until August 1961, and that the drug was not withdrawn from the English market until December 1961, it appears highly unlikely that the English company would have had such knowledge.

If the product contains an ingredient which is known to be injurious to the health of a certain category of consumers, the manufacturer will be held liable in the event of his not giving an adequate warning. Thus in *Biaachi v. Denholm & McKay Co.*<sup>52</sup> the seller of face powder containing a *known* irritant to the skin of some persons was held liable for breach of implied warranty of fitness where injury resulted from the use of the product by a buyer whose skin was sensitive to such an irritant. There was no finding as to the size of the class of allergic people and the court's decision for the plaintiff despite this fact would seem contrary to the opinion expressed earlier that liability may well be based on quantitative analyses of the consumer market. Indeed the Court of Appeals in *Wright v. Carter Products*<sup>53</sup> went so far as to suggest that duties to warn of probable ill effects are not, in all cases, measured solely by quantitative standards. That latter case, however, was one which showed a tendency towards strict liability in such matters, albeit that the court concerned itself with the issue of negligence as well.<sup>54</sup>

Liability in negligence for failure to discharge that duty by inserting appropriate words of caution is rightly borne as one of the costs of producing and selling a commodity for use by members of the public whose knowledge of potential danger to themselves may be greatly inferior to that possessed by the manufacturer.

Strict tortious liability was similarly considered appropriate by the court in *Proctor & Gamble v. Superior Court of State, in and for Marin County.*<sup>55</sup>

It has been held that if a seller knows or should know that an article sold by him is dangerous to *some* persons, even though few in number as compared with the number of users of the article, he is negligent if he fails to warn the ignorant of the hidden dangers.<sup>56</sup>

Clearly the developing foetus shows a unique susceptibility to the ill effects of Thalidomide; equally clearly is the individual foetus a member of a distinct class, in which event the proportion of consumer susceptibility could probably be quantitatively assessed. It would appear from several of the foregoing decisions, however, that some knowledge of the defect on the manufacturer's part is a prerequisite to liability.<sup>57</sup>

<sup>52</sup> 19 N.E. 2d. 697 (1939).

<sup>53</sup> 244 F. 2d. 53 (1957).

<sup>54</sup> *ibid.*, 59.

<sup>55</sup> 268, P. 2d. 199, 202 (1954).

<sup>56</sup> Similarly *Gober v. Revlon Inc.*, 317 F. 2d. 47 (1963).

<sup>57</sup> *Watson v. Buckley, Osborne, Garrett and Co. Ltd, and Wyrovovs Products Ltd*, [1940] 1 All E.R. 174, 184 per Stable, J.

It seems to me that, when they know that the thing they are putting on the market is of a class which is dangerous, although they claim that theirs is the exception to the rule, and know, particularly here, that the hair dye, the solution, the percentage which they think they are putting on the market, is dangerous in fact to quite a percentage of people by whom it will be used, then I think they fall under that principle which demands an unusual standard of care in putting abroad a dangerous article, and which does create a duty between any person by whom the dangerous article is distributed and the consumer who is ultimately injured by reason of some carelessness for which the distributor or manufacturer is responsible.

This is, however, a question more relevant to the subsequent discussion on negligence and strict tortious liability. Assuming the acceptance of the standard “that the defendant knew or should have known” of the likelihood of defects, it appears probable that the courts will continue their reliance on the victim *talem qualem* rule. Here again, there will be disparity in medical and legal opinion. To the lawyer, the victim *talem qualem* rule is a means of avoiding difficulties of proof in causation: it expresses the legal principle that a wrongdoer must take his victim with all his susceptibilities, abnormalities and propensities. To the lawyer, and to the judge, it is sufficient if a drop of molten galvanizing material ultimately results in cancer; it is immaterial that the plaintiff’s skin was already in a premalignant condition.<sup>58</sup> So, too, may the courts consider it immaterial that the plaintiffs in Thalidomide injury cases were biologically different from the majority of consumers at the time of the injury. The lawyer asks merely, “but for act A would harm B have resulted? If the answer is in the negative and if its probability is not so slight as to warrant being discarded under the *de minimis* principle, then the lawyer’s task as to causation although not necessarily as to liability, is complete.”<sup>59</sup> The inherent defect in the strictly causal approach in so far as liability is concerned has already been suggested: it is always open to the defendant to say that he, as a reasonable man, could not have anticipated the presence of an unborn child within the scope of the risks created by his conduct. Nevertheless, bearing in mind the special position of a manufacturer, particularly a manufacturer of drugs, it is submitted that the courts may well find that:<sup>60</sup>

The defendant’s status as an expert would . . . seem doubly relevant: (1) as bearing on its duty to communicate its superior knowledge to those who, because of their own limited information, would otherwise be unable to protect themselves, and (2) as tending to show that the defendant knew, or should have known, of the possible harm that might befall some users of its product.

