

***Product Liability and DES in The United  
States and The Netherlands***

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## ***Product liability and DES in The United States and The Netherlands***

### ***Introduction***

In this paper I provide a comparison between Anglo American Tort Law and Dutch '*Onrechtmatige Daadsrecht*', strictly translated as unlawful act. I have chosen this subject because it has my special interest and I want to use this independent study as a basis for further comparison between American and Dutch Tort Law and more specifically, product liability and more precisely the Law on prescription drugs.

Of course a paper of this size can not make a complete comparison between the whole area of the Anglo American Torts Law and the Dutch '*Onrechtmatige Daadsrecht*'. I divided this paper into two parts.

In the first chapter I will describe the Anglo American Product Liability Law and the Netherlands' '*Productaansprakelijkheidsrecht*'. In the second chapter I will compare 'Tort Law' of those Legal Systems in the area of pharmaceutical industry. For this I will use two cases a Dutch case: DES daughters and an American case: *Sindell v. Abbott Labs* .

When comparing two law systems exact translation of words is very difficult and can easily lead to misunderstanding. Same terms do not always cover the same overtone. Take for instance the Dutch word '*jurisprudentie*' you take your dictionary and find the English word '*jurisprudence*'. A Dutch lawyer and an American lawyer can have a conversation about jurisprudence thinking they fully understand each other, but they might not. The American lawyer means by talking about jurisprudence non-binding

judicial study and literature, but the Dutch lawyer with the term ‘*jurisprudentie*’ at the back of his mind is thinking about binding Case Law!

Another thing which can be quite confusing is the word “Law”. Translated to Dutch it is ‘Wet’, but then again the term covers another subject. The Anglo American word ‘*Law*’ covers the same subject as the Dutch word ‘*Rechten*’, ‘*Rights*’. The word ‘*Wet*’ covers the same area as the Anglo American word, *Statute*. In this paper I had to translate articles from the Dutch Civil code. Because of the problems I just described inaccuracies might have crept in.

The Anglo American Tort Law, (Common Law) and the Dutch, Law, ‘*Onrechtmatige Daadsrecht*’ (Civil Law) are very different. There are many different Torts, while there is only one ‘*Onrechtmatige Daad*’. Both are not part of their Criminal Law systems but of their Private Law systems. But in Anglo American Law some objectives are regulated by Tort Law while in Civil Law they come under Criminal Law.

In Dutch legal proceedings unlike in the United States a jury is never used. In the United States a jury is also used for personal injury cases. The jury values the real damages but also the so-called unreal damages. *Real damages* are all that we know in the Dutch Private Law as damages. In the American Tort Law the *unreal damages, punitive damages, (also called exemplary damages)* are added up to the real damages.<sup>1</sup>

Some people in the Netherlands are afraid of American practices in the Netherlands’ system. They are afraid that very high claims could become custom in the Netherlands too. This is simply impossible because in that system compensation in damages does not go further than the real damage.

European Law slowly makes progress in the development of harmonizing the laws of the European States. The European Union

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<sup>1</sup> Kenneth S. Abraham, *The Form and Functions of Tort Law* 221 ed., Foundation Press, 2001

also developed a directive in the area of product liability law, which is now adopted in The Netherlands, further development is likely but at the moment it is scarcely out of the egg.

The recent law on prescription drugs still does not lead to satisfying solutions. This part of law is very difficult and has a very high scientific degree. The causation is very hard to determine because harmful effects from prescription drugs might show up long after those are used, maybe generations later. Next to that it is hard to show if the diseases people suffer are caused by the medicine or for instance by smoking, eating, or drinking habits or maybe just it is just a person's genes.

The cases in the second chapter especially deal with how to divide the burden of proof between the consumer and the manufacturer and the problem to identify the manufacturer who provided the affecting prescription drugs the latter can become very hard or impossible after a very long latency period.

## ***Chapter I, Product Liability***

### ***Introduction***

In the Netherlands the development of product liability started much later than in the United States. Different from the United States the Dutch Law did not have a distinct Law for the regulation of Product Liability.<sup>2</sup> Cases were determined on the basis of the general provision of the ‘wrongful act’.

The Third Department of the Third Chapter of Book 6 Dutch Civil Code (containing articles 6:185 – 193 BW) entered into force on 1st November 1990. This department is based on the European directive 85/374 of Product Liability of 1985, in the light the Harmonization of Laws within the European Union. Not all the points of this subject are harmonized within the European Union and National Law has still discretion to regulate elements, for instance who is eligible for immaterial damage.

