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The Ambiguous Concept of Product Defectiveness and the Business Risk: Different Approaches of European and U.S. Courts Comparing the Producer's and User's Behaviour

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The Ambiguous Concept of Product Defectiveness and the Business Risk: Different Approaches of European and U.S. Courts Comparing the Producer's and User's Behaviour*

Eleonora Rajneri

Abstract

The European directive on product liability defines as defective a product that "does not provide the safety which a person is entitled to expect." In the last years, European national courts have given a number of diverse interpretations of such a broadly and ambiguous defined provision. For an analytical comparison among court decisions, I suggest to distinguish between (1) risk of damages that were foreseeable and avoidable at the time when the product was put into circulation, (2) risk of damages that were unforeseeable and unavoidable, and (3) risk of damages that were statistically foreseeable yet unavoidable.

As regards the first category, the Italian *Corte di Cassazione* has pointed out that the legal provision implies a comparison between the conduct of the victim and that of the producer in order to assess which one of two was in the best position to avoid this risk of damage. Therefore, the mechanism of apportionment of the risk is not different from the one implied by a fault liability rule. It is interesting to note that the third American Restatement on torts does not make any reference to the user's behavior in its black letter on product defectiveness. The analysis shows how this different approach impacts on judicial decision-making.

With respect to the second category, the development risk defense clause (expressly provided for by the directive) produces the effect of leaving the victim uncompensated, despite the fact that the European lawmaker has declared his intention to place a liability without fault upon the producer.

The problem arises with the third category, because the directive has not envisaged a specific rule for those damages that were statistically foreseeable yet unavoidable, such as the manufacturing defects. On the contrary, Italian law makes explicit that a product "is defective if it does not provide the safety normally provided by other products in the same series." Under this rule (that is one of the application of a more broad doctrine on business risk), the producer is deemed

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strictly liable for those damages that, even though unavoidable, were manageable as quantifiable in advance. The question is whether this doctrine could be applied also to those design defects actually foreseen by the producer. Following the business risk doctrine, the producer should be held strictly liable as he had accepted the risk in full awareness, having taken it into account in his cost/benefit analysis. However, according to those European courts that do apply the risk/utility test (such as the German courts), the producer is insulated from liability if the cost of an alternative design overweighed the foreseeable risk of damage.

KEYWORDS: product liability, product defectiveness, European law, business risk

1. The functional ambiguity of the European product liability law and the elusive concept of defectiveness[1]

In 2007 the Italian Supreme Court (*Corte di Cassazione*) issued two of its first decisions relating to defective products under Directive 85/374/EEC (implemented in Italy by Presidential Decree n. 224/88 and subsequently incorporated into Title II of the Consumer Code)[2]. The fact that the *Corte di Cassazione* has not yet had many opportunities to make decisions on this subject is, in itself, not particularly surprising since it is well known that the Directive has had a limited impact to date, especially when compared with the high rate of product liability litigation in the USA[3]. The reasons, both from the procedural and substantive points of view, for which the Directive has scarcely been applied in any European Union (EU) member state (with the exception of Austria) are considered elsewhere[4]. Farther, it has to be considered that the ambiguity in the legal provisions made the outcome of any legal action unpredictable, with the result of discouraging those individuals who – having already suffered damage – are not inclined to face the risk of also having to pay litigation costs[5].

Therefore these decisions are worth mentioning because they encourage the *Corte di Cassazione* to specify the principles for the allocation of the burden of proof between the producer and the victim, as well as principles for the interpretation of that Article of the Directive that is the most important as well as the most ambiguous: article 6 defining the concept of defect. Its ambiguity is first due to the fact that defectiveness is a relative concept, a concept which imply a tradeoff between additional expenditures of funds and safety gains they will

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[1] The expression "elusive concept of defectiveness" has been used in the decision of the celebrated Pinto case (Grimshaw v. Ford Motor Co., 1 19 Cal.App.3d 757, 174 Cal. Rptr. 348, 1981).

[2] Among dedicated works in Italian civil law on the issue of liability for damage due to defective products, see: G. GHIDINI, *La responsabilità del produttore di beni di consumo*, Milano, 1970; U. CARNEVALI, *La responsabilità del produttore*, Milano, 1979; V. CASTRONOVO, *Problema e sistema del danno da prodotti*, Milano, 1979; G. ALPA e P. BESSONE, *La responsabilità del produttore*, Milano, 2nd ed., 1987; A. GORASSINI, *Contributo per un sistema della responsabilità del produttore*, Milano, 1990. For criminal law see: C. PIERGALLINI, *Danno da prodotto e responsabilità penale,* Milano, 2004; PETRINI, *Reati di pericolo e tutela della salute dei consumatori,* Milano, 1990.

[3] In case law reports, apart from the two 2007 decision, see: Cass. Civ. 18th April 2005 n. 12750.

[4] A. CAVALIERE, *Product Liability in the European Union: Compensation and Deterrence Issues,* in *European J. of Law and Economics*, 18: 299–318, 2004. Please refer to E. RAJNERI, *Interaction Between the European Directive on Product Liability and the Former Liability Regime in Italy*, in D.FAIRGRIEVE, (ed.), *Product Liability Law in Comparative Perspective,* Cambridge University Press, 2005, pages 67-82.

[5] The possibility of entering into champerty (contingency fee agreement in the US) with one's lawyer, introduced in Italy through Law Decree n. 233 of 4 July 2006, does not at any rate relieve the losing party from the obligation of paying the legal expenses of the opponent.

produce; in fact it cannot be reasonably expect producers to make their products completely safe (otherwise every car "would have to be built like a tank"[6]). Furthermore it is very well known, that the product liability law is always the result of a balance among two opposing needs: the first is to offer consumers protection that is adequate for a developed industrial economic system; the other is the need to encourage competition of companies in the global market, promoting, amongst other things, technological research and innovation. While the first requirement is stated in the legal text of the European Directive, this latter has remained hidden in the folds of a legal text that provides a complex procedural mechanism in which the right of the victim to claim compensation without having to prove the producer's fault is counterbalanced by a range of defenses and exclusions offered to the producer[7].

The underlying ambiguity on the actual aims of the rule inevitably imposes on the judge the burden of making a choice which is, ultimately, political[8]. The uncertainty about the result of the application of the Directive creates inefficiency as it makes difficult for enterprises to assess the risk they assume carrying on their business and, by consequence, the evaluation of the insurance rates. The decisions of the *Corte di Cassazione* therefore, as this article explains, have the merit of reducing the uncertainty making explicit some of the principles to be taken into account in order to apply a rule ambiguous in its aims and the elusive concept of defectiveness.

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[6] W.K. Viscusi, *Reforming Products Liability,* Harvard Un. Press, 1991, p.2.

[7] For example, the producer is not liable if "having regard to the circumstances, it is probable that the defect which caused the damage did not exist at the time when the product was put into circulation by him or that this defect came into being afterwards" (article 120, para. 2); again, he is not liable if ten years have elapsed from the moment when the product was put on the market (which rules out the liability of the producer, for example, in cases of illnesses having a latency period of more than ten years); or he is not liable "if the defect is due to compliance of the product with mandatory regulations issued by the public authorities" (article 118(d)); furthermore, he is not liable "if the state of scientific and technical knowledge at the time when the product was put into circulation was not such as to enable the defect to be discovered" (article 118(e)). Not to mention the limits set by lawmakers on the quantification of damages for compensation, limits that are sometimes not supported by a consistent theoretical justification (see J. STAPLETON, *Product Liability*, Butterworths, 1994, p. 99).

[8] This delicate role of law was highlighted by several essays published on the *Rassegna di Diritto Civile*. In particular, see: P. PERLINGIERI, *Mercato, solidarietà e diritti umani*, in *Rassegna di Diritto Civile* 1995, p. 85-.; N. LIPARI, *Riflessioni di un giurista sul rapporto tra mercato e solidarietà*, ivi, 1995, p. 24-. The political role of the private law lawmaker was highlighted during the debate on the European Civil Code in: U. MATTEI, *Hard Minimal Code Now! A critique of softness and plea for responsibility in the European debate over codification,* in S. GRUNDMANN and J. STUYCK (ed.), *An academic green paper on European contract law,* page 215. Following on the subject, the *Study Group on Social Justice in European Private Law* was founded (see: *Social Justice in European Contract Law: a Manifesto*, in *European Law Journal,* 2004, pages 653-674).

US legal analysts, as a matter of fact, have been discussing the definition of defect for over forty years in an attempt to set out abstract principles for selecting the legally relevant cases from a diverse range[9]. Currently, the new *Restatement on Torts* of 1998 (the Third) dedicates pages to breaking down the concept of defect into ever smaller categories in order to find a balance between the opposing interests of the parties that also takes into account the interest of the collectivity**,** as it is explained farther down[10].

2. *The Italian* Corte di Cassazione *decides on the principles for the allocation of the burden of proof between producers and injured parties*

Both decisions of the *Corte di Cassazione* focus on the principles for the allocation of the burden of proof between the parties[11].

In decision n. 6007/2007, the plaintiff alleged that she sustained injuries following an allergic reaction caused by a hair dye applied by a hairdresser in a salon. She brought an action against both the company producing the hair dye and the owner of the hairdressing salon, asking the judge to award joint damages. Both the damage and the causal relationship between the use of the product and the injury were established. In the lower court, the claim succeeded and the defendants were held liable jointly to pay ten million Lire in compensation to the plaintiff[12]. However, the Court of Appeal found that the defect had not been

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[9] D.OWEN, *Towards a proper test for detective design defectiveness,* 75 (1997)*, Tex Law Rev*., 1661.

[10] See §6.