As stated above, a legal approach to liability establishes cause. Liability is fixed by balancing all the causes and if, on balance, a cause that can be attributed to the defendant’s fault is isolated as the

<sup>58</sup> *Smith v. Leech, Brain and Co.* [1961] 3 All E.R. 1159.

<sup>59</sup> D. A. Gordon, *op cit. ante*, n.33, at 601.

<sup>60</sup> *Wright v. Carter Products*, 244 F. 2d. 53, 59 (1957).

most important, he is saddled with responsibility. Once cause has been established, it is necessary to determine the nature of the liability. In cases of Thalidomide injury there appear to be three possible heads of liability:

1. Negligence.
2. Contract: (a) Warranty  
(b) Misrepresentation.
3. Manufacturers' liability<sup>60A</sup> for: (a) Warranty  
(b) Tort.

1. *Negligence*: Assuming that the court accepts the conclusions of *Williams v. State*<sup>61</sup> and *Montreal Tramways v. Leveille*,<sup>62</sup> it may be concluded that the manufacturer of drugs owes a duty to the unborn child as a consumer albeit that he received the effects of the drug transplacentally and, therefore, indirectly. It will, no doubt, be more difficult to show a breach of that duty.

In this connection the legal mind turns almost inevitably to *Donoghue v. Stevenson*,<sup>63</sup> and more particularly to the judgment of Lord Atkin, to a passage perhaps less well known than his familiar "neighbour principle", but one that nevertheless bears repetition:<sup>64</sup>

... a manufacturer of products, which he sells in such a form as to show that he intends them to reach the ultimate consumer in the form in which they left him with no reasonable possibility of intermediate examination and with the knowledge that the absence of reasonable care in the preparation or putting up of the products will result in an injury to the consumer's life or property, owes a duty to the consumer to take that reasonable care.

This principle similarly applies where the product passes through the hands of a distributor, so long as the probability of intermediate examination of the product before it reaches the consumer remains the same:<sup>65</sup>

I do not think it matters whether the man is a manufacturer or whether he is a distributor. It seems to me to be the same in the case of a person through whose hands there has passed a commodity which ultimately reaches a consumer to his detriment. Where that person has intentionally so excluded interference with, or examination of, the article by the consumer, then he has, of his own accord, brought himself into direct relationship with that consumer so as to be responsible to the consumer for any injury the consumer may sustain as a result of the distributor's negligence. The duty is there.

As originally formulated the principle of inspection applied where there was no reasonable possibility of intermediate examination. Now,

<sup>60A</sup> A new American development based on the concept of strict liability.

<sup>61</sup> 46 Misc. 2d. 824, 260 N.Y.S. 953 (1965).

<sup>62</sup> (1933) 4 D.L.R. 337.

<sup>63</sup> [1932] A.C. 562.

<sup>64</sup> *ibid.*, 599.

<sup>65</sup> *Watson v. Buckley, Osborne, Garratt and Co. Ltd and Wyrovovs Products Ltd*, [1940] 1 All. E.R. 174, 183, per Stable, J.



however, the law requires that there be at least a reasonable probability of adequate examination before the manufacturer or distributor is relieved of responsibility. This illustrates, perhaps, a slight tendency of the common law towards the American view of products liability discussed subsequently. In fact, Professor Winfield submits that<sup>66</sup>

The time has come to acknowledge that the question of intermediate examination is simply an aspect of breach of duty or of causation, as the case may be.