In this chapter I compare The department on product liability of the Dutch Civil code with the American provision: § 402A Special Liability of Seller of Product for Physical Harm to User or Consumer.

### ***Dutch Civil Code on product liability***

The definition of the Dutch product liability lies in article 6:186 BW:

*1. A product has a flaw when it doesn't offer the safety one can expect of it, all the circumstances taken into account and especially:*

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<sup>2</sup> Van Dam, Aansprakelijkheidsrecht, Boom Juridische Uitgevers, Den Haag 2000, nr. 1306.

- a. *the presentation of the product,*
  - b. *the fair expectation of the way the product is used,*
  - c. *the time when the product was brought on the market.*
2. *A product ought not to be considered as containing a fault solely because a better product was brought on to the market later.*

Article 6:185 BW: The manufacturer is Liable for the damage that is caused by a flaw in his product. The injured party has to prove on the basis of article 6:188 BW, the relation between the flaw and the causal connection between the flaw and the damage. Not of importance is if the manufacturer is blameworthy, because this is a matter of 'risk liability' or 'strict liability'. Article 6:185 BW summarizes six exceptions to the rule that a manufacturer is liable for a flaw in his product. Moreover the department of Product Liability contains several defences the manufacturer can appeal to, Article 6:185 BW:

1. *The manufacturer is liable for the damage caused by a flaw in his product, unless:*
  - a) *he didn't bring the product onto the market.*
  - b) *the circumstances taken into account it is plausible that the flaw that caused the damage, didn't exist at the moment when the product was brought onto the market, or if this flaw developed later.*
  - c) *the product is manufactured neither for sale nor for any other form of distribution with economical objective of the manufacturer, nor is manufactured within the scope of practice of profession or business.*
  - d) *the flaw is caused by the fact that the product is manufactured in accordance with strict governmental regulations.*
  - e) *it was impossible to discover the existence of the flaw on the basis of the state of the art knowledge at the moment when the product was brought on to the market.*
  - f) *for the manufacturer of raw materials or a manufacturer of components counts, that the flaw is attributable to the design of the product of which the raw material or component is an element, or to instructions that are provided by the manufacturer of the product.*
2. *The liability of the manufacturer is reduced or removed when taken into account all the circumstances, if the injury is caused by the flaw of the product as well as by the fault of the harmed person or a person that is responsible for that harmed person.*
3. *The liability of the manufacturer does not get reduced, if the injury is caused by a flaw in the product as well as by the performance of a third party.*

## ***American Second Restatement of Torts on product liability***

§ 402A Special Liability of Seller of Product for Physical Harm to User or Consumer:

*“(1) One who sells any product in a defective condition unreasonably dangerous to the user or consumer or to his property is subject to liability for physical harm thereby caused to the ultimate user or consumer, or to his property if*  
*(a) the seller is engaged in the business of selling such a product, and*  
*(b) it is expected to and does reach the user or consumer without substantial change in the condition in which it is sold.*  
*(2) The rule stated in Subsection (1) applies although*  
*(a) the seller has exercised all possible care in the preparation and sale of his product, and*  
*(b) the user or consumer has not bought the product from or entered into any contractual relation with the seller.”*

## ***Dutch and American provisions compared***

To compare the Dutch and American provision I also refer to the comments provided with § 402A of the Second Restatement of Torts.

### *Unreasonably dangerous*

Section 402A, states that to hold the seller liable the defect in the product must be ‘*unreasonably dangerous*’. The Dutch Civil Code does not require the unreasonably dangerous element expressly, but uses a comparable standard:

*“A product has a flaw when the product does not offer the safety which one is to expect when every circumstance is taken into consideration, article 6:196 BW.”<sup>3</sup>*

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<sup>3</sup> See *American law on this consumer expectations test*, Kenneth S. Abraham, *The Form and Functions of Tort Law* 196 ed., Foundation Press, 2001

For instance when using tobacco, the simple fact that a product brings harm to health, does not justify the conclusion that the product has a flaw, because the damage is a normal foreseeable effect of the use of tobacco.<sup>4</sup>

### *Manufacturer and seller*

The American provision seems to have a broader scope than the Dutch provision. The Dutch provision applies strictly to manufacturers, the American provision applies to:

*“any manufacturer of such a product, to any wholesale or retail dealer or distributor, and to the operator of a restaurant.”<sup>5</sup>*

It is not so that in Dutch law sellers or operators of a restaurant can not be held liable for injury or damage caused by a product but only for damage not exceeding the amount of € 500, caused to the property of the user. When the €500 limit is exceeded the buyer has to claim immediately from the manufacturer, art, 6:190 BW.