[11] The fact that the resolution of disputes depends almost exclusively on the allocation of the burden of proof shows how this, far from being a mere procedural instrument, produces undeniable consequences on a substantial level. The dynamics of the trial process shapes the substantial definition of the liability under consideration. Also the presumption of fault introduced by case law in the period before the implementation of the Directive on the basis of the *id quod plerumque accidit* principle, even if from a formal point of view does not change the ground of the case (A. GORASSINI, *Contributo per un sistema della responsabilità del produttore*, as above, p. 66), at least in exceptional cases, it may change the resolution of the case substantially. When the plaintiff in the liability dispute is not able to prove the fault of the defendant and the defendant, for his part, is not able to prove his lack of fault, if the fault rule is applied, the plaintiff loses and the defendant is exempted from any liability. Vice-versa, if the lawmaker (or the judge) presumes the existence of fault, the defendant loses. More generally, on the use in case law of technical measures such as presumptions to adapt positive law to economic/social evolution, see: G. ALPA, *L'arte di giudicare,* Bari, 1996.

[12] With reference to the possibility of a number of liable parties, article 121 of the Consumer Code specifically made use of the concept of risk individually created in order to calculate the amount of damages to be paid by each of them; this is noteworthy not only because it is an extension with respect to the provisions of the EC Directive, but especially because it appears to be the first time

proved and that the product had in fact been used for decades without any report of harmful effects on consumers. Consequently, the Court of Appeal reversed the first instance decision, rejecting the claim against the producer (the sole appellant).

The *Corte di Cassazione*, in turn, confirmed the Court of Appeal's decision, stating firstly that the burden is on the plaintiff to prove the product defect as a basic premise for the right claimed under article 2967 of the Civil Code (as specifically provided for in Article 4 of the Directive, implemented in Italy by article 120 of the Consumer Code). In justifying this allocation of the burden of proof between the parties, the *Corte di Cassazione* observed that, if it were sufficient for the victim to prove the damage and the causal relationship between this and the use of the product, then would give rise to absolute objective liability of the producer. This interpretation, however, would clash with rules that specifically limit the liability of the producer to those cases of damage occurring through normal use of the product (art. 6 lett.b of the Directive specifically refers to "the use to which it could reasonably be expected that the product would be put"). In other words, (and this is the feature of great relevance in decision n. 6007/2007), the Court confirmed that there are damages, although causally related to the use of the product, for which the producer escapes liability because (in light of the law) they should be attributed to self-liability of the victim who could have avoided the damage if only s/he had used the product with more care. In the case under consideration, the Court stated that it is the injured person who should bear the "abnormal immune reaction of her body to foreign substances that are normally harmless"; more so since the instructions for use of the dye warned of the possibility that it may cause an allergic reaction and specifically recommended conducting a sensitivity test.

In decision n. 20985/2007, the *Corte di Cassazione* further pronounced on the allocation of the burden of proof for civil liability for damages caused by defective products under article 8 of Presidential Decree n. 224/1988[13]. In this case, the claimant had obtained a breast implant. After little more than two years, however, the implant inexplicably leaked and the saline solution inside it spread into the local tissue, necessitating further surgery for the removal of the implant shell, drainage of tissues and other therapies. The producer (joined together as defendant with the supplier of the implant and the hospital where the implant was inserted) stated in defense that there was no proof that the defect existed at the time the product was put on the market. The *Corte di Cassazione* overturned the

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that the Italian lawmakers specifically mention the concept of risk, (even if not on the basis of the principle of attribution of liability, but as a criteria of division of damages among the liable parties)**;** M. FRANZONI, *Dei fatti illeciti,* in Scialoja- Branca (dir.)*, Commentario al Codice Civile,* Bologna, 1993 p.754-756. See note 16.

[13] Art. 120 of the Consumer Code.

appeal decision stating the following principle: "The first paragraph of article 8 of Presidential Decree n.224 of 24 May 1988 is to be interpreted such that the damaged party must prove (in addition to the damage and the causal relationship mentioned above) that the use of the product led to abnormal results with respect to normal expectations such as to show the existence of a defect under article 5 of the Decree; the producer must prove (under articles 6 and 8 of the Decree) that it is probable that the defect did not exist at the moment at which the product was put onto the market". Consequently, the *Corte di Cassazione* remitted to the Corte di Appello di Rinvio (in referral proceedings) the task of evaluating the evidence brought by the producer relating to any lack of defects in the implant at the moment at which it was put onto the market[14].

3. The plaintiff has the burden of proving product defectiveness

In both 2007 decisions, the *Corte di Cassazione* had to clarify that the victim bears the burden of proving product defect. This is surprising when compared to the unequivocal statement of Article 4 of the Directive, which is: "[t]he injured person shall be required to prove the damage, the defect and the causal relationship between defect and damage". This provision was adopted literally by the Italian lawmakers in article 120 of the Consumer Code. What happened subsequently is that, in certain cases, the first instance courts considered the product's defect as being established by way of deductive reasoning, holding that it is probable that damage occurring during the use of the product may be linked to a defect in the product itself rather than to other causes.

Consider, for example, the case of the car accident decided by the Courts of Rome in 2003[15]. The car in question, following gently braking at the beginning of a wide bend to the left, started spinning and hitting the right- and left-hand side guard-rails, leading to the death of one passenger and the injury of three others. The expert evidence showed that the veering of the car at that speed could only have occurred due to the erratic blocking of the wheels which may be attributed "with a good degree of probability" to a fault in the braking system. The decisive factor in this case was that a few months before the accident the producer had sent a letter to its customers asking them to inspect the front brake pipes as soon as

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[14] The *Corte di Cassazione* remitted to the Court of Appeal also the duty of evaluating whether the generic warnings issued by the producer concerning the risks that may derive from the positioning of a breast implant validly represent an exemption of liability under article 10 para. 2 of the Presidential Decree ("Compensation is not due when the victim was aware of the defect in the product and of the risk deriving therefrom and nonetheless exposed him/herself to such risk"). On the issue avoided by the Court see below § 9 lett. c).

[15] Tribunal of Rome, 4th Dec. 2003, in *Danno e Resp.,* 2004, 527 (with note by G.PONZANELLI).

possible since a number of checks on similar cars in that series had shown that such pipes may have leaks.

This decision is not far from the approach of case law according to which proof of a causal relationship in civil law inevitably involves a judgment based on probability: only recently, the *Corte di Cassazione*, in clarifying the functional differences between the concepts of causation in civil law and in criminal law, stated "The phrase *ascertainment of the causal relationship* in itself hides an initial, lexical trap, since any *ascertainment* invites and tends towards a logically deductive or logically inductive process leading to a conclusion that is, in fact, *certain*: while an investigation, as strict as it may be, aimed at predicting its existence in terms of law often stops, at least on the civil side, at the threshold of probabilistic judgment"[16] .

However, in the case of the accident occurred to the driver of a motorbike that crashed due to a collapse in the steering, the same Courts of Rome held the producer liable, basing its decision on expert evidence expressed in merely probabilistic terms and in the absence of any other element of proof, even if only

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[16] Corte di Cass. S.U. n. 21619/07. In legal theory: P. TRIMARCHI, *Causalità e danno,* Milano, 1967. Having therefore said that a causal nexus consists in the evaluation of the statistical incidence of a given cause on a given effect in relation to other causes, in certain legal systems some case law decisions tried to avoid the radical choice between awarding compensation against the defendant or leaving the damages with the victim, reflecting this uncertainty in the quantification of damages. For example, in a case of tumor due to exposure to asbestos in the course of a series of jobs for several employers, in view of the impossibility of proving exactly at what moment the condition was caused, the House of Lords awarded against each defendant a proportion of the damages, calculated as a ratio of the increased risk to which each of them had exposed the victim (*Barker v. Corus plc and other*s, 2006, UKHL 20, for a comment on this case see: N. COGGIOLA, *L'accertamento del nesso di causalità nei casi di mesoteliomi conseguenti ad esposizione ad amianto: una nuova pronuncia della House of Lords,* in *Resp. Civ. e Prev.,* 2006, p. 1796 onwards**)**. In Italian legal theory such a solution is supported in: FORCHIELLI, *Il rapporto di causalità nella responsabilità civile,*Padova, 1960, 145. In the case decided by the *Corte di Cassazione*, the Court of Appeal of Genova reduced the compensation by 50% due to the strong uncertainties on the degree of incidence of the negligent conduct of the defendant with respect to the cause of the damage. (Court of Appeal of Genova, 27 April 2002 n. 432). The *Corte di Cassazione* first of all stated that the establishment of the causal nexus does not in any way involve the quantification of damages to be paid in compensation, since the first concerns the relationship between conduct and harmful event, while the second concerns the relationship between the harmful event and the damages subsequently suffered by the victim. In this way the decision, though in the absence of any specific statement on the point, appears to avoid any possibility of connecting the quantification of damages with the degree of causal incidence of the conduct of the defendant. It must be observed, however, that despite the effort of the Court to keep the various elements of the wrongful fact separate, the conceptual differences between causal nexus and the fault dissolve when the fault of another co-responsible person or of the victim interrupts the causal chain, or becomes a "cause sufficient in itself to produce the event".

circumstantial[17]. Since it was therefore impossible to rule out that the accident may have been attributed to the carelessness of the motorcycle driver, the Courts stated that Presidential Decree n. 224/88 attributes the producer with a "presumptive" liability and that "it is advisable to remember that the unknown cause is attributed to the party who is also attributed with presumptive liability".

Another case in which little was needed to prove the defect is that of a woman who claimed she had suffered injury to her jaw caused by the presence of a shard of iron contained in a vegetable condiment for rice. The Justice of Peace of Monza considered the presence of the shard in the condiment (and not in the rice to which the condiment was added) as being established on the basis of the statements of the mother and sister of the injured person, according to whom the rice and salt used had been carefully checked and cleaned before cooking; consequently, the request by the producer to show that the jars containing the vegetable condiment are passed through a metal detector before being sealed was considered to be irrelevant[18].

It is a short step from here to state the reversal of the burden of proof, such that the defendant producer is asked to prove the absence of product defect in order to escape liability. In other words, the decisions of the first instance courts have gradually softened the burden of proof of the plaintiff, firstly by considering the product's defect as being proved on the basis of mere inferences, then by being satisfied with merely probabilistic reasoning, to stating that the law under consideration introduces a presumption of defect such that it is sufficient for the victim to prove the damage and the fact that this damage derived from the use of the product, in order to be awarded compensation.