Before a new drug is released onto the market it is generally subjected to several years of extensive testing, usually by the manufacturer himself or his agent. Insofar as the plaintiff can rely on this fact, he can establish thereby the existence of a duty on the manufacturer's part to take reasonable care. Ironically, the manufacturer could conceivably rely on the same fact to show that he had taken all reasonable precautions before releasing the drug. If only for this reason, it appears that a plaintiff would be hard put to show negligence on the manufacturer's part.

It has earlier been suggested that drugs may be a commodity which could be classified as things dangerous *per se*. If this is so then there is a duty to take precaution imposed upon those who distribute such commodities.<sup>67</sup>

The duty being to take precaution, it is no excuse to say that the accident could not have happened unless some other agency than that of the defendant had intermeddled with the matter.

As a matter of law, drugs are capable of coming within the category of things dangerous in themselves; but as a question of fact, it is less clear whether drugs are dangerous in all circumstances. Clearly, to classify drugs as dangerous, and to leave the matter at that, would be to ignore the substantial benefits to be gained from the controlled administration of therapeutic drugs. Both Lord Macmillan and Lord Atkin in *Donoghue v. Stevenson*<sup>68</sup> pointed out that whether a thing is dangerous or not is a question of degree and of circumstances, and is relevant only to the degree of care required of the person in charge of it. To this extent, it is preferable to say that:<sup>69</sup>

There is really no category of dangerous things; there are only some things which require more and some less care.

The plaintiff may seek to establish, by means of the principle of *res ipsa loquitur*, that, because injury resulted from the use of the drug, that drug must have been negligently manufactured. Indeed, there may be no other method of proving negligence, as all the relevant

<sup>66</sup> Winfield, *The Law of Tort*, 8th ed., 1967, 223.

<sup>67</sup> *Dominion Natural Gas Co. v. Collins* [1909] A.C. 640, 646, per Lord Dunedin.

<sup>68</sup> [1932] A.C. 562.

<sup>69</sup> *Read v. J. Lyons and Co. Ltd.*, [1947] A.C. 156, 161, argument of Sir Hartley Shawcross, A. G.

data is in the manufacturer's hands. In this respect, Winfield suggests that the plaintiff will "generally discharge his burden of proof by showing that the article was defective and that, on a balance of probabilities, the defect arose in the course of manufacture by the defendant."<sup>70</sup> But it is not a necessary assumption that negligence is the cause of the injury: one may look at the use of *res ipsa loquitur* in malpractice suits. It is submitted that the following dictum represents the desirable balancing of medical and legal interests: the medical interest in scientific progress, the legal interest in the safety of the individual (which, one hastens to add, is indubitably an interest of prime importance to medical science):<sup>71</sup>

The great difficulty in the application of the doctrine is to determine where to draw the line. To apply it in all cases where an unexpected result occurs would hamstring the development of medical science. No medical man would dare to use new procedures especially in surgery, because if injury resulted he would be prima facie guilty of negligence . . . [A] great responsibility rests on the courts to determine the point at which the doctrine will apply in order to be fair to a patient who has received a result which either common knowledge of laymen or of medical men teaches ordinarily would not occur without negligence, and to be fair to the medical men if there is a result which would occur without negligence and which should not impose upon them the presumption of negligence.

Bray J. then considered a number of cases and concluded that the doctrine was only applicable "where it is a matter of common knowledge among laymen or medical men or both that the injury would not have occurred without negligence."<sup>72</sup>

The present writer submits that, by analogy, it would be an unwarranted assumption to state that because Thalidomide caused injury of a certain kind, the manufacturers thereof were negligent. All that is required of the defendant is the exercise of reasonable care, though, following *Wright v. Carter Products*,<sup>73</sup> a manufacturer may be seen as a reasonable man invested with a special skill, and therefore with a corresponding duty to use that special skill diligently. In the absence of contrary proof it cannot be assumed that the manufacturers failed in their duty to test their product adequately and according to standard procedures. To hold them accountable in negligence for an unforeseeable consequence such as did occur would be unnecessarily to hamper the development of new therapeutic drugs. It is not denied that, in view of the clear possibility of further teratogenic effects resulting from new drugs, there is a clear need for control of the industry, but this is the sphere for legislation rather than for what may appear at times to be the arbitrary whim of individual judges.

<sup>70</sup> Winfield, *op. cit.*, 224-225.

<sup>71</sup> *Salgo v. Leland Stanford Jr. University Board of Trust*, 317 P. 2d. 170, 175, per Bray, J.