### *The moment when the defect occurred*

Comment G states, that:

*“the rule applies only where the product is, at the time it leaves the seller’s hands, in a condition that is an ‘unreasonably dangerous’ condition to the ultimate consumer.”*

This corresponds with article 6:185 (b) BW which excludes strict liability from the manufacturer when it,:

*“is plausible that the flaw that caused the damage, didn’t exist at the moment when the product was brought on to the market, or if this flaw developed later.”*

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<sup>4</sup> VPRO article about damages in the United States France, and Netherlands, by Mw. mr. A.L.M. Keirse;

<http://www.vpro.nl/attachment.db/AA%20Tabak%201.doc?28748154>

<sup>5</sup> § 402A of the Second Restatement of Torts, *Comment F*.

Comment G also states that the burden of proof rests upon the shoulders of the plaintiff, to prove that on the moment that the product left the manufacturer it was defective. This corresponds with Dutch law. The plaintiff has to prove on the basis of article 6:188 BW, the relation between the flaw and the causal connection between the flaw and the damage. If the plaintiff can not show that the product was defect on the moment it left the manufacturer the plaintiff does not meet this requirement.

### *Product safety*

Comment H states that the product does not have a defective condition when it is:

*“...safe for normal handling and consumption”.*

The Dutch provision of article 6:186 BW states that the product has a flaw when it does not offer the safety one can expect of it.

*“E.g. Everybody knows that whisky is bad for health and if it is distilled the right way we can not talk about a defective condition. When in the distillation process next to ethanol the dangerous variant methanol is developed then we can talk about a defective condition.”*

Under the Dutch provision, the whisky containing methanol does not offer the safety one can expect of it, because you do not expect to end up in hospital after drinking one glass of whisky. A product is not in a defective condition, comment H, if it is safe for normal handling or consumption, a contrario the product is in a defective condition if it is not *“safe for normal handling or consumption”*. If a person ends up in hospital consuming one glass of whisky the product is not considered safe for normal consumption and has therefore a defective condition (assumed that the person is in normal health).

### *Adequate directions and warnings*

Providing *warnings* on products makes it possible for the consumer to judge for himself if the benefit of using the product outweighs the risk. The idea is that providing those warnings transfers the responsibility and therefore the liability from the product seller to the consumer.<sup>6</sup>

Comment J states that:

*“adequate directions or warnings can prevent the product from being unreasonably unsafe.”*

The manufacturer can try to avoid liability to provide an adequate warning. But which warning is adequate and which is not? This question is up to the jury to decide.<sup>7</sup>

In Dutch law the same counts; if the manufacturer is aware or should be aware of the risk of damage the product involves. He has a duty to provide warnings and information with the product. The manufacturer has to take measures which can be expected of a manufacturer who takes good care to prevent that the products he brought on the market cause damage.

If a manufacturer fails to provide that warning and information he breaches the ‘*Standard of care*’, codified in article 6:162 BW and can therefore be held liable.

### *Unavoidably unsafe*

A product can be ‘*unavoidably unsafe*’, comment K. The Third Restatement of Torts and recent Case Law rephrases this term and talks about product that involve an ‘*unavoidable risk*’. Sometimes a product can be very dangerous, but the end justifies the means, because the product is for the use in case of emergency. Imagine this hypothetical situation that somebody has a malignant tumour and that the only chance of survival is to destroy it with a medi-

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<sup>6</sup> Kenneth S. Abraham, *The Form and Functions of Tort Law* 199 ed., Foundation Press, 2001

<sup>7</sup> Kenneth S. Abraham, *The Form and Functions of Tort Law* 200 ed., Foundation Press, 2001

cine that breaks down this tumour, but the medicine is very aggressive and there is also a chance that it kills good body tissue and the person too. A choice has to be made between two evils and the use of the medicine seems the lesser evil; this is a situation when you can say that the medicine is unavoidably unsafe or that the risk taking it is unavoidable. In the product liability department of the Dutch Civil Code '*unavoidably unsafe*' is not mentioned. But of course no Dutch judge will bypass this element. This element can for instance be extracted from article 6:186 BW which states that the product has a flaw when it does not offer the safety one can expect of it. A medicine of this kind can be expected to be very dangerous, even if there is no clear knowledge about the effects.