The decision by the *Corte di Cassazione*, therefore, reverses the approach of first instance courts following the principles for the application of the law that were specifically envisaged by the EC lawmakers.

These principles, on the other hand, appear to be strictly followed by other European judges. A brief look at the judgments of other EU member states reveals that other courts are in general quite strict in gathering and evaluating all the technical data required for purposes of establishing whether the product used may be defined as being defective under the Directive, ruling out any other possible cause: especially in Germany, UK and Netherland courts require the plaintiff not just to prove that the product malfunctioned but also the exact technical reason of the malfunctioning[19].

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[17] Tribunal of Rome 3rd Nov. 2003, in *Danno e Resp.,* 2004, 529.

[18] Justice of Peace of Monza 20th March 1997 n. 1386, in *Arch.Civ.,* 1997, 876 (with note by V. SANTARSIERE).

[19] For example, in the case of a bottle containing a fizzy drink that exploded in the hands of a barman, the Dutch Supreme Court held that if the victim is not able to prove the defect in the product that has been destroyed, s/he must then positively prove that there are no other possible

4. The Corte di Cassazione *explains that the concept of defect takes into account the relationship between the conduct of the user and that of the producer*

Having stated that the defect must be proved by the victim (either positively or by ruling out other causes for damage), we return to the crucial issue of the law under consideration, that is, the definition of product defect. Article 6 of the Directive (incorporated literally by the Italian lawmaker into article 117 of the Consumer Code) defines as a defective product one that does not offer the level of safety that users might legitimately expect. And here we are within the limits of tautology. Jane Stapleton observes that EC lawmakers produced a circular definition[20]. However, Article 6 then states that, in evaluating legitimate expectations, they have to be taken into account various external factors, such as the presentation of the product and the use to which it could reasonably be expected to be put. The Directive refers to a new element with respect to those identified in US jurisprudence, that is, the behavior of the user of the product: the Directive makes it clear that there may be damages resulting from the use of the product that may be linked to the responsibility of whoever used the product in a certain way instead of to a presumed defect in the product itself[21]. Therefore this definition of defect brings to light a relationship between the behavior of the victim and producer such that the latter may be held liable for the damage only when the

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causes for the damage beyond the defect in the product, and in particular, s/he must prove that s/he used the product in an appropriate manner (HR 24th December 1993, NJ 1994, 214).

[20] J. STAPLETON, *Restatement (Third) of Torts: Product Liability, an Anglo-Australian Perspective,* in *Weshburn Law J.,* vol. 39 (2000), 377.

[21] In other words, the negligence attributed to the victim of the damages rules out the defect in the product. This is a case that is very different from the one in which, having ascertained that the damage was caused by a defect in the product, the negligence by the user leads to further harmful consequences with respect to those that would have occurred anyway, also in the case of proper use. In this case, there will simply be a reduction in the amount of compensation to be paid to the victim under article 122 of the Consumer Code, referring to article 1227 of the Civil Code. For example, in the case concerning damages suffered due to the explosion of fireworks lit by a person lacking the required licenses, the *Corte di Cassazione* reduced the compensation by 50%. During the trial, it was proven as a matter of fact that the product was undoubtedly defective since it exploded on the ground and not in flight; however, it was held that an expert user would have realized the abnormal working of the firework and would have immediately walked away, with the result of mitigating the consequences of the early explosion of the device (Cass. Civ. 18th April 2005 n. 12750, as mentioned).

former is exempted from any responsibility for his or her actions having used the product in a proper way[22].

It appears that the EC lawmakers, in comparing the two behaviors, implicitly referred to the well-known principles of the cheapest cost avoider devised by Guido Calabresi[23], forcing the interpreter to ask which of the two subjects was in the best position to avoid the risk of damage, or more precisely, which of the two, having the opportunity of foreseeing that specific risk of damage, actually had the opportunity of choosing whether to take on that risk or avoid it[24]. As clarified by Calabresi, this type of evaluation of behavior of the individuals involved requires from the judge an *ex ante* reasoning, based on the information accessible to the two parties at the moment in which they acted, rather than an *ex post* analysis on who, at the end of the day, could have avoided that damage at the lowest cost[25]. EC lawmakers specified in Article 6 of the Directive that the effort to contextualize *ex ante* the behavior of the actors (assuming that they were strangers one to the other) should be made on the basis of the information that was available to anyone, i.e. based on objective, external, visible elements of the case, such as the presentation of the product, the way in which it was advertised and the category of subjects to whom it is specifically addressed (children, adults, adults suffering from specific illnesses, etc.). In this sense, the Directive's definition of defect does not coincide with the so-called consumer expectation test that, was rejected by US legal experts on the basis that, instead of reasoning by general categories, it induces the jury to take into account the specific cases of the parties, their subjective inclinations, idiosyncrasies and

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[22] In general, on the principle of self-liability in civil law, see: S. PUGLIATTI, *Autoresponsabilità,* in Enc. Giur., Milano, 1959, *ad vocem*

[23] G. CALABRESI, *The Cost of Accidents, A Legal and Economic Analysis,* Yale University Press, 1970. On the application of the theory in question to the regulation of liability for defective products, see also: P. TRIMARCHI, *La responsabilità del fabbricante nella direttiva comunitaria*, in *Riv. Soc.*, 1986, p. 595.

[24] The theory of the cheapest cost avoider induces the interpreter to make an analysis based only on the comparison between the interests of the two parties in the case, without considering the general interest, which is instead a relevant factor in terms of the risk-utility test (see §6).

[25] G. CALABRESI and J.T. HIRSCHOFF, *Toward a Test for Strict Liability in Tort,* 81 Yale L.J. 1055 (1972): "The issue becomes not *whether* avoidance is worth it, but which of the parties is relatively more likely to find out whether avoidance is worth it". In this sense the authors explain the difference between their theory and the Learned Hand Formula and, as stated below, they draw closer to the type of assessment made by Italian judges when they apply a concept of concrete fault (on the Learned Hand Formula see: F. Parisi, *Learned Hand formula of negligence*, in Digesto IV Ed. Sez. Civ., Torino, 1987, *ad vocem*).

personal cognitive limitations, leading to a process that easily induces the jury to justify anyway the behavior of the victim[26].

The decision by the *Corte di Cassazione* therefore has the merit of highlighting how the relationship between the behavior of the subjects involved ought to be considered for a proper application of the definition of defect. The decision states: "reference to normal conditions of use that define the scope of duty of care by the producer exclude the guarantee of safety in conditions of abnormal use which may logically occur not only from abuse or prohibited use (which may be obvious on a first reading) but also from abnormal circumstances which, albeit not ascribable to the consumer, turn the normally harmless product into a vehicle for damage (to health). Among these circumstances may and must be included specific prohibitive health conditions of the consumer, even if temporary, at the moment in which s/he uses the product, and in particular, the abnormal immune reactions of his/her body towards normally harmless external substances which make the product, or some of its components, suddenly become an allergen for the consumer". This means that each time the consumer, as in our case, suffers from a condition that makes him/her particularly sensitive towards certain substances, it is undoubtedly more effective to allocate to him/her the duty of care, with the burden of checking the specific risk of injury by using suitable precautions (possibly purchasing products specifically designed for allergic users), rather than imposing on the producer the obligation to take into account potential abnormal reactions in a very small percentage of consumers. Such an obligation would in fact raise production costs and consequently the product's price, to the harm of all users, including those who do not require a specific non-allergenic product[27].

5. The victim, from self-responsibility to paternalism: the choice for the judge

It must be said however that, beyond abstract formulae devised by economic lawyers and directions on method that may be issued by a judge striving for consistent interpretation and application of the law, the factors to be taken into account to identify the cheapest cost avoider are not ones that can be quantified

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[26] A.D. TWERSKI, *From Risk-utility to Consumer Expectation: enhancing the Role of judicial Screening in Product Liability Litigation*, in 11*Hofstra Law Review* 861 (1983). J. STAPLETON, *Product Liability*, as above, pages 234-236.

[27] The same reasoning could probably provide an answer to the question asked by Jane Stapleton on who should be held liable for damages caused by the collapse of a chair under the weight of a 300 pound man: the producer of the chair or the 300 pound man? (J. STAPLETON, *Restatement (third) of torts,* as above 379).

and, therefore, it is once again up to the judge to decide how far to implement the principle of self-responsibility[28].

As an example of how the different attitudes of judges may have an influence in this sense, consider the case of the McDonalds coffee that was presented in the same way to a US and an English judge. In these cases, consumers on both sides of the Atlantic claimed they were scalded after spilling cups of hot coffee on themselves. The plaintiffs argued that McDonalds should be held liable for having sold a product that did not have a level of safety that consumers may legitimately be entitled to expect, due to the hot temperature of the coffee, which expert witnesses testified was hotter than usual standards. The US judge awarded the injured consumer a considerable amount in compensation (2.7 million US dollars), thanks to the mechanism of punitive damages[29]; the English judge, on the other hand, did no more than remind the consumer to handle hot beverages with care, sending him home without compensation of any sort[30].

The attitude of the judge plays a key role in particular in cases concerning a warning defect. Cases of omitted information are those in which the product does not create problems if used correctly, but causes injury if used in unusual ways. These are, in other words, the cases with the most doubtful solution because the producer could be considered liable for not having appropriately informed the consumer of the consequences of a different use from normal, or alternatively hold the consumer liable for having used the product in an unusual way.

Although pre-dating the implementation of the EC Directive, two earlier Polish cases show the consequences of an excessively paternalistic attitude towards the consumer[31]. The first decision, issued by the Polish Supreme Court in 1972[32], concerns the case of the farmer who bought a chemical product to be used in his warehouse. The instructions on the package warned that use in a closed

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[28] For this reason the database project created by the British Institute of International and Comparative Law (BIICL)] in London, to which I participated as national *rapporteur*, was of great interest. The project consisted in gathering all the decisions from various national cases applying the EC Product Liability Directive. The data was gathered, translated into English and presented in an agreed conceptual framework for each country and published on the BIICL website to enable cross research by legal reference or key word.

[29] *Liebeck v. McDonald's Restaurants* P.T.S. Inc. (N.M. Dist. 1994).