<sup>72</sup> *ibid.*, 176.

<sup>73</sup> 244 F. 2d. 53 (1957).

An associated problem may briefly be discussed in relation to the negligence issue: that of the duty of the manufacturer to warn of known defects. If the defendant has actual knowledge of the dangers of his product and fails to give adequate warning, he is clearly liable in the event of injuries occurring.<sup>74</sup> The criterion here is “knowledge”, and it is submitted that, if a negligence action fails, so too must an action based on failure to warn. It may be further noted that once the duty to warn is established, it is still necessary to resolve the issue of causation. It must therefore be shown that, had the consumer known of the risks, he would not in fact have consented to the treatment.

2. *Contract*: Should the plaintiff seek a remedy in this area of law he will immediately encounter the almost insuperable problems relating to privity. In Commonwealth jurisdictions, warranty remains strictly contractual and, as such, would deny the injured child a remedy against the Thalidomide manufacturer in the absence of privity. Misrepresentation, as an action in contract, presents similar problems.

To succeed in an action for breach of warranty, the plaintiffs would need either to prove an express warranty of fitness or safety, or an implied warranty under the Sale of Goods Act, 1908 (N.Z.). Though the advertisements for Thalidomide products appear to have contained statements such as: “Put your mind at rest. Depend on the safety of Distaval”,<sup>75</sup> these statements were in no way embodied in a contract with the plaintiffs. The existence of an implied warranty of fitness may, as a question of fact, be a less difficult matter for the courts to prove, but the problem of absence of privity remains. The recent developments towards strict liability in warranty in American law will be discussed below.

Misrepresentation is generally regarded as a cause of action for injuries occasioned by the use of defective products. Technically speaking, however, a misrepresentation does not require a defective product: it requires merely reliance upon the misrepresentation and resultant injury. Whether a person has relied upon a misrepresentation is a question of fact and in the particular circumstances of the present case, such a fact would be beyond proof.

3. *Manufacturer’s Liability*: In this area of law discussion will again centre upon American developments: in the area of products liability the American judiciary has indeed proved to be a progressive force.<sup>76</sup> (a) *Warranty*: In the second decade of this century exceptions to the privity requirement established by *Winterbottom v. Wright*<sup>77</sup> began to

<sup>74</sup> *Barnes v. Irwell Valley Water Board*, [1939] 1 K.B. 21.

<sup>75</sup> B. Inglis, *op. cit. supra*, p. 181.

<sup>76</sup> For a general survey see: W. L. Prosser, “The Fall of the Citadel”. (1965–66) 50 *Minnesota L. Rev.* 791.

<sup>77</sup> 10 M. and W. 109, 152 E.R. 402.

appear. The early exceptions such as in *MacPherson v. Buick Motor Co.*,<sup>78</sup> abolished the privity requirement for negligence actions. Insofar as the courts were concerned with abolishing privity in warranty actions, one may draw an analogy with dicta in such cases as *Rogers v. Toni Home Permanent Co.*:<sup>79</sup>

The consuming public ordinarily relies exclusively on the representations of the manufacturer in his advertisements. What sensible or sound reason then exists as to why, when the goods purchased by the ultimate consumer on the strength of the advertisements aimed squarely at him, do not possess their described qualities and goodness and cause him harm, he should not be permitted to move against the manufacturer to recoup his loss. In our minds no good or valid reason exists for denying him that right. Surely under modern merchandising practices the manufacturer owes a very real obligation toward those who consume or use his products. The warranties made by the manufacturer in his advertisement and by the labels on his products are inducements to the ultimate consumers, and the manufacturer ought to be held to strict accountability to any consumer who buys the product in reliance on such representations and later suffers injury and the product proves to be defective or deleterious.

It may appear that to hold a manufacturer strictly liable, either in warranty or in tort, would be to contradict what was said earlier, namely that there is a risk of hampering medical development. However, the vital distinction is that, in negligence actions, particularly where *res ipsa loquitur* is pleaded, there is no guarantee of consistency in the results. Were a manufacturer to be held liable not for what may or may not be construed as negligence, but rather for his conscious statements as to the quality of his product, the results would be to lessen the quantity of spurious advertising, not to restrict development in therapeutic drugs. It must be further noted that the liability is strict, not absolute, and, therefore, conditioned upon the existence of an unreasonable warranty, or an unreasonably dangerous quality in the product.