### *Acceptance of risk*

Can a manufacturer apply successfully to '*acceptance of risk*' to defend himself against liability? For instance a tobacco manufacturer could argue that the smoker has accepted the risk involved by smoking cigarettes.

In Dutch Law the '*Hoge Raad*' (Dutch Supreme Court) stated that the result of the doctrine of '*acceptance of risk*', is depending on the weight of the nature and the circumstances of the event. It is covered entirely on the one hand by the question if the performances against the injured party are considered as 'wrongful' and the other hand the question if the injured party can be held accountable for circumstances that on the basis of article 6:101 BW have to lead to exclusion or reduction of the compensation in damage.

This development of non contractual liability on the basis of '*acceptance of risk*' to partly liability based on own fault has also been developed in the in the United States.<sup>8</sup> It is a matter of own fault when, next to the event for which the wrongdoer is held accountable, there is also damage attributable to the injured party.

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<sup>8</sup> See *Assumption of Risk*, Kenneth S. Abraham, The Form and Functions of Tort Law 154 ed., Foundation Press, 2001

This article 6:101 BW is comparable with the American rule of ‘*Contributory Negligence*’. Comment N gives an example of when:

*“the consumer discovers the defect and is aware of the danger, and nevertheless proceeds unreasonably to make use of the product and is injured by it, he is barred from recovery.*

In accordance with article 6:101 BW the attribution of the injured party gets subtracted in proportion from the total damage the wrongdoer caused. Other calculations can be possible in the light of reasonableness.

### *Uncertain causal connection*

Sometimes it is very hard to determine if there is a causal connection between the performance of the manufacturer and the damage of the injured party.

The problem with medicine can be that there is a very long *latency period* before the damage occurs, which can lead to problems to prove the causal connection. Did the medicine cause the problem, or was it the persons eating habit, or did he smoke or use alcohol, or was it just in his genes? This problem is sometimes called an ‘*uncertain causal connection*’.

There are arguments for new methods of causality determination because in several circumstances a causal connection is hard to prove. One of those methods is to determine the extent of attribution on the basis of the calculation of probability.

Some people argue for the possibility of proportional liability, pro rata the probability of which the damage actually has been caused by the liable person.

This trend is also observable in the development of Dutch Case Law, e.g. *DES-dochters*, and American Case Law, *Sindell v. Abbott Labs*, which sees to it that the plaintiff, in spite of the uncertain causality, gets his damage compensated.<sup>9</sup>

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<sup>9</sup> DES; *Dochters*, HR 9 oktober 1992, NJ 1994, 535, *Sindell v. Abbott Labs*. 607 P.2.d 924 (Cal 1980)\*.

## ***Chapter II, Tort Cases on Prescription Drugs***

### ***Introduction***

The development of Law on this subject gained momentum very recently. Law Theories on this subject are especially developed in the United States. Not only because of the fact that the United States is known for its claim culture, but also because most Pharmaceuticals hold office in this country. I open this chapter with a Dutch Case on this subject.

### ***A Dutch Case, DES Dochters***<sup>10</sup>

#### ***Background***

Several companies in the sixties brought the product diethylstilbesterol (DES) on to the market which had the purpose to avoid miscarriages.

In the Netherlands the mothers of the plaintiffs used DES in the period between 1953 and 1967. Since 1974 the use of DES during pregnancy is forbidden in the Netherlands. The pharmaceutical companies still brought DES on the market after 1974.

Later the daughters of the DES users suffered great harm caused by the DES use of their mothers. The latency period of the harmful effects of DES is at least 10 years. The disease is fast-spreading and deadly. Radical and or other surgery is necessary to withhold it from spreading.

The Des Dochters started proceedings against a number of pharmaceutical companies that produced DES.

The daughters alleged that the pharmaceutical companies acted wrongfully against them because they brought DES on to the market after the relevant period. They stated that this was wrongful

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<sup>10</sup> DES; dochters, HR 9 oktober 1992, NJ 1994, 535

because by doing so the pharmaceuticals consciously or carelessly accepted the risk that DES could have harmful effects for the users or their offspring, because the pharmaceuticals lacked own research or just conformed to the inadequate research of others, especially while there were recommendations to research this product from the scientists who warned against dangerous side effects. Next to that the plaintiffs alleged that the defendants lacked to provide adequate instructions and warnings against the risk of the product and moreover, that they concealed the risks and intensely promoted the wholesome effect of using DES.