[30] *Bogle and Others v. McDonald's Restaurants* Ltd (2002) All ER (D) 436. See para. 80: "They expect precautions to be taken to guard this risk but not to the point that they are denied the basic utility of being able to buy hot drinks to be consumed on the premises from a cup with the lid off".

[31] The Polish legal system attributed to the producer liability for damages caused by defective products by way of the general non-contractual liability regime, presuming the defendant's guilt on the basis of a *res ipsa loquitur* reasoning (M. TULIBACKA, *Product Liability law in Transition,* 2009, Ashgate; M SENGAYEN TULIBACKA, *Product liability law in Central Europe and the true impact of the Product Liability Directive,* in D.FAIRGRIEVE, (editor), *Product Liability Law in Comparative Perspective* as above, pages 244-294)

[32] Polish Supreme Court, 28 June 1972, n. 228.

space may lead to poisoning and recommended the use of a mask to protect against contamination from benzol. The farmer used the product once without the mask and was hospitalized for poisoning. Having left hospital, he used the product again, this time with a mask, but not a mask for benzol. As a consequence, the farmer and his son died of poisoning. The court attributed liability to the producer for not having specified in the warnings that poisoning could lead to death! In a case decided in 2000 before a Polish Court of Appeal[33], the plaintiff used spray cans to clean the bathroom. Warnings on the product recommended airing the room after use and to take care because the product was inflammable. Immediately after spraying two cans in the bathroom, the consumer flicked the switch on the washing machine, which activated a spark, causing an explosion of the gas in the room. The court determined that the producer of the cans was liable for those damages since he had not warned the consumer with sufficient clarity about the risks of explosion associated with the use of an inflammable product.

The paternalistic attitude shown by the Polish judge is explained by the fact that these decisions were taken when the socialist regime was still in power: in a non-competitive market, particularly strict *ex ante* and *ex post* control mechanisms are required in order to prevent the marketing of defective products. The same attitude would therefore not be justifiable in the market economies of EU member states where competition between companies (and therefore, reputational risk) effectively acts as a deterrent.

In this sense, the Italian case where the producer of a coffee machine was held liable for damages caused by its explosion is puzzling[34]. The expert testified that the explosion was caused by a lime scale obstruction of the safety valve, which had not been replaced for years. The judge held the coffee machine producer liable for not having advised the consumer to change the valve when it became obstructed. This decision is puzzling since, by inducing the producer to include information that should be widely known, the range of information and warnings to the consumer could be vastly increased, reducing the visibility of what is really important.

More generally, rules with a purposeful paternalistic attitude, that goes further the simple duty of filling in gaps in information, or in specific and well-defined cognitive limitations of the consumer, risk being inefficient as they free the consumer from any form of responsibility for his or her actions[35].

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[33] Apages Bialystock, 30 November 2000, n. 340.
[34] Tribunal of Vercelli 14 February 2005, in *Danno e Resp.,* 2005, 1125.
[35] In the conflict between paternalism and freedom in self-determination pervading the consumer protection regime, the legal analyst may make use of cognitive science, as wisely suggested in: R. CATERINA, *Paternalismo e antipaternalismo nel diritto privato*, in *Rivista di diritto civile*, 2005, *II*, 771–796.

6. The definition of defectiveness in the US legal system from the second to the third Restatement on torts

The interrelationship between producer's and user's behaviors implied by the European Directive is of particular interest if compared with the definition of defectiveness given by the American Restatement (third) on torts. Before that, the § 402A of the Restatement (second) had only taken into account the so called manufacturing defects, i.d. those defects which affect some of the products of the same line, making the producer strictly liable for damages caused by them. The progressive growth of product liability costs and litigation (which produced the tripling of insurance premium from 1984 to 1986) led to realize that the United States was in the midst of a "product liability crisis"[36]. The following various attempts of reform ended in 1998 with the definition of defectiveness drafted by the two co-reporters of the Restatement third on product liability, proff. Aaron D. Twerki and James A. Henderson. They divided the concept of product defect into the three subcategories that American courts had come to recognize, setting apart manufacturing defects, from design defects and failures to warn defects[37]. The latter arise in products that carry inherent non obvious dangers which could be mitigated through adequate warnings to the user, while a product "is defective in design when the foreseeable risks of harm posed by the product could have been reduced or avoided by the adoption of a reasonable alternative design by the seller or other distributor, or a predecessor in the commercial chain of distribution, and the omission of the alternative design renders the product not reasonably safe".

Otherwise said, the co-reporters, aiming to implicitly reintroduce a liability rule based on negligence (as they admitted later on)[38], focused the definition of design defect on the risk/utility test, which has been previously elaborated by J. Wade[39], subsequently revised by the legal doctrine and adopted in different ways by some courts[40].

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[36] W.K.Viscusi, *Reforming products liability,* cit., p. 4.

[37] See RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § § 1-2 (1998).

[38] A. TWERSKI and J. HENDERSON, *The Products Liability Restatement: Was It a Success?: Manufacturers' Liability for Defective Product Designs: The Triumph of Risk-Utility* ,74 Brooklyn L. Rev. [2009], pag. 1061.

[39]Wade offered a list of factors he deemed significant in applying the "unreasonably dangerous standard: (1) The usefulness and desirability of the product-its utility to the user and to the public as a whole. (2) The safety aspects of the product-the likelihood that it will cause injury, and the probable seriousness of the injury. (3) The availability of a substitute product which would meet the same need and not be as unsafe. (4) The manufacturer's ability to eliminate the unsafe character of the product without impairing its usefulness or making it too expensive to maintain its utility. (5) The user's ability to avoid danger by the exercise of care in the use of the product. (6)

The test involves an assessment of whether the cost that the producer would have had to incur in order to prevent the risk of injury (by using a different design) would have been lower than the overall cost of damages that were foreseeable at the moment the product was put onto the market, also taking into account the social utility of the type of product[41]. This is therefore a hypothetical assessment, focused on the analysis of the behavior of the producer before the moment at which the harmful event occurred. Plaintiff must offer plausible proof that her injuries would have been reduced or avoided by the adoption of an alternative design; but this is not enough: in order to held the producer liable for the injuries occurred, the alternative design has to be reasonable. This means that its price has to be lower than the overall cost of damages that were foreseeable at the moment the product was put onto the market.

Nevertheless, even if it is proven the existence of an affordable alternative design, the liability of the manufacturer is still questionable. For instance a chair can easily (i.e. without significant additional costs) be made more resistant in order to avoid accident to a person weighting 300 pound, a knife less sharp, a coffee less hot or a car less speed, but those reasons are not good enough to held liable the producer of such products. As remarked by Jane Stapleton, at this point of the reasoning we are missing a factor of comparison[42]. This is exactly where the difference between the formulation adopted by European drafters on one side, and American drafters on the other, comes out. In fact, rather than taking into

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The user's anticipated awareness of the dangers inherent in the product and their avoidability, because of general public knowledge of the obvious condition of the product, or of the existence of suitable warnings or instructions. (7) The feasibility ,on the part of the manufacturer, of spreading the loss by setting the price of the product or carrying liability insurance. John W. WADE, *On the Nature of Strict Tort Liability for Products*, 4 4 MISS.L .J. 825, 837-38 (1973). But see James A. HENDERSON, Jr. & Aaron D. TWERSKI, *Closing the American Products Liability Frontier: The Rejection of Liability Without Defect,* 66 N.Y.U. L. Rev. 1263, 1267 n.9 (1991) (criticizing Wade as the intellectual precursor of the "liability without defect" trend).

[40] George W. CONK, *Is There a Design Defect in the Restatement (Third) of Torts: Products Liability?*, *The Yale Law Journal*, Vol. 109, No. 5 (Mar., 2000), pp. 1087-1133. The Author affirms: "Many courts, including those in New Jersey and California, have derived their risk-utility tests from Wade. See, e.g., Barker v . Lull Eng' g Co., 573 P.2d 443, 455 (Cal. 1978) (adopting the following five factors in its design-defect analysis: the gravity of the danger posed by the challenged design, the likelihood that such danger would occur, the mechanical feasibility of a safer alternative design, the financial cost of an improved design, and the adverse consequences to the product and to the consumer that would result from an alternative design); Cepeda v. Cumberland Eng's Co., 386 A.2d 816, 826-27 (N.J. 1978), citing Wade's factors in its design-defect analysis".

[41] A.D. TWERSKI, *From Risk-Utility to Consumer Expectation: Enhancing the Role of Judicial Screening in Product Liability Litigation*, in *Hofstra Law Review* (1983).

[42] J. STAPLETON, Restatement (Third) of Torts: Products Liability, an Anglo-Australian Perspective, as above, 363.

account the specific interests of the two parties in trial (comparing the behavior that should be expected by the producer with the behavior of the user), the American legal doctrine focuses her attention on the interest of the collectivity. The question asked to the jury is not whether the user's conduct could have avoided this specific damage easier than the producer; it is rather whether, in light of all the relevant costs and benefits, the defendant's design was "good for America"[43]. While in Europe the general interest is considered as an exception which could justify diseconomies, in United States it is included within the balancing of the individual interests of the parties[44].

The role of American courts in assessing whether a product is defective has in effect turned their decentralized decisions into a form of national product risk regulation[45], which decides for the public that some products are not useful or essential, or, on the contrary, that a victim should bear the cost of the accident caused by a product because this product is useful for the others. While in a civil law system the function of civil courts is kept separated from the function of the public authorities, it is not surprising that this separation is not conceived in the same way in a common law system, where courts are also lawmakers, where they are asked to take care of the general interests and where not rarely they do the job that in a civil law system is more frequently done by a criminal courts. This explains also why an American judge is provided with instruments, such as punitive damages or the class action, which give to his decision an impact far beyond the interests of two parties in trial.