Two recent American decisions do, however, appear to be inconsistent with one another, and to this extent show the remnants of a lingering uncertainty in products liability. In *Gottsdanker v. Cutter Laboratories*,<sup>80</sup> the plaintiffs, who contracted polio after using the defendant's polio vaccine, succeeded in their contention that the implied warranties of fitness and merchantability had been breached. Liability was imposed even though the jury found that by using reasonable means (in that Government standards had been fulfilled), the defendant could not have known that its vaccine would cause polio. From this it would appear the efforts of even the excessively diligent and more than reasonable manufacturer would be of no avail. On the other hand, the Court of Appeal in *Green v. American Tobacco*

<sup>78</sup> 217 N.Y. 382; 111 N.E. 1050 (1916).

<sup>79</sup> 167 Ohio St 244; 147 N.E. 2d. 612 (1958).

<sup>80</sup> 167 Cal. App. 2d. 603, 6 Cal. Rep. 320 (Dist. Ct. App. 1960).

Co.<sup>81</sup> held that, though the plaintiff's lung cancer had been proximately caused by the defendant's cigarettes, because of the state of scientific knowledge in 1956 the "defendant could not be held liable as an absolute insurer against consequences of which no developed human skill and foresight could afford knowledge." Perhaps the certainty hoped for earlier is not yet with us. In referring to the need not to detract from experimental impetus derived from the social utility of drugs, the court in *Gottsdanker v. Cutter Laboratories* said:<sup>82</sup>

The argument is that development of medicines will be retarded if manufacturers are held to strict liability for their defects. While this argument might have merit if the warranty involved had to do with the mere failure of a medicine to cure or of a vaccine to prevent, it seems to be of little weight where, as here, the warranty is limited to an assurance that the product will not actively cause the disease it was designed to prevent.

The manufacturers of Thalidomide can be seen only to have made the warranty that their product was "safe". Following the *Gottsdanker* principle it would appear proper to hold them accountable for breach of this warranty. Perhaps the sole rationale behind such a principle is found in *Escola v. Coco-Cola Bottling Co.*:<sup>83</sup> the risk of injury can be insured against by the manufacturer and distributed among the public as a cost of doing business.

(b) Tort: A similar rationale to the above may also justify the imposition of strict liability in tort. The trend was started by *MacPherson v. Buick Motor Co.*<sup>84</sup> in which the court abolished the privity requirements in negligence actions. The development of exceptions to the privity requirement was largely a judicial attempt to avoid warranty and its contractual implications, and to concentrate on behavioural rather than transactional liability. This being so, privity, disclaimers, and other niceties of the law of sales are not relevant.<sup>85</sup> Dicta in a more recent case, *Greenman v. Yuba Power Products Inc.*<sup>86</sup> show a marked similarity to the statements of Lord Atkin in *Donoghue v. Stevenson* cited earlier. In adjudicating upon the liability of the manufacturer of a defective power tool which injured the plaintiff, the court said:<sup>87</sup>

A manufacturer is strictly liable in tort when an article he places on the market, knowing that it is to be used without inspection for defects, proves to have a defect that causes injury to a human being. Recognised first in the case of unwholesome food products, such liability has now been extended to a variety of other products that create as great or greater hazards if defective.

<sup>81</sup> 304 F. 2d. 70, 76 (1962).

<sup>82</sup> 167 Cal. App. 2d. at 611 (1960).

<sup>83</sup> 24 Cal. 2d. 453, 150 P. 2d. 436.

<sup>84</sup> 217 N.Y. 382, 111 N.E. 1050 (1916).

<sup>85</sup> D. E. Epstein, "Personal Injuries from Defective Products—Some 'Dots and Dashes'", (1967) 9 *Ariz. L. Rev.*, 163, 172.

<sup>86</sup> 59 Cal. 2d. 57; 377 P. 2d. 897 (1962).

<sup>87</sup> 377 P. 2d. 897, 900 (1962).