*Article 6:99 Netherlands' Civil Code*

Because none of the DES Dochters exactly knew from which company the DES originated they based their arguments on article 6:99 BW. This article states that:<sup>11</sup>

*“When the damage could be caused by two or more events and for each event a different person can be held accountable, and it is proven that the damage is caused by at least one of those events, the obligation to compensate the damage rests on each of those persons, unless one of these persons can prove that the damage is not caused by the event he is accountable for.”*

*Court of Appeals:*

*“unable to identify the manufacturers”*

The DES Dochters argue that every manufacturer of DES could have caused the damage and that therefore they are all jointly accountable. The Court of Appeals ‘*Het Hof*’ nevertheless states that this rule is not applicable in this case, because none of the plaintiffs was able to indicate concrete misbehaviour of the individual manufacturers against their mothers. Furthermore they were not able to accuse the complete group of manufacturers simply be-

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<sup>11</sup> See *inability to identify the relevant seller*, John Goldberg, et al., *Tort Law: Responsibilities and Redress* 901, Aspen Publishers (2004).

cause there was not enough evidence to prove which companies did or did not manufacture DES.

### *The Supreme Court*

The Supreme Court '*De Hoge Raad*' states that in the 1960's the article 6:99 BW was already good (valid) law. The article does not require concrete behaviour of one or more defendants against the plaintiff.

*"The group of liable persons can not be defined precisely but that is not of concern in this case. The alternative is that none of the manufacturers can be held liable, that is unacceptable."*

### *The burden of proof*

Article 6:99 BW is meant to meet the struggle of the injured parties' with the problem of providing evidence. Therefore every daughter only has to start a procedure against one of the manufacturers and it is enough to allege that: Firstly: The defendant in the relevant period brought DES on to the consumer market and therefore can be held accountable for '*Onrechtmatige Daad*'. Secondly: That during this period there were other manufacturers who were liable because of the same mistake. And Thirdly: That the injured party suffered injury, because of the use of DES of her mother, but that it can not be established from which manufacturer the product originates.

The *burden of proof* for the points above rests on the DES Dochter. When she succeeds to prove this every manufacturer can still prove he is not liable by producing evidence that the concrete damage was not caused by the DES he manufactured.<sup>12</sup> When he is not able to bring this evidence he will in principle be held liable for the complete damage.

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<sup>12</sup> Compare *Sindell*, John Goldberg, et al., *Tort Law: Responsibilities and Redress* 905, Aspen Publishers (2004).

If it is established that one of the manufacturers did not make a “mistake”, it does not discharge the other manufacturers from liability, unless that would be in violation of the ‘*fair- and reasonableness*’.

*Article 6:99 BW and the  
uncertain causal connection*

The only question was if causality could be established. The daughters were not able to prove that the damage was caused by a particular manufacturer, it was a case of an ‘*uncertain causal connection*’. They were not sure if there was a relation between the damage of the injured party and the act of the defendant and they will never be able to prove this.

To avoid this problem of evidence, the Supreme Court ‘*De Hoge Raad*’ held that article 6:99 BW applicable. Article 6:99 BW:

*“If more persons act “wrongfully” and therefore could have caused the damage, but it is not clear who caused the damages precisely then all those persons will be held liable except if one of them can prove that his act did not cause the damage.”*

Standard situation; two gunmen both shoot the same person but is not clear from whom the bullet originates. On the basis of article 6:99 BW both shooters can be held liable, because the damage is at least from one of them. The obligation to compensate rests on both shooters. Under this article the plaintiff only has to claim the whole damage from one of the shooters. The shooter who paid for the whole damage has to claim the proportional share of the other shooter.

With the DES Dochters this was also the case. All defending manufacturers are held liable. But to what extent were the manufacturers held liable?

### *Market Share liability?*

'*Advocaat Generaal*' Hartkamp, member of the commission of advise of the Supreme Court '*Hoge Raad*', proposed that each of the manufactures should be held liable in proportion to their market share. In the Des Dochters Case the '*Hoge Raad*' discussed the 'market share liability' construction but decided that the use of this construction is not acceptable. The '*Hoge Raad*' stated that it did not lead to satisfaction because in this way the risk that a manufacturer has got insufficient funds or the risk that a manufacturer does not exist anymore or is not identifiable anymore is placed upon the shoulder of the injured party and not on that of the manufacturer.

The '*Hoge Raad*' states that another disadvantage for the plaintiff would be that the plaintiff should claim from several or maybe from a great many manufacturers and that between him and the manufacturers has to be determined for what share of the market they are responsible.