The relevance given to the general interest by the risk/utility analysis has the consequence of decreasing the attention on user's behavior in the assessment of defectiveness[46], contrary to what seems to happen in European courts. It is also

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[43] *Ibidem*

[44] One of the difficulties found by American legal theorists in producing the definition of defect is due to their desire to merge different types of interests within one single rule. The cases in which there is a conflict between the general interest and the individual interest are governed in the Directive by those provisions setting out an exception with respect to the general rule of resolution of the conflict between the parties (consider, for example, the exemption of liability of the producer when defect is due to compliance with a mandatory regulation). The heterogeneity in the concept of general or collective interest with respect to individual interest is analyzed in: P. FEMIA, *Interessi e conflitti culturali nell'autonomia privata e nella responsabilità civile*, Napoli, 1996, 124- onwards.

[45] The remark is in W.K. VISCUSI, *Reforming product Liability,* cit., p.83. "(I)f regulatory requirements exist and lead to an efficient level of safety for a product, then a risk/utility test in the courts is extraneous. In effect, the analyses supporting the regulations would have already provided the answers to the risk/utility test in that they have shown that the resulting guidelines are efficient"..

[46] That does not means that the evaluation of user's behavior is disappeared, as it is still taken into consideration explicitly or implicitly as shown in J.C.P. Goldberg, A.J. Sebok, B.C. Zipursky, *Tort Law: Responsibilities and Redress. Cases and materials,* 2nd ed., 2008, Aspen Pub.

true that the §2 of the Restatement third mentions the user's conduct at the letter p) of the comment, declaring: "Product misuse, modification and alteration are forms of post-sale conduct by product users or others that can be relevant to the determination of the issues of defect, causation or comparative responsibility. Whether such conduct affects one or more of the issues depends on the nature of the conduct and whether the manufacturer should have adopted a reasonable alternative design or provided a reasonable warning to protect against such conduct".

Nevertheless, the fact that the user's behavior is not mentioned in the black letter of the Restatement, but simply in one of the last comments, taken together with the accent posed by the legal doctrine on the risk/utility test (emphasizing or criticizing its efficacy[47]), all this creates a rhetoric which leads to obliterate the relevance of user's behavior shifting the attention of courts almost exclusively on the producer. Otherwise said, the way we describe the law has an influence on the application of the law, as it is demonstrated by those judgments which do not pay any attention to the user's behavior, denying the principle of self-responsibility of the victim, even if the danger was obvious and the damage could have been easily avoided with some more care by the user, such as the McDonald case, mentioned above, or the lighter case brought in front of the Illinois court[48].

7. The policy of EU lawmakers between strict liability and liability for fault

As explained above, the US doctrine has intentionally (even though implicitly) reintroduced a fault liability on the producer after the product liability crises

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[47] The debate is still open, as shown in: Symposium: The Products Liability Restatement: Was It a Success?, (2009), 74 *Brookling L. Rev.*

[48] It is the case of a mother who left at home her 11 years old daughter with her twin three year olds brothers. When she returned she founded a fire at her home because one of the twin played with a utility lighter she had purchased. Therefore she filed against the producer of the lighter claiming that the lighter was defectively designed and unreasonably dangerous because it did not contain a child resistant safety device. The Illinois Supreme court stated that the responsibility of the producer has to be assessed through the risk/utility test, comparing the cost of the safety design with the risk of fire caused by children playing with lighter, despite the fact that the danger is obvious and easily avoidable by the mother either being careful not to let the lighter at disposal of the children, either avoiding to purchase utility lighter not safe for children.
This extreme paternalism of the Us judge has also be explained by the fact that the lack of a public health system make the need of the injured person more urgent in the US than in Europe (A. CAVALIERE, *Product Liability in the European Union: Compensation and Deterrence Issues,*as above).

which caused in the 80's a progressive growth of litigation costs and of insurance rates.

At the same time the European lawmaker was drafting the product liability Directive which appears to mark a turning point, since it is the first instrument of consumer protection introduced in the EU[49]. Before that, in the development phase of industrial society, it was necessary to prove the fault of the producer who had put defective products on the market in order to receive compensation for damages from that producer. It has been observed that, "the emphasis on fault and times taken for the fulfillment of the burden of proof by the plaintiff meant that, right at the moment of the development of the industrial setting, companies remained removed from the cost of accidents (…). In financial terms, any other solution would have cut short those companies at birth"[50]. After the financial upturn following the war, while in the US the consumer protection movement progressively grew stronger, Italian case law introduced an initial form of consumer protection incorporating elements of legal theory that support the doctrine of business risk[51]. In that period, cases of damages caused by defective products were subject to fault liability under article 2043 of the Civil Code. In a 1964 decision, for the first time, the *Corte di Cassazione* relieved the plaintiff from the burden of having to prove the fault of the producer, considering that the fault is *in re ipsa*, that is, it could be inferred from the fact itself that the proper use of that product caused damage[52].

In other European countries, which also lacked specific laws relating to product liability, similar solutions were arrived at either by attributing non-contractual liability to the producer with a concurrent reversal of the burden of proof of fault (as is the case in Germany and the UK) or, as in France, attributing contractual liability to the producer, considering the breach in implicit guarantees in favor of the final consumer.

The preamble of the Directive states that: "liability without fault on the part of the producer is the sole means of adequately solving the problem, peculiar to our age of increasing technicality, of a fair apportionment of the risks inherent in modern technological production".

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[49] In 1973 the Commission set up a consulting committee for consumers and in 1975 it adopted the first five-year action plan dedicated to a *Policy for the protection of and information to consumers,* followed in 1981 by a second and more detailed five-year plan. The Single European Act 1987 mentioned the consumer for the first time in Article 100/A.

[50] DIAS and MARKESINIS,*Tort Law,*1984, pages 23-24.

[51] Following the business risk doctrine, the entrepreneur should bear all the foreseeable external costs of his activity , even though faultlessly generated. From a viewpoint of economic efficiency of the system the doctrine finds its source in Italy in P. TRIMARCHI, *Rischio e responsabilità oggettiva, as above*; from the viewpoint of social solidarity see: S. RODOTÀ, *Il problema della responsabilità civile,* as above.

[52] The *leading case* is Schettini vs. Saiwa (Cass. Civ. 25-5-1964 n. 1270, *Foro It.*, 1965, I, 2098).

At first sight we therefore move from liability for fault to liability for presumed fault all the way to a purported strict liability of the producer. The term "fault" disappears from the wording of the law, while the burden of proof on the plaintiff focuses on the concept of defect.

However, in observing close-up the mechanisms for proof of defect, we discover that they focus on those same elements that are taken into account when evaluating fault. In the same way as the finding of fault implies a relationship since the judge must decide which party is best placed to bear an obligation to behave in such a way as to avoid damage[53], as we have seen, proof of defect forces the judge to compare the behavior of the parties in order to decide which is to be held liable. Since the possibility of avoiding damages logically presumes that they may be foreseen, the assignment of liability occurs only in relation to foreseeable damages: in the absence of foreseeability the damages will be left where they land, that is, on the victim[54]. Not incidentally the foreseeability of the harmful event is indicated as an essential component of the concept of fault both in the various legal theories on the topic, and in their applications in case law, in every legal system[55]. So saying, far from wanting to look into the uncertain meaning of the concept of fault (a meaning that legally speaking must also deal with the difficulty in transferring a subjective element onto objective proof), we now have a more modest purpose of determining whether the definition of defect in the Directive has the effect of increasing the liability of the producer compared to the pre-existing rules presuming fault. For this purpose, I suggest to divide the approach of the law into three cases of damage: foreseeable and avoidable, foreseeable but unavoidable and unforeseeable.

8. Liability for foreseeable and avoidable damages

In the first category, the definition of defect offered in the Directive (as the *Corte di Cassazione* clarified in decision n. 6007/2007) has the effect of attributing the damage to the party in the best position to avoid, and therefore, foresee it.

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[53] The further implication, in the proof of fault, of the interaction between the conduct of the parties in the analysis of causation of damage was analyzed in detail in: F. CAFAGGI, *Profili di relazionalità della colpa,* Padova 1996.

[54] MAJORCA, *Colpa civile (Teoria gen.),* item in *Enc. Del Dir.,* VII, Milano, 1960 p 568 and following. Case law analysis in: VISINTINI, *L'imputabilità e la colpa in rapporto agli altri criteri di imputazione della responsabilità,* Padova, 1998, page 79; P:G.MONATERI, *I fatti illeciti,* as above*,* page 74.

[55] For a comparison among the concept of fault in the English and in the French legal system: S. WHITTAKER, *Liability for products. English law, French law and European harmonization,* 2005, Oxford Univ. press.

Therefore, holding the producer liable for this type of damage is consistent with the attribution of liability for fault. It is true with respect to proof of defect that the foreseeability of damage is measured on objective standards, removed from any psychological analysis of the intentions of the party held liable. However, this is not sufficient to contradict the fact that this is a case of liability for fault, since the analysis of the legal theory generates a concept of fault devoid of any subjective feature[56]. The process of objectification of the concept of fault progressed hand in hand with the emergence of the deterrence function that civil liability offers[57], to the detriment of the function of punishment of those conducts that are considered inconsistent with the moral code[58]: while in fact, the purported self-evidence of the rule of the moral code started dissolving during post-modernist relativism, the legal theorist took possession of economics principles to be used for the attribution of liability for damages[59]. Language and reasoning changed: it is no longer a case of punishing whomever is at fault on the basis of a moral rule, but of deciding which of the two parties involved in the process of causing the damage would have best been encouraged to invest in preventative measures aimed at

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[56] M. BUSSANI, *La colpa soggettiva,* Padova, 1991; VISINTINI, *L'imputabilità e la colpa in rapporto agli altri criteri di imputazione della responsabilità,* as above. For a survey on the continuing debate between supporters of the objective understanding and supporters of the subjective understanding of fault, see: G. CIAN, *Antigiuridicità e colpevolezza,* Padova, 1966, p. 207-214. It was observed that, as the understanding of fault progressively became objective, "(In) the same way, the categories of interpretation of the legal act, of the assignment, of the very *matching of consensus* moved from the field of internal will to the one of external appearance and of objective circumstances in which the work is done", (G. ALPA, M. BESSONE, V. ZENO ZENCOVICH, *I fatti illeciti,* in Trattato di Dir. Priv., dir. P. Rescigno, Torino, 1995, page 80).