It will immediately be noted that the exception was first recognised in the case of "unwholesome food products": it would not be unwarranted to say that "food" may be construed to include drugs, i.e. articles intended for human consumption. The "food exception" has been taken further in the law of negligence in that, so far as it is sought to rely on *res ipsa loquitur*, the plaintiff, apparently need no longer prove that the instrumentality causing the damage was under the defendant's exclusive control.<sup>88</sup>

The requisite of exclusive control receives a special interpretation when applied to cases involving injury from food and beverages containing deleterious foreign substances.

Clearly then, liability of this nature is one imposed by law, and not assumed by agreement, express or implied. Nevertheless, the plaintiff will still need to prove the dangerous quality in the product: strict liability merely removes the necessity of proving negligence. In this respect, the plaintiff injured by Thalidomide has no guarantee of success. The court in *Merrill v. Beaute Vues Corp.*<sup>89</sup> was reluctant to assume that the occurrence of injury proved the existence of a dangerous condition in the product. No doubt the plaintiff injured by a drug has a clearer prospect of success than does the plaintiff injured by a hair tonic or soap powder, but in each case the plaintiff will need to prove the existence of the defect. In Thalidomide cases it will be open to the plaintiff to prove this through the testimony of an expert who has examined the product after the accident and identified the specific defect. Again it may be noted that it is immaterial that this is knowledge acquired after the occurrence of the injury—strict liability does not require the knowledge of the manufacturer of the defect.

The rationale, then, behind both heads of strict liability rests on consumer protection.<sup>90</sup>

The purpose of such liability is to insure that the costs of injuries resulting from defective products are borne by the manufacturers that put such products on the market rather than by the injured persons who are powerless to protect themselves. Sales warranties serve this purpose fitfully at best.

It is clearly within the scope of judicial legislation to protect human health and life, whether the decisions be justified on the grounds of public policy or otherwise.

### III. Food and Drug Control

Despite the recent developments in strict liability it might still be felt that judicial legislation neither offers sufficient protection to the

<sup>88</sup> *Crystal Coca-Cola Bottling Co. v. Cathey*, 83 Ariz. 163, 169, 317 P. 2d. 1094, 1098 (1957).

<sup>89</sup> 235 F. 2d. 893.

<sup>90</sup> *Greenman v. Yuba Power Products Inc.*, 377 P. 2d. 897, 902.

public, nor provides sufficient certainty to allay the fears of experimenters in the field of therapeutics. Following the Thalidomide tragedy several countries felt the immediate need to review their drug control legislation. The result in the United States was the Kefauver-Harris Amendment (1962) to the Food, Drug and Cosmetic Act. The Kefauver Report published the findings of a Commission which investigated not only drug control possibilities, but also the activities of major pharmaceutical companies, and came up with some rather startling results, not the least of which was evidence of collusion among the companies to “fix” prices. In concerning itself with consumer protection, the Commission looked also at the matter of misleading advertising:<sup>91</sup>

The multiplicity of names for products in the drug industry exceeds the bounds of human imagination. First, there is the chemical name which attempts to spell out the structural make-up of the drug; and here a variety of forms of expression is possible. Next comes the generic name, which may or may not represent an abbreviation of the more complex chemical name; this is the name commonly used to identify the drug in formularies, the teaching of medicines, etc. Ordinarily a drug has one generic name, but there are cases where two or three are employed. Finally, a drug usually has a host of individual trade names used by the various companies engaged in the promotion of the product. In consequence, a single drug product is represented in the market by such a complex body of nomenclature as to intimidate even initiates in the field. And if one can visualise this situation for a single drug multiplied by the thousands of drugs currently marketed, he can get some impression of the chaos existing in the area of drug nomenclature.

This problem is clearly exemplified in the case of Thalidomide: the chemical name is alpha [N-Phthalimido] glutarimide, the generic name is Thalidomide, and the various trade names are Distaval (in England and Australia), Softenon (in Portugal), Contergan (in Germany), Kevadon (in the United States), and Talimol (in Canada). A letter to the editor of the *New England Journal of Medicine*<sup>92</sup> expresses a plea of similar import from a hospital pharmacist to physicians, wherein the former calls upon the medical profession to demand a certain quality and adequacy in the information supplied with new drugs. Not only should the manufacturer provide the generic name and structural formula of the drug, but he should also provide data on all side effects, toxic manifestations and comparable compounds. This, it is rightly stated, would prevent the manufacturers from putting out an old product under a new name in the event of the old product being discredited as having undesirable side effects or toxicity.