And moreover from the view of victim protection there is no appetite for market share liability, because according to article 6:99 BW each liable manufacturer is in principle liable for the whole injury/ damage. It is up to the manufacturer to get the proportional damage/ injury from the other manufacturers and therewith market share can play a role.

### *Conclusion*

The '*Hoge Raad*' held that all the manufacturers could be held liable on the basis of article 6:99 BW, so the manufacturers are held liable collectively. The individual alleged manufacturers were held liable for the complete damage.

The advantage for the DES Dochters was firstly that they did not have to find out who was the particular manufacturer of the DES. And secondly that the manufacturers were held jointly and severably accountable.

Afterwards the manufacturers had to research internally what their obliged payment was, and they had to settle this between each other. Market share can play a role in this of course.

### ***An American Case, on Prescription Drugs Sindell v. Abbott Labs***<sup>13</sup>

#### *Background*

In this case the market share liability is imposed on the manufacturers of DES. The facts are the same as in the Dutch Case; the daughters were unable to identify the exact manufacturers or sellers who sold their mothers the defecting DES. The Californian Court reviewing this case stated that it used the *market share liability* to relieve the injured plaintiffs of the hard task of proof when unable to identify the relevant “seller(s)”.<sup>14</sup>

Even though the Food and Health Administration ordered that the manufacturers had to stop marketing DES, the manufacturers went on marketing it and bringing it on to the market. The defendants knew or should have known that the DES they brought on the market was dangerous; they did not research the product sufficiently and they did not provide sufficient warnings.<sup>15</sup>

The first allegation by the plaintiffs was that manufacturers of DES should be held *jointly liable* irrespective of the fact that the plaintiffs were unable to point out which brand of DES their mothers used exactly.<sup>16</sup>

A way to relieve the plaintiff from the problem of proof is to transit the burden of proof from the plaintiff to the manufacturer, also

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<sup>13</sup> Sindell v. Abbott Labs. 607 P.2.d 924 (Cal 1980)\*. John Goldberg, et al., Tort Law: Responsibilities and Redress 901, Aspen Publishers (2004).

<sup>14</sup> John Goldberg, et al., Tort Law: Responsibilities and Redress 900, Aspen Publishers (2004).

<sup>15</sup> John Goldberg, et al., Tort Law: Responsibilities and Redress 902, Aspen Publishers (2004).

<sup>16</sup> John Goldberg, et al., Tort Law: Responsibilities and Redress 903, Aspen Publishers (2004).

called *alternative liability*.<sup>17</sup> A second way to try to establish the liability of the manufacturers is to argue that they *acted in concert*. And a third way is to spread the liability “*industry wide*.”

The Court stated that the shift of the burden of proof was not reasonable because there was a substantial likelihood that none of the five defendants made the DES which caused the plaintiffs’ injury, because there were 200 companies that manufactured DES.<sup>18</sup>

### *Act in concert*

The elements of the “act in concert” doctrine are provided in section 876 of the (second) Restatement of Torts.

*“For harm resulting to a third person from the tortious conduct of another, one is subject to liability if he (a) does a tortious act in concert with the other or pursuant to a common design with him, or (b) knows that the other’s conduct constitutes a breach of duty and gives substantial assistance or encouragement to the other so to conduct himself, or (c) gives substantial assistance to the other in accomplishing a tortious result and his own conduct, separately considered, constitutes a breach of duty to a third person”.*

The Court states that although the manufacturers relied on each others insufficient test reports, this does not mean that there was a tacit understanding or a common plan between the manufacturers and that they did not act in concert as meant in section 876 of the Restatement of Torts.<sup>19</sup>

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<sup>17</sup> See (P904 Summers v. Tice (1948) 33 Cal. 2d 80, 199 P.2d 1). John Goldberg, et al., Tort Law: Responsibilities and Redress 904, Aspen Publishers (2004). Kenneth S. Abraham, The Form and Functions of Tort Law 110 ed., Foundation Press, 2001

<sup>18</sup> John Goldberg, et al., Tort Law: Responsibilities and Redress 906, Aspen Publishers (2004).

<sup>19</sup> John Goldberg, et al., Tort Law: Responsibilities and Redress 907, Aspen Publishers (2004).