[57] Our discussion does not involve the fact that the mechanisms for the attribution of civil liability are not sufficient for satisfying the function of prevention of damages unless they are accompanied by a system ensuring access to justice to all victims of damage, as well as compensation levels appropriate to act as an effective deterrent. Not incidentally, in the face of the disappointing impact of the EC product liability Directive, while the EU lawmakers were attempting to introduce a range of preventative controls, some national lawmakers, including Italy, started to consider the introduction of class actions and punitive damages as effective deterrents. On the interaction between the institutions of civil liability for damages due to defective products and regulation, see: W.K. VISCUSI, *Product Liability and Regulation: Establishing the Appropriate Institutional Division of Labour*, in *American Economic Review* 77 (1988) 300–304; more in general: S. SHAVELL, *Liability for harm versus regulation of safety,* in *J. of Legal Studies*, 1984, 357.

[58] The following, among others, focused on reprehensible conduct: De CUPIS, *Il danno. Teoria generale della responsabilità civile,* I, Milan, 1966 pages 115-118.

[59] On the contrary, the neuroscience are currently promoting the so called natural moral, aiming to objectify the moral rules proving that they have origins of a biological nature (see, in particular, M. HAUSER, *Moral minds: how Nature Designed Our Universal Sense of Right and Wrong,* New York, 2006).

averting that risk of damage[60]. Since we are dealing with two people who previously were unknown to each other, the conduct of one with respect to the other is assessed on the basis of what one could have known of the other based on external, visible signals that supply information to others in general[61]. Consistently with such assumptions, therefore, the definition of product defect specifies that the interaction of the parties' respective conducts should be measured on the basis of the information that each party could access at the moment in which s/he acted, i.e.: the instructions and warnings accompanying the product, and the way in which it was marketed, from the point of view of the consumer; the characteristics of the category of subjects to whom the product is addressed, from the point of view of the producer[62].

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[60] The starting point has been found in: R. POSNER, *A Theory of Negligence*, 1 J. LEGAL STUD. 29, 29, 32-34 (1972). Calabresi separated the figure of the *cheapest cost avoider* from the subject in *negligence* (G. CALABRESI e J.T. HIRSCHOFF, *Toward a Test for Strict Liability in Tort,* as above, 1060). However, the differences between identifying the cheapest cost avoider and identifying the subject who is at fault for the damages lose clarity at the point at which the fault is objectified and is proven by the fact that civil liability should essentially represent a form of prevention, rather than a punitive form or a form of mere compensation (in the latter case it would as a matter of fact be much more efficient to simply set up a compensation fund for victims of damages, saving all costs required to identify the party at fault).

[61] Even if recent discoveries in neuroscience on mirror neurons open new frontiers on the skill of individuals to grasp the emotional state of others, such skills are at any rate based on the observation of external behavior (G. RIZZOLATTI and C. SINIGAGLIA, *So quel che fai. Il cervello che agisce e i neuroni a specchio*, 2006, Cortina Raffaello); therefore it does not appear to be possible to read the minds of others if not through the physical world ("It does not attempt to see men as God sees them" is stated in O.W. HOLMES, *The Common Law*, Boston,1881, par. 108). Having said that, in the case of non-contractual liability, we should lower the level of care required from a physically impaired person on condition that it is visible and recognizable by the other party or, vice-versa, raise the level of care of the professional who makes his/her special skills known in offering clients particularly high prices. Holmes wrote, "There are exceptions to the principle that every man is presumed to possess ordinary capacity to avoid harm to his neighbors, which illustrate the rule, and also the moral basis of liability in general. When a man has a distinct defect of such a nature that all can recognize it as making certain precautions impossible, he will not be held answerable for not taking them (…). Notwithstanding the fact that the grounds of legal liability are moral to the extent above explained, it must be borne in mind that law only works within the sphere of the senses. If the external phenomena, the manifest acts and omissions, are such as it requires, it is wholly indifferent to the internal phenomena of conscience". O.W. HOLMES, *The Common Law*, as above, par.110.

[62] In this sense there was criticism on decision n. 10274 by the *Corte di Cassazione* (though applying the previously-existing provisions, it specifically stated it referred to the rules introduced by the Directive). In this case, an 11-year-old child suffered serious injuries when playing standing up on the seat of a swing. The courts held the victim liable because he had not used the swing in the proper way, instead of holding liable the producer who had devised a swing without preventing the risk of an injury that would have easily been prevented by simply keeping in mind the expected behavior of a child. In another case, however, the liability for damages suffered due to the collapse of a mountain bike used on a bumpy road was correctly attributed to the producer,

9. Liability for foreseeable and unavoidable damages

a) Manufacturing defects

Then there are those damages that are statistically foreseeable yet unavoidable. This category includes so-called manufacturing defects, that is those defects that occur in a statistically predictable yet not entirely avoidable way during production and that render a specific product inconsistent with respect to others in the same series. They are different from defects in product design and warning under the tripartite distinction set out by US judges and academics and drawn in the Restatement third (subsequently picked up by German case law[63]). Such a distinction, albeit neglected by the EC lawmakers, plays a role not only for descriptive purposes but also on the operational level. It has to be noticed that Italian lawmakers, independently from the wording of the Directive, recognized the specificity of the rules on manufacturing defects by stating, "a product is defective if it does not provide the safety normally provided by other products in the same series" (article 117 n.3).

The typical example of the manufacturing defect is that of glass bottles (often re-cycled glass) exploding because they contain cracks that are invisible and therefore not identifiable, or at the most, they may be identified at exorbitant cost with respect to the risk of damage. In these cases, it is not necessary to prove the existence of the specific defect that caused the damage in order to attribute producer's liability (also since, in the majority of cases, the inconsistent product was destroyed, leaving experts with little evidence on which to work). Instead, it is necessary to prove that, under equal external conditions and modes of use, the product caused damage that other products belonging to the same series (and therefore marketed in the same conditions) do not cause. Therefore, the positive proof of the existence of a defect is substituted by a test to rule out any other possible cause of the damage through a temporal and technical analysis of the means and conditions of use of the product[64].

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holding him liable for having spread an advertising message that induced people to consider the product to be particularly resistant and suitable for tackling impracticable routes (Tribunale of Monza 20 July 1993).

[63] BGH 9 May 1995, 2162; OLG Dűsseldorf 20 December 2002, 14 U 99/02; OLG Hamm NJW-RR 2001, 1248.

[64] However, in most cases the test cannot rule out any other possible cause of damage with absolute certainty. In this sense we can explain the reasoning of the Italian judge in decisions on car and motorcycle accidents mentioned above, even though we may also discuss the degree of probability to be considered as suitable for assigning the burden of proof in these cases (even more

If any other possible cause for that damage is ruled out, the producer will undoubtedly be held liable even if he manages to prove that there are no preventative means other than ceasing activities. In fact, we may agree with the opinion expressed by the *Bundesgerichtshof* in another case of a bottle exploding without external cause, according to which the producer may not rely on the development risks defense to avoid liability when it is a case of damages due to manufacturing defects[65]. The German courts clarify that the development risks defense applies exclusively to the case of defects that were not foreseeable, and not defects that, even if abstractly foreseeable, could not be effectively identified by the producer through technical and scientific know-how available at the time the product was put on the market.

Therefore, there is no threshold of exemption from liability: even if the producer proves he adopted all appropriate measures to avoid the damage[66], he still is liable since he faced the risk in full awareness. In other words, article 117 n.3 of the Consumers Code appears to be an explicit recognition at a legal level of the doctrine of liability for business risk that Italian academics have elaborated since the 1960s and that has often been accused of lacking legal grounds[67]. This doctrine presumes that, since it is a case of risk of damage quantifiable in advance, the entrepreneur is the one who is more capable than anyone of managing it by "obtaining insurance against it, or directly allocating funds for the compensation of damages caused by the activity, and recovering them through a corresponding increase in prices of the goods and services sold"[68].

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so since the Italian lawmakers chose to lighten the burden of proof for one of the parties using in article 120 c. 2 and 3 of the Consumer Code the terms "probable" and "likely", unusual in the Italian legal system; on this point see S. PATTI, *Ripartizione dell'onere, probabilità e verosimiglianza nella prova del danno da prodotto*, in S. Patti (ed.), *Il danno da prodotti,* Padova, 1990, pages 139 onwards).

[65] BGH 9 May 1995, as above. For a comment on the sentence see: S. LENZE, *German product liability law: between European Directives, American Restatements and common sense,* in D. Fairgrieve (ed), *Product Liability in Comparative perspective*, as above, 115; C. HODGES, *The case of the exploding bottle of water,* 18, *Product Liability Int.* 73 (1996).

[66] In the case of the exploding bottle, for example, the German Courts discovered that the producer made an initial manual check of the recycled glass bottles, they were then passed through an electronic system appropriate to identify cracks through a special lighting technique. Subsequently, bottles underwent a pressure test 1.7 times in excess of the pressure of ordinary fizzy water. Finally, they were filled with water and once again checked one by one by employees (BGH 9 May 1995, 2162, as above).

[67] This criticism was also made, among others, by: SCOGNAMIGLIO, *Responsabilità per colpa e responsabilità oggettiva,* in *Studi in memoria* by A. Torrente, II, Milano, 1968, p.1104; G. VISINTINI, *Principi e clausole generali con particolare riguardo alla responsabilità civile,* in *Studi in onore* by P. RESCIGNO, V, Milano, 1998, p. 667.

[68] P.TRIMARCHI, *Rischio e responsabilità oggettiva,* as above, p.30.