The problem appears to have been recognised in New Zealand, but unfortunately only to the extent that the Food and Drug Act 1969<sup>93</sup> places restrictions on “misleading” branding. The new legislation does, however, seek to promote consumer protection in that s. 12 (2) thereof requires that:

<sup>91</sup> Cited in Inglis, *op. cit.*, p. 15.

<sup>92</sup> (1962) 267 *New England Journal of Medicine*, 1266.

<sup>93</sup> In effect from April, 1970.

No person shall sell, or distribute by way of gift, loan, or sample or in any manner whatsoever, or advertise the availability of any therapeutic drug to which this section applies before the consent of the Minister to the distribution of the drug has been notified in the *Gazette*.

However, legislation of this nature is necessarily wide and will need to be made more specific by Regulations, for which provision is made in s. 46. Though under s. 19, analysts and officers may be appointed, as may advisory and technical committees (s. 20), it is by no means a remote possibility that an apparently safe drug, which had been extensively tested, could be released on the market with the same drastic results as Thalidomide. After all, the advisory committees are only approached from time to time, as the Minister thinks fit. Perhaps pressure from drug companies forced the vague nature of the legislation: this clearly happened with respect to s. 18 (1) which was amended to read:

Every person commits an offence against the Act who sells any therapeutic drug by means of a vending machine or by auctioning the drug.

That subsection had formerly included the words: "or by hawking, peddling, or auctioning the drug, or from any moveable stall or road vehicle". Pressure from a respectable drug company forced the deletion of those words.

A White Paper on the "forthcoming legislation on the safety, quality and description of drugs and medicines",<sup>94</sup> released by the United Kingdom Government, was also the result of the Thalidomide tragedy. Following the tragedy a joint sub-committee under the chairmanship of Lord Cohen of Birkenhead was set up by the English and Scottish Standing Medical Advisory Committees to consider the situation. It recommended that the responsibility for experimental laboratory testing of new drugs before they were used in clinical trials should remain with the individual pharmaceutical manufacturer. It was seen as undesirable, if not impractical, that this responsibility should be transferred to a central authority. Indeed, it would be a clear possibility for drug firms to argue, in the event of injury, that, if the testing is done by a central authority, then that same authority is liable for any defects there may be in the drug. Nevertheless, the new legislation proposed to erect safeguards to ensure that the new drugs should not be put on the market before every possible step, in the light of current scientific and medical knowledge, had been taken to bring harmful side effects to the notice of doctors, who would then be able to weigh the risks against the expected therapeutic effect. No doubt there will be further cases of unexpected toxic effects, but, as with Thalidomide, there is a calculated risk in the release of all new drugs, the ultimate test comes with widespread use.

<sup>94</sup> *Forthcoming Legislation on the Safety, Quality and Description of Drugs and Medicines* (1967, Cmnd. 3395).



It would appear from this that there is a new burden placed on doctors in the nature of a duty to regard with due caution and cynicism the representations of advertisements and company representatives. Clearly a doctor should not be required to carry out his own detailed chemical tests, but equally clearly he should be aware of the true nature of the drug he is prescribing. The planned obsolescence of many new drugs makes it imperative that doctors keep abreast of current trends. This, it is conceded, places a great burden on the profession in view of the ever-increasing quantity of new drugs. For this reason there should be an even heavier burden on pharmaceutical companies not to succumb to commercial pressures to produce ever bigger and brighter products with which to lure the unknowing customer. No doubt, drug companies have every inducement to turn out products which sell at the highest possible profit, and to see commerce, and not mere altruism as a reasonable objective. The problem then, becomes one of combining the talents and interests of a progressive industry and a conservative profession: the former to meet the needs of medical science, the latter to temper experimental ardour with professional caution.

In a sense, the problem is a social one: not only does a competitive economy foster commercial rivalry, but there is also a present tendency towards greater reliance upon the purported panacea in drugs. The law must not fail to recognise medical science's investigative functions, but neither must it ignore its position of trust as the protector of public safety. Perhaps to hope for a satisfactory balance between the two functions is to hope for the impossible, but public faith in the law may well be founded on such hope.