### *Industry- wide liability*

The concept of “industry- wide” or enterprise liability was rejected by the Court. The court said that this case is different from *Hall*<sup>20</sup>, because in *Hall* the defendants were six blasting cap manufacturers who were comprising virtually the whole blasting cap industry in the United States, besides they delegated functions relating to safety of their product to their trade organisation. The Court in the *Sindell* case stated that this case was different because the defendants in *Sindell* did not comprise virtually the whole industry; there were five defendants of the 200 manufacturers market.<sup>21</sup>

### *Market Share liability*

But lucky for the plaintiffs the Court comes with a fourth concept of liability in proportion to the market share. The Court states that society has become increasingly industrially complex and that it is sometimes impossible to trace the specific producer of the product which caused harm to the consumer. Applying the existing doctrines would mean that the injured consumer won't get recovery. The Court wants to meet the changing standards by fashioning a remedy and it chooses for the liability in proportion to market share. The Court says that it is neither the plaintiffs' nor the manufacturers' fault when providing proof of causation fails, because the conduct of the manufacturer marketing a drug the effects of which are delayed for many years played a significant role in creating the unavailability of proof. The Court also argues that the manufacturers of the defect product are better able to bear the costs and that they are in the best position to discover and guard

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<sup>20</sup> *Hall v. E. I. Du Pont de Nemours & Co., Inc.* (E.D.N.Y. 1972) 345 F. Supp. 353.

<sup>21</sup> John Goldberg, et al., *Tort Law: Responsibilities and Redress* 907, Aspen Publishers (2004).& Kenneth S. Abraham, *The Form and Functions of Tort Law* 111 ed., Foundation Press, 2001

against defects in their products and to warn against harmful effects. Holding the manufacturer liable for defects and failure to warn against harmful effects will provide an incentive for product safety.<sup>22</sup>

The Court states that the mere shift of the burden of proof is not appropriate because there is a chance that none of the five defendants produced the offending substance and that the responsible manufacturer would escape liability. But when a substantial share of the market is taken by the manufacturer, a shift of the burden of proof may be appropriate. And in this case five of the six manufacturers are deemed to have produced 90% of the entire DES market. The Court also states that the apportionment of the damages between the defendants can be determined in proportion of market share.

### ***Comparing Des Dochters and Sindell v. Abbott Labs***

These cases are exceptionally suited to compare the Dutch and American Law systems, because both cases involve the same product and the facts are almost identical

In The Netherlands the mothers of the plaintiffs used DES in the period between 1953 and 1967. In the United States the defendants were engaged in the business of manufacturing, promoting, and marketing DES between 1941 and 1971. The American Food and Health Organisation authorized in 1947 the marketing of DES as a miscarriage preventive but only on an experimental basis and including a warning element. From the Dutch case also comes forward that scientists warned the industry against the danger of the DES and they recommended further investigation. In both systems a clear incentive seems to be given to the manufacturers to research the side effects of DES or at least give adequate warnings.

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<sup>22</sup> John Goldberg, et al., *Tort Law: Responsibilities and Redress* 908, Aspen Publishers (2004).

Although in 1971 the American Food and Health Administration ordered to cease marketing and promoting DES for the purpose of preventing miscarriages the manufacturers went on bringing the product on to the market. In 1974 The Dutch Government prohibited the use of DES during pregnancy, and the industry went just on with medicine containing DES. In both cases it is not so that the mothers of the daughters used the drugs after the period that the drugs became prohibited or the order was made that they should cease the marketing and promoting of DES, but it does show the carelessness of the manufactures.

### *The problem to identify the manufacturer*

In both cases the plaintiffs argue that the burden of proof should be shifted to the defendant. A shift in the Burden of proof in law is used to discriminate a weaker party positively, this is sometimes called alternative liability in American law or alternative causation in Dutch law. After a shift the defendant has to prove that he was not responsible for the harm. In both cases a method is sought to relieve the plaintiffs' Burden of Proof. In both cases it is argued that the manufacturers of the defect product are better able to bear the costs and that they are in the best position to discover and guard against defects in their products and to warn against harmful effects. Holding the manufacturer liable for defects and failure of warning against harmful effects will provide an incentive for product safety.

In the Sindell Case the Californian Court uses the 'Market Share Liability' to achieve this relief and in the Des Dochters Case the Dutch Court uses article 6:99 BW to achieve this result.

### *Market Share liability*

The Californian Court wanted to meet the changing standards by fashioning a remedy and it chooses for the liability in proportion

to market share.<sup>23</sup> It concludes that when a substantial share of the market is taken by the manufacturer, a shift of the burden of proof may be appropriate. And in this case five of the six manufacturers are deemed to have produced 90% of the entire DES market. The Court also states that the apportionment of the damages between the defendants can be determined in proportion of market share.