Richard Posner observed that, in the face of an abstractly foreseeable yet unavoidable defect, the producer may decide whether it is convenient to pursue that activity accepting in full awareness the liability for damages that follows, or else whether to give up performing those activities because expected advantages do not balance the presumed risk[69]. If he decides to pursue the activity accepting the risks in full awareness, he will be encouraged to invest in scientific and technological research aimed at finding prevention and inspection tools for the products able to reduce that risk of damage for which the consumer has no remedy. In this sense, the economic analysis of law justifies the rule that ascribes strict liability to the producer for manufacturing defects[70].

b) Foreseeable and unavoidable design defects: the Pinto case

Granted that it is not always easy to make a clear distinction between manufacturing defects and design defects, it can be questioned if the business risk doctrine could also be applied to those design defects cases that presuppose an aware assumption of a foreseeable risk by the producer. These are cases where the producer decides to adopt a certain design knowing that it makes the product safer for the majority of hypothesis but creates a risk in few others. A paradigmatical example is represented by the celebrated Ford Pinto case[71]. In May 1972, Lily Gray was traveling with thirteen year old Richard Grimshaw in a 1972 Pinto when their car was struck by another car traveling approximately thirty miles per

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[69] On the basis of these premises, we can infer that the assignment of objective liability should presume a producer acting in a free market situation. This explains the difficulties found by the English judge and by the Dutch judge called to apply the Directive in two cases of victims of infected blood transfusions. What was not considered is the fact that the health authority that made the transfusions is obliged to offer that service, and therefore, in the face of a very high risk of damages, it is not free to decide whether to cease its activities (or to increase the price asked for the service). In both cases, the defendant asked to be exempted from liability through the application of the development risks defense. The English judge held that the clause may not be applied in order to exempt the producer from liability when the risk of damages was known, as in this case (3 ALL E.R. 289 [2001]); Justice Burton, in para. 74 of his detailed and documented judgment, states "If there is a known risk, i.e., the existence of the defect is known or should have been known in the light of non-Manchurianly accessible information, then the producer continues to produce and supply at his own risk". On the other hand, the Dutch judge considered that the clause may be applied also in the case when, though the risk of that damage is known, there is no knowledge of suitable methods to prevent it (Rb. Amsterdam 3 February 1999, NJ 1999, 621). For a report on the English law case see: M. BROOKE e I. FORRESTER, *The use of comparative law in A. & Others v. National Blood Authority,* in D. Fairgrieve (ed), *Product Liability in Comparative perspective*, as above, 13.

[70] W.M. LANDES e R. POSNER, *A positive economic analysis of product liability,* in *Journal of Legal Studies,* vol. XIV (1985), 555.

[71] Grimshaw v. Ford Motor Co., 1 19 Cal.App.3d 757, 174 Cal. Rptr. 348 (1981)

hour. The impact ignited a fire in the Pinto which killed Lily Gray and left Richard Grimshaw with devastating injuries. The plaintiff claimed that Ford had improperly placed the gas tank in a place where the gas could, after a crash from the rear, explode. Ford defended itself showing that a cost/benefit analysis of different gas tank placements had been done correctly, as the cost of putting the tank in a safer place was too high in relation to the number of lives that would be saved by doing so[72]. Otherwise said, Ford argued that what it had done could not be faulted. Nevertheless, the jury held Ford liable and awarded the Grimshaw family $2.5 million in compensatory damages and $125 million in punitive damages as well (subsequently reduced to $3.5 million).

Obviously a strict application of the risk/utility test would have led to say that the design of the car is beneficial under a general point of view and consequently that the car is not defective and the producer not liable for the accident. This explains why the decision in the Pinto case has been defined as self-contradictory by legal economists [73]. My opinion is that the contradiction, far from been irrational, shows that the risk utility test cannot be properly applied in every design case. In fact, there are design defect cases that present the very same factors which justify the adoption of a strict liability rules in manufacturing defects, following the doctrine of business risk[74]. This factors are, on one side,

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[72] Ford estimated the cost to make this production adjustment to the Pinto would have been $11 per vehicle. Ford contended that its reason for making the cost/benefit analysis was that the National Highway Traffic Safety Administration required them to do so. Moreover, Ford said that the NHTSA supplied them with the $200,000 as the figure for the value of a lost life. Therefore the result of the Ford cost/benefit analysis was:
Benefits:
Savings: 180 burn deaths, 180 serious burn injuries, 2100 burned vehicles
Unit Cost: $200,000 per death, $67,000 per injury, $700 per vehicle
Total Benefit: 180 x ($200,000) + 180 x ($67,000) + 2100 x ($700) = $49.5 Million
Costs:
Sales: 11 million cars, 1.5 million light trucks
Unit Cost: $11 per car, $11 per truck
Total Cost: 11,000,000 x ($11) + 1,500,000 x ($ I 1) = $137 Million
From Ford Motor Company internal memorandum: "Fatalities Associated with Crash-Induced Fuel Leakage and Fires." Source: Douglas BIRSCH and John H. FIELDER, *The ford pinto case: a study in applied ethics. business, and technology*. p. 28.1994

[73] G. CALABRESI, *the complexity of torts –the case of punitive damages, in* M. Stuart Madden (ed.), *Exploring tort law, Cambridge un. Press,* 2005, pag.341. The Author explains the decision pointing out how, when taken on a case-by-case basis, the application of the risk/utility test seems to be a blatant disregard for human life and therefore it is unacceptable from a human right perspective.

[74] The co-reporters of the Restatement third recognized the existence of "a special subset of design defects involving products that malfunction, thereby failing to perform their manifestly intended function in a self-defeating manner. In those special design cases the defects are functionally equivalent to manufacturing defects, so strict liability works as well for them" (A. TWERSKI and

that the risk of damage has been foreseen by the producer who has consciously assumed it following a cost/benefit balance; on the other side that the user, even though aware of the risk, did not have any way to avoid it. The application of the business risk doctrine to these cases would lead to condemn the producer to compensate those damages that he had already quantified in his cost/benefit analysis. What is contradictory it is rather the application of punitive damages, despite the fact that the producer cannot be considered at fault as his cost benefit/analysis has been done correctly.

Nevertheless, as the business risk doctrine is explicitly adopted just for manufacturing defect case, it is likely that the application of the European product liability law to these unavoidable design defect cases will lead to divergent decision among the member states. For instance in Germany, where the risk/utility doctrine is strictly applied, the judge will be inclined to exempt the producer from liability as it recently has happend in the cherry cake case, where the *Bundesgerichtshof* has decided that it would be disproportionate to expect a producer of cherry cakes to do everything possible to ensure that no cherry stone or bits of it remain in the cherry cake, giving the little risk to health connected to the issue[75]. On the contrary, in Countries where the risk/utility test is not applied, because the search for the cheapest cost avoider does not help where the damage is unavoidable by both parties, the judge might held the producer liable emphasizing the fact that European lawmaker has declared to adopt a strict liability rule on the producer in the premises of the Directive.

c) Foreseeable and unavoidable damages: the shift of liability through the use of warnings

Another relevant question concerning foreseeable and unavoidable damages is whether a proper warning about them could shift the liability from the producer to the user on the assumption that the latter has then accepted the risk of damage in full awareness[76]. Under a general and systematic point of view it is quite obvious that to allow this practice would lead to inappropriate consequences. In a first instance it would become easy to elude article 12 of the European Directive that states "(T)he liability of the producer arising from this Directive may not, in relation to the injured person, be limited or excluded by a provision limiting his

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J. HENDERSON, The Products Liability Restatement: Was It a Success?: Manufacturers' Liability for Defective Product Designs: The Triumph of Risk-Utility, as above, p. 1062).

[75] BGH, NJW 2009, 1669, against the lower instance court.

[76] The Italian law implanting the European Directive specified that the producer is exempted from liability when "the victim was aware of the defect in the product and of the danger deriving therefrom and nonetheless voluntarily exposed him/herself to it" (article 122 of the Consumer Code).

liability or exempting him from liability". Furthermore this solution will lead to the invalidation of the entire law which held the producer strictly liable for manufacturing defects or for the design defects cases mentioned above, as he could hide behind a warning like "handle carefully: the bottle might explode", in an attempt to insulate himself from his responsibility for damages. Then it seems more appropriate to affirm that the warning can be an instrument of exemption of liability for the producer just when it has the function of explaining to the user how to reduce or avoid a certain risk of damage, as explicitly suggested by §2 of the Restatement which states: "(c) a product is defective because of inadequate instructions or warnings when the foreseeable risks of harm posed by the product could have been reduced or avoided by the provision of reasonable instructions or warnings".

That being assumed, it has nevertheless to be noticed that there are peculiar categories of product that generally escape from the application of the business risk doctrine making the producer exempted from his liability if he had adequately warned the user about the inherent unavoidable risk of damage. This is the case of the so called inherently dangerous products (such as cigarettes and alcohol) [77] and it might be the case of the prescriptive drugs having some known side effects due to an unavoidable design defect.

Concerning the first category of product, the reason why the producer is exempted from liability through the use of warning is certainly related with the concepts of free choice and individual responsibility of the consumer who consciously chooses to use (and abuse) of those products, that are not specifically necessary, knowing that they are dangerous[78].

On the other side, the European Directive on product liability does not provide a specific rule for prescriptive drugs. Therefore, they are theoretically subject to the general provision as any other kind of product, giving no guidance to the interpreter whenever the damage, even though foreseeable, could not be avoided by both parties. On the contrary, under § 6 of the American Restatement third, a claim of producer liability arising from the design or formulation of a prescription drug will prevail only upon a showing that the product would be unduly dangerous for any class of patients, or specifically, when "reasonable health care providers, knowing of foreseeable risks and therapeutic benefits, would not prescribe the drug or medical device for any class of patients"[79].

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[77] The category is analyzed in: D. G. Owen, *Inherent Product Hazards*, Kentucky College of Law Kentucky Law Journal, (2005), 93, 377.

[78] See, e.g., Myers v. Philip Morris Co., 50 P.3d 751, 755-56 (Cal. 2002).

[79] Section 6, entitled "Liability of Commercial Seller or Distributor for Harm Caused by Defective Prescription Drugs and Medical Devices," states: (a) A manufacturer of a prescription drug or medical device who sells or otherwise distributes a defective drug or medical device is subject to

Otherwise said, in the USA, whenever the benefits of a prescriptive drug outweighs its foreseeable side effects, the producer is exempt from liability if he had properly warned the user (or the "learned intermediary") about the risk[80]. Here again an adequate warning can exceptionally shift the liability on the faultless victim because of the societal desire that the research, development, and marketing of potentially important new drugs not be impeded by the more rigorous liability rules applicable to ordinary products. It is not by chance that frequently the cases on defective drugs are brought in front of the US courts claiming that the label was inadequate.

Considering these specific societal needs and the interests related to the market of pharmaceutical products, it is possible that in Europe the various sensibility of the national judges will lead to opposing results, as already happened with the infected blood cases decided by the English and the Netherland court. Germany again is the only Country which adopted since 1978 a specific rule on pharmaceutical defective products (*Arzneimittelhaftungsrechts*), that gives substantially the same results of the US decisions on that matter[81].

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liability for harm to persons caused by the defect. A prescription drug or medical device is one that may be legally sold or otherwise distributed only pursuant to a health-care provider's prescription.
(b) For purposes of liability under Subsection (a), a prescription drug or medical device is defective if at the time of sale or other distribution the drug or medical device:
(1) contains a manufacturing defect as defined in 2(a); or
(2) is not reasonably safe due to defective design as defined in Subsection (c); or
(3) is not reasonably safe due to inadequate instructions or warnings as defined in Subsection (d).
(c) A prescription drug or medical device is not reasonably safe due to defective design if the foreseeable risks of harm posed by the drug or medical device are sufficiently great in relation to its foreseeable therapeutic benefits that reasonable health-care providers, knowing such foreseeable risks and therapeutic benefits, would not prescribe the drug or medical device for any class of patients.
(d) A prescription drug or medical device is not reasonably safe due to inadequate instructions or warnings if reasonable instructions or warnings regarding foreseeable risks of harm are not provided to:
(1) prescribing and other health-care providers who are in a position to reduce the risks of harm in accordance with the instructions or warnings; or
(2) the patient when the manufacturer knows or has reason to know that health-care providers will not be in a position to reduce the risks of harm in accordance with the instructions or warnings.
(e) A retail seller or other distributor of a prescription drug or medical device is subject to liability for harm caused by the drug or device if:
(1) at the time of sale or other distribution the drug or medical device contains a manufacturing defect as defined in 2(a); or
(2) at or before the time of sale or other distribution of the drug or medical device the retail seller or other distributor fails to exercise reasonable care and such failure causes harm to persons.

[80] M. STUART MADDEN, *The Enduring Paradox of Products Liability Law Relating to Prescription Pharmaceuticals,* 2001, 21 Pace L. Rev. 313

[81] According to §84 n.1 the pharmaceutical enterprise is liable if "a drug used correctly, has harmful effects which, taking into account the state of medical knowledge, exceed a tolerable

10. Liability for unforeseeable damages

On the basis of the above, therefore, the effectiveness of the protection for the victim of damages in the strict liability regime lies in respect of those damages that neither party was able to predict and, as a consequence, avoid. As a matter of fact, only for this category of damages is there a full case of absolute strict liability of the producer, or of responsibility that is attributed to a pre-determined category of individuals even in the absence of an exonerating level of care. Theoretically, the fact that the damaging party and the damaged party belong to categories of subjects that may be identified beforehand (the producer and the user), enables the use of a mechanism of strict liability that transfers the damage from one to the other *a priori*. This means that there are no technical obstacles to stop the lawmaker from freely choosing whether to attribute the damage to the helpless victim or to transfer it to the faultless producer. EC lawmakers withdrew from this choice, leaving it up to individual member states to opt for the "development risks defense", with the predictable result that the defense has been adopted almost everywhere[82]. Under Article 7(e), damages due to defects that were not discoverable in the light of technical or scientific knowledge available at the time at which the product was put on the market are left where they land, on the damaged party.

11. Final observations: the efficiency of the system and the reason for solidarity.

In conclusion, it appears that the EU regime has the effect of attributing to the producer liability for damages caused by defects in his products that were foreseeable and avoidable, unless the user could avoid the damage more easily. In fact, the European lawmaker seems to have adopted a mechanism of attribution of responsibility that follow the cheapest cost avoider doctrine, as pointed out by the recent decisions of the Italian *Corte di Cassazione*. On the contrary, because the American doctrine is inclined to neglect the principle of self-responsibility of the victim for the reasons mentioned above, in the same cases the US courts might adopt an extremely paternalistic decision in favor of the victim.

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level". That is the case if the overall risks of the product outweigh the overall benefits or if the risks could have been reduced by the adoption of a reasonable safer design (S. LENZE, *German product liability law: between European Directives, American restatements and common sense,* as above, 120).

[82] The defense was adopted by all countries that implemented the Directive, with the exception of Luxembourg and Finland.

Under the European law, liability of producer is also extended to the risk of manufacturing defects, or those defects which, although unavoidable, are at any rate statistically foreseeable, or liable to be managed, following the business risk doctrine. The question left unsolved by the European product liability law is whether the business risk doctrine could also be applied to those design defect cases where the risk of damage has been foreseen by the producer and fully accepted as a result of a correct cost/benefit analysis. The application of the strict liability rule under a business risk doctrine, as suggested in this paper, will give a result completely opposed to what it would be following the American risk/utility test. However it has been noticed that the risk/utility test is not always rigorously applied by US courts, especially when the producer has accepted the risk of damage in full awareness, as it happened in the Pinto case.

All other damages, those due to unforeseeable defects, are ascribed to the injured parties because of development risk defense.

From an operational point of view therefore, the distribution of risks between the parties substantially corresponds to that previously reached by the Italian courts (and by other European courts) through *res ipsa loquitur* reasoning. The presumption of fault, in fact, imposed on the plaintiff the burden of proving the product's defect, as happens with the current regime. The defendant was asked to prove the absence of fault on his part in order to be exempted from liability, i.e. the fact that he could not foresee and avoid the damage. The examination of the existing case law reveals that he was not at any rate exempt from liability for damages due to manufacturing defects since he could not state that he had not foreseen them. So much so that, among decisions taken by the judges in applying the previous regime, there are decisions holding the producer liable for damages caused by the explosion of a bottle containing a fizzy drink[83]. Therefore, despite what is expressly stated in the Directive, the regime of producer's liability introduced by the Directive cannot be fully defined as strict liability, or at least, is not far removed from what could previously be obtained by applying fault liability with the reversal of the burden of proving fault[84]. Nevertheless it can create a new sensibility more careful to victim's interests at least in cases where the legal provision gives more ambiguous results, such as the design defects

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[83] Cass. 28 October 1980 n. 5795, *Resp. Civ. e Prev.,* 1981, 392; App. Rome 30 July 1992, *ivi,* 1996, 672.

[84] The following commentators highlight the role played by fault as a principle for the assignment of liability to the producer under the EC regime: BIANCA, *La responsabilità,* in *Diritto civile,* vol.5, Milano, 1994, p.744-745. C. SALVI, *La responsabilità civile,* Milano, 1998, page 263. G.PONZANELLI, *Dal biscotto alla "mountain bike": la responsabilità del prodotto difettoso in Italia. Nota a Trib. Monza 20 luglio 1993,* in *Foro it.*, 1994, 254. The following is against a subjective interpretation of the EC regime: A. GORASSINI, *Contributo per un sistema della responsabilità del produttore,* as above, pages 217-219. The author explains that if we consider

which caused a damage unavoidable by producer and by user, but foreseen by the first one.

This means that EU lawmakers focused on implementing a deterrent mechanism with respect to those damages that are foreseeable, and at the same time encouraged competition between EU companies (and EU importers) avoiding burdening them with unpredictable risks.

It has to be remarked however that both of the stated requirements (of protection of consumers and encouraging competition) may have been equally satisfied without necessarily having to sacrifice the need for solidarity in favor of faultless victims. For this purpose, it would have been sufficient to create a public compensation fund to ensure compensation to the victims of those damages that, being unforeseeable, none of the parties were able to prevent[85]. The financing and functioning of the public fund in any chosen form may have at any rate averted the risk of burdening companies with excessive costs[86]. As things stand, however, this suggestion to the Commission in research carried out by Fondazione Rosselli in Turin appears not to have been taken into consideration[87].

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that the product liability regime introduced a case of objective liability of the producer, then its impact on the Italian legal system (due to restrictions in the right to compensation and defenses aimed in favor of the producer) would have the effect of limiting or reducing the right that the victim could already claim with the pre-existing rules. This observation appears to be correct; in fact it happens that, even under EC provisions, victims of damages ask for the application of the general tort law. See for example Courts of Rome, 20 April 2002, in *Foro it.,* 2002, I, 3225. In this case the Courts assigned liability to the importer for a heart condition set off by taking a weight-loss product under article 2050 of the Civil Code. In this way, the challenge based on the statute of limitations was avoided; this could have been raised under the EC regime, since three years had passed from the moment the damage and its cause were identified.

[85] This system is already differently applied in some northern Country (Norway and Finland for example) for damages caused by defective prescription drugs and in France for damages caused faultlessly in medical practice (about the French public fund see: www.oniam.fr).

[86] On the public fund see: G. CALABRESI, *The cost of accident[s]: a Legal and Economic Analysis,* 1970, Yale University Press; R.L. RABIN, *Some reflections on the process of tort reform*, in 25 San Diego L. Rev. 13, 15-23 (1988), as above in R.L. Rabin, *Perspectives on tort law,* Boston, 1995, pages 362 onwards; for the Italian experience on compensation funds: G. COMANDÉ, *Risarcimento del danno alla persona e alternative istituzionali,* Torino, 1999

[87] Fondazione Rosselli, *Analysis of the Economic Impact of the Development Risk Clause as provided by Directive 85/374EEC on Liability for Detective Product*, 2004. In this report on the implementation of the Directive, the European Commission noted that the work of Fondazione Rosselli proves that the development risks defence should be maintained for the purposes of encouraging technological innovation, pointing out that it helps to avoid diverting financial resources destined to R&D for the payment of insurance against damages. However, the Commission does not mention the fact that Fondazione Rosselli also suggested the creation of a compensation fund as a necessary balance to keeping the clause on risks from development. (Third Council report on the application of the Directive on the reconciliation of laws, regulations and administrations of Member States in terms of liability for damages due to defective products COM (2006) 496) .