### *Article 6:99 Netherlands' Civil Code*

The 'Hoge Raad' states in the DES Dochters case that article 6:99 BW is meant to help the plaintiff with his burden of proof. On the ground of this article the plaintiff, the daughter, has to start a procedure against one of the manufacturers and only has to allege that the defendant in the relevant period brought DES on to the consumer market in the relevant period and that during this period there were other manufacturers who were liable because of the same mistake, and that the injured party suffered injury, because of the use of DES of her mother, but that it can not be established from which manufacturer the product originates. The *burden of proof* for the points above rests on the DES Dochter.

Article 6:99 BW is a construction to keep a group jointly liable. John Goldberg argues that the Sindell case left open a critical question of apportionment, namely if the liability imposed on the manufactures would be joint and several. In the case *Brown v. Superior Court*<sup>24</sup>, the Court states that it is not.

### *A different level of the burden of proof*

So when the Dutch plaintiff only has to prove that his injury was caused by DES, that in the relevant period the DES manufacturer was active and that there were more manufacturers, the American plaintiff still struggles with identifying the manufacturers on the

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<sup>23</sup> John Goldberg, et al., *Tort Law: Responsibilities and Redress* 908, Aspen Publishers (2004).

<sup>24</sup> *Brown v. Superior Court*, 751 P.2d 470 (Cal. 1988).

basis of market share liability, which worked out in the Sindell case, because in this case five of the six manufacturers are deemed to have produced 90% of the entire DES market.

*Law on prescription drugs can be  
harmful for public health*

Being too hard on the pharmaceutical industry might have some unhealthy side effects. A punishment of the manufacturer can become an indirect slam in the face of society.

Of course one of the first things you think when a manufacturer brought medicine on to the market which later results in a malignant disease is that the manufacturer should be punished. Punishment not only as a ‘relief’ for the injured person but also as a strong incentive for the pharmaceutical to be very careful; to take all the precautionary measures reasonably possible and to do every reasonably possible research on the product and to provide adequate warnings.

I think Dean Prosser provides us with an adequate warning by arguing that making it too easy to hold the manufacturer liable would deter pharmaceuticals to bring new “good” products on to the market and would raise the price of medicine.<sup>25</sup>

This seems a very good argument for both American and Dutch Legal systems. Although it appears from comparing the two cases it seems that Dutch law helps the plaintiff more with the problem of proof, and therefore the manufacturer can be sooner held liable than in the American system, when the manufacturer is held liable. In the American law system the price he pays will be much higher. *Real damages* are all those which the Dutch Private Law knows as damages. In the American Tort Law the *unreal damages, punitive damages, (also called exemplary damages)* are added up to

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<sup>25</sup> John Goldberg, et al., *Tort Law: Responsibilities and Redress* 914, Aspen Publishers (2004).

the real damages.<sup>26</sup> Punitive damages can be very high and can bring much harm to a pharmaceutical company, consequently insurance costs go up and the costs of risks are calculated in the price of the products, which results in more expensive medicine or no medicine at all.

For instance in the Sindell case the plaintiff seeks compensatory damages of \$ 1 million dollars and punitive damages of \$ 10 million dollars. So in Dutch Law only the first amount can be compensated and that makes a very big difference. A simple calculation shows that if Dutch law holds the manufacturer 11 times sooner liable than American Law the negative effect on the economical side of the medicine market is even and therefore the argument of the easiness to hold a manufacturer liable is for Dutch law less powerful, but still not powerless.

*Making sure that a medicine manufacturer  
takes good care*

In the last paragraph I explained that being too harsh on a manufacturer of medicine can have a negative side effect for society. On the other hand being too easy on these manufacturers could have a very negative side effect too. We saw that the total of damages in the American Law system can be much higher than in the Dutch system, on the other hand we saw that the manufacturers can be held liable earlier in the Dutch system.

Of course it is the task of law to give manufacturers a good incentive to take all the reasonable care and deter them from lacking to take precautionary measures, adequate research and the providing of adequate warnings. Each system has to find an optimal balance to push the manufacturer to take good care of his product without having negative side effects, like extremely high prices for medicine or a decrease of medicine development.

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<sup>26</sup> Kenneth S. Abraham, *The Form and Functions of Tort Law* 221 ed., Foundation Press, 2001

The American '*punitive damage*' system gives a strong incentive to the manufacturer to take good care of his product. A question that could be made is if only '*real damages*' would be a strong enough incentive for the manufacturer to take good care for his product. I think the Dutch system compensates this difference to relieve the plaintiff more in his burden of proof.